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Original Paper

# Mobile Health Medication Adherence and Blood Pressure Control in Renal Transplant Recipients: A Proof-of-Concept Randomized Controlled Trial

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## Abstract

**Background:** Mobile phone based programs for kidney transplant recipients are promising tools for improving long-term graft outcomes and better managing comorbidities (eg, hypertension, diabetes). These tools provide an easy to use self-management framework allowing optimal medication adherence that is guided by the patients' physiological data. This technology is also relatively inexpensive, has an intuitive interface, and provides the capability for real-time personalized feedback to help motivate patient self-efficacy. Automated summary reports of patients' adherence and blood pressure can easily be uploaded to providers' networks helping reduce clinical inertia by reducing regimen alteration time.

**Objective:** The aim of this study was to assess the feasibility, acceptability, and preliminary outcomes of a prototype mobile health (mHealth) medication and blood pressure (BP) self-management system for kidney transplant patients with uncontrolled hypertension.

**Methods:** A smartphone enabled medication adherence and BP self-management system was developed using a patient and provider centered design. The development framework utilized self-determination theory with iterative stages that were guided and refined based on patient/provider feedback. A 3-month proof-of-concept randomized controlled trial was conducted in 20 hypertensive kidney transplant patients identified as non-adherent to their current medication regimen based on a month long screening using an electronic medication tray. Participants randomized to the mHealth intervention had the reminder functions of their electronic medication tray enabled and received a bluetooth capable BP monitor and a smartphone that received and transmitted encrypted physiological data and delivered reminders to measure BP using text messaging. Controls received standard of care and their adherence continued to be monitored with the medication tray reminders turned off. Providers received weekly summary reports of patient medication adherence and BP readings.

**Results:** Participation and retention rates were 41/55 (75%) and 31/34 (91%), respectively. The prototype system appears to be safe, highly acceptable, and useful to patients and providers. Compared to the standard care control group (SC), the mHealth intervention group exhibited significant improvements in medication adherence and significant reductions in clinic-measured systolic blood pressures across the monthly evaluations. Physicians made more anti-hypertensive medication adjustments in the mHealth group versus the standard care group (7 adjustments in 5 patients versus 3 adjustments in 3 patients) during the 3-month trial based on the information provided in the weekly reports.



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**Conclusions:** These data support the acceptability and feasibility of the prototype mHealth system. Further trials with larger sample sizes and additional biomarkers (eg, whole blood medication levels) are needed to examine efficacy and effectiveness of the system for improving medication adherence and blood pressure control after kidney transplantation over longer time periods.

**Trial Registration:** Clinicaltrials.gov NCT01859273; http://clinicaltrials.gov/ct2/show/NCT01859273 (Archived by WebCite at http://www.webcitation.org/6IqfCa3A3).

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**KEYWORDS**

smartphone; kidney transplantation; medication adherence; mobile health

## Introduction

### Background

Nearly 400,000 people living in the United States suffer with end stage renal disease; of these, approximately 84,000 are currently awaiting kidney transplantation [1,2]. Kidney transplantation is the treatment of choice for eligible patients with end stage renal disease. Kidney transplantation has been shown to offer superior quality of life, improved life expectancy, and better psychosocial functioning, all at less cost than maintenance hemodialysis [3-6].

Despite numerous advances in the medical and surgical care of transplant recipients, significant improvements in long-term graft survival have not been realized. The current 3-year graft survival rate is only 81% [2] and graft half-life is only about 9 years [7]. Remediable factors like poor medication adherence and poor control of comorbid medical conditions negatively impact kidney transplantation outcomes [8-13]. Non-adherence to prescribed medical regimens has been identified as a primary risk factor for graft rejection, graft loss, and death [14-18]. Even in the absence of rejection, non-adherent patients suffer a more rapid loss of renal function over time [17]. While the risk with non-adherence is a continuum, even very small degrees of non-adherence confer a significantly increased risk of graft rejection or graft loss [16,18]. In a recent meta-analysis, researchers found approximately 35% of American kidney recipients demonstrate non-adherent behavior post-transplant [19]. Non-adherence to medication regimens has been shown to develop within just a few weeks of transplantation and its early development increases the risk for persistent poor adherence [16].

Although medication adherence is critical for optimal kidney transplant outcomes, there is a dearth of research examining interventions directed at improving adherence. A recent review of medication non-adherence studies performed in solid organ transplant recipients identified only 12 studies, 7 of which involved kidney transplant recipients [20]. Intervention approaches included patient or primary care provider education and patient-focused motivational, behavioral, or psychological/affective state change. Less than half of the studies observed a significant improvement in adherence to a single medication. Adherence was often evaluated based upon self report and/or medication possession ratio. None of these approaches were completely successful in reaching desired adherence levels.

One approach that has shown promise involved a telephone-delivered adherence self improvement training program coupled with monthly feedback on adherence rates, as measured by an electronic medication event monitoring system (ie, MEMS) [21]. A novel adherence algorithm based on a twice a day dosing schedule was used to calculate an adherence score based on both whether or not the bottle was opened and when relative to the prescribed dosing time it was opened. The intervention group had a significantly higher overall medication adherence score (0.88) than the standard care control group (0.77) over the 6-month randomized controlled trial. However, the impact of the intervention on therapeutic drug levels or physiologic health indices was not assessed.

Following guidelines for user-centered, iterative based, theory-guided development of empirically validated mHealth programs and informed by reviews of prior mHealth interventions [22,23], we conducted semi-structured interviews with renal transplant recipients and their healthcare providers. The objective was to gain an understanding of their awareness, attitudes, and preferences regarding the use of mHealth technology in assisting healthcare delivery and patient self-management. These findings informed the development and administration of a formal survey directed at better understanding kidney transplant recipients' attitudes, preferences, and utilization of mHealth technology [24]. Of the 99 patients that completed the survey, 90% owned a mobile phone, 52% had access to or owned a smart mobile phone, and the majority was optimistic about the utility of mHealth technology. After being given a demonstration of a prototype mHealth system that was developed based upon the initial interview findings, 90% were receptive to incorporating it into their medical care. Based on findings from this work and additional guidance from patients and healthcare providers, we further refined the prototype mHealth system guided by tenants of self-determination theory to enhance self-efficacy and intrinsic motivation for sustained adherence with medication intake and blood pressure (BP) monitoring [25,26]. BP was selected as the physiologic parameter as the overwhelming majority of kidney transplant recipients have hypertension and many are poorly controlled [27-29].

### Objective

This manuscript describes the results of a proof-of-concept randomized controlled trial (RCT) utilizing this prototype mHealth system in renal transplant recipients with hypertension. The aims of this study were threefold: first, to assess patient and provider acceptability (recruitment and participation rates) and adherence to the protocols; second, to assess the feasibility



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of using our mHealth system to monitor and enhance medication adherence and BP control; and third, to obtain estimates of variability for the outcome measures and to obtain preliminary indicators of treatment effectiveness, as necessary input for design of a future efficacy/effectiveness RCT.

## Methods

### Study Participants

Study participants were recruited from the Kidney Transplant Clinic at the Medical University of South Carolina (MUSC), Charleston, South Carolina. Potentially eligible study patients were identified through weekly data extractions from the appointment database. Initial inclusion criteria were (1) first time recipient of a functioning solitary kidney transplant performed 3-months earlier, (2) prescribed a total of at least 3 medications for immunosuppression and hypertension, and (3) transplant physician's assent that patient is able to participate. Exclusion criteria included: (1) inability to self-administer medications, (2) inability to measure own BP, (3) inability to use a mobile phone, (4) history of psychiatric illness or substance abuse, (5) pregnant, lactating or intention of becoming pregnant during the trial, (6) participant in another study, (7) inabilities to speak, hear, or understand English, and (8) poor cellular coverage in their home.

### Prototype mHealth System

The prototype mHealth system consisted of a wireless GSM electronic medication tray (MedMinder, Maya, Inc, Needham, MA)[30] (see Figure 1), a wireless bluetooth enabled BP monitor (FORA D15b, Fora Care Inc, Newberry Park, CA)[31], and a smartphone (Droid X, Motorola, Schaumburg, IL)[32]. The medication tray plugs into an ordinary 110V outlet, has 28 compartments (up to 4 doses per day for 7 days), time stamps compartment use, and provides customizable reminder signals. At the prescribed dosing day and time a blinking light from the specific dose compartment was activated. If, after 30 minutes that compartment had not been opened, removed , and returned, a loud chime automatically activated for 30 minutes. If the compartment still had not been opened, an automated reminder phone call or text message was delivered to the subject's mobile phone. Failure to open the compartment at 90 minutes also generated an automated text message or email that was delivered to the study coordinator. Patients were sent text messages every 3 days as a reminder to measure BP using the FORA device using the standardized resting BP protocol (described below). Blood pressure readings (FORA D15b)[31] were automatically sent via bluetooth to a mobile phone (Motorola Droid X)[32] and from there, via cellular network, to the data repository. No patient names were transmitted and no identifying information was stored on the smartphone. Patients were contacted via the patients' preferred mode (text, email, or phone) when alerts indicated medication non-adherence, failure to measure BP as scheduled, or that measured BP was outside of threshold ranges established by the patient's treating physician. In the event that BP readings were outside of safe ranges, the study coordinator was alerted who then contacted the patients and instructed them to obtain additional BP measurements. Persistently unsafe BPs were immediately reported to the treating physician. A weekly summary report, tailored to the treating physician's preferences, was delivered via email and summarized each subject's adherence to medication dosing and BP monitoring, as well as breakdown of the BP readings that included systolic and diastolic averages along with the percent of readings that fell into normal and the various stages of hypertension (stage 1 pre-hypertension through stage 2 hypertension). The treating physician made adjustments to the medical regimen as indicated and notified the study coordinator of the changes via email. Any changes made by the treating physician were mirrored in the programming of the medication tray after the study coordinator confirmed with the patient that the changes had been enacted.

**Figure 1.** Electronic medication tray (MedMinder).




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### Calculation of Adherence Score

A detailed description of Russell et al's adherence score calculation is available elsewhere [33]. We employed a modification of her algorithm to allow for dosing schedules other than twice daily. Our subjects were instructed that to be considered fully adherent their medications had to be taken within a 3-hour window centered on the prescribed dosing time. A dose taken within the 3-hour window resulted in a full score for that dosing time; a dose taken outside the 3-hour window but within a 6 hour window resulted in a half score for that dosing time; and missed dose resulted in a score of 0. Each subject was assigned score from 0.0 to 1.0 for each day. The scores for each subject were averaged over each month.

### Identification of Non-Adherent Subjects

Patients who met initial eligibility criteria and provided informed consent were enrolled in a 30-day screening period using the medication tray with its reminder functions disabled. Subjects were given an individual demonstration of how to properly use the medication tray. They were required to demonstrate successful use of the device before completion of their enrollment visit. They worked out tactics with the study coordinator to increase adherence (eg, desired location for device, establishing the protocol as part of daily routine). They received written and oral instructions that to be considered adherent they must take their medications within 90 minutes on either side of the prescribed time. After confirming successful connection with the server, the tray was programmed to accurately reflect the subjects' medication dosing schedule. At the conclusion of the 1 month screening period our modification of the Russell et al adherence algorithm was used to calculate an adherence score for each subject. In order to construct a non-adherent study population only participants identified as having an adherence score of <0.85 for the month were eligible for randomization into either the mHealth group or the standard care group.

A total of 55 patients were approached for initial recruitment and 41 consented to participate (41/55, 75%)(See Figure 2. CONSORT flow diagram [34]). Of the 14 that declined to participate, 6 stated that they were already adherent with the medication regimen and didn't need to participate. The other 8 that declined cited concerns with time, travel, and the bulkiness of the medication tray. Each participant provided written informed consent and received gift cards for their participation. A single subject withdrew after consent but before entering the screening period due to concerns about travel related to the study. There were 5 subjects who were removed from the study early after enrollment due to technical issues that were most often related to inadequate cellular phone signal strength at their home. A single subject was removed from the study during the 1-month screening due to graft failure and a return to dialysis.

Of the 34 subjects that completed the screening phase, there were 7 with an adherence score >0.85 and were ineligible for randomization. Only 3 of the remaining 27 declined to be randomized into the second phase of the study. From the 3, 2 declined cited time concerns while the third did not explicitly state their reason for withdrawing. There were 3 subjects with adherence scores <0.85 who were not randomized because the study had reached target enrollment and 1 subject was withdrawn after randomization due to difficulties with clinic scheduling. The remaining 20 subjects were randomly assigned to either the mHealth intervention or to standard care. Demographic and transplant-related clinical characteristics of the study participants are summarized in Table 1. The study was approved by the institution's institutional review board (Clinicaltrials.gov: NCT01859273).

### Standard Care Control Group

The standard care (SC) control group received standard care at the MUSC kidney transplant clinic, which includes visiting the clinic every 4 weeks to 6 weeks depending on the medical indication and time since transplantation. Standard care also includes education on all matters related to post-transplantation medical care and 24-hour phone availability of transplant coordinators. Participants randomized to the SC group continued to use their medication tray, with its reminder functions disabled, for an additional 3 months.

### mHealth Group

The participants randomized to the mHealth group used the prototype mHealth system, described above, for 3 months. The reminder functions of the medication tray were enabled. The subjects in the mHealth group were provided instruction on the use of the FORA device [31] and the smartphone [32] and were required to provide a successful demonstration before completion of their visit. Technical support was available by phone throughout the study. At the conclusion of the study, subjects completed a brief questionnaire assessing their opinions of the mHealth system [35].

### Clinic Resting BP

Evaluations were conducted at pre-intervention and again at months 1, 2, and 3. Patients were seated upright with right arm resting on a table at heart level and a proper cuff size was fitted. The FORA D15 [31] device was used to take the BP measurements. A reading was immediately taken, and after 5 minutes rest, 2 additional readings were taken separated by a 2-minute interval. The average of the last 2 readings was used in the analyses. Subjects in the mHealth group used this same protocol at home for BP self-monitoring. Where a protocol BP was not available, a registered nurse measured clinic BP from the same day was substituted (9 of 76 measurements).



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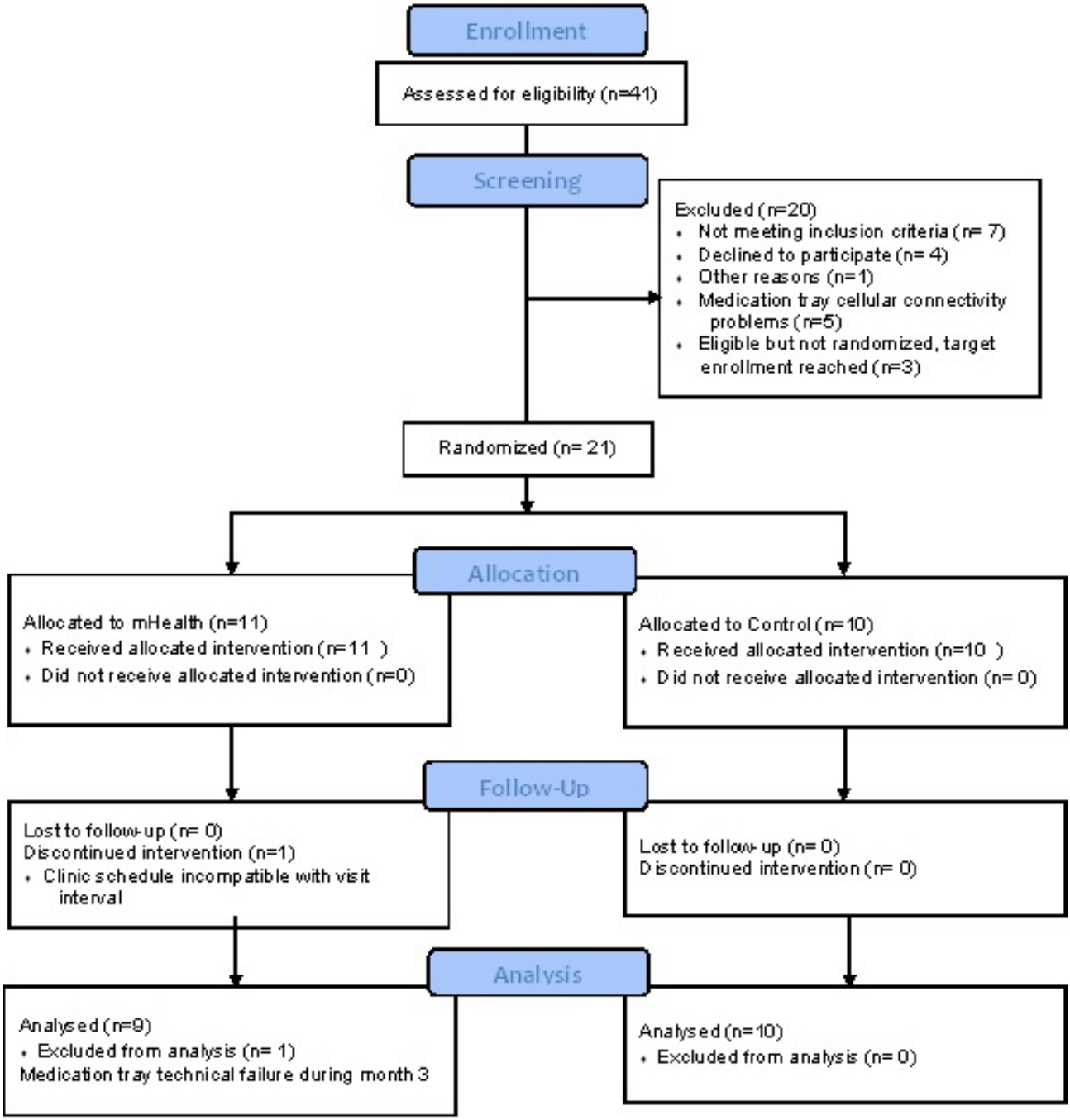
**Figure 2.** CONSORT flow diagram. A mobile health medication adherence and blood pressure control proof-of-concept trial in renal transplant recipients.




# Results

## Demographic and Clinical Characteristics

The baseline demographic and clinical characteristics of the 2 groups of patients are shown in Table 1. The subjects are representative of the patient population in the MUSC Kidney Transplant Clinic. Although subjects were randomly assigned to treatment condition an independent *t* test $t_{17}$ =3.23, *P*=.002 revealed participants in the SC group (57.6 SE=8.3) were significantly older than mHealth group members (42.4 SE=12.0). However, participants did not differ significantly on months since transplant (*P*=.09) or number of prescribed medications (*P*=.09).

## Acceptability and Feasibility

The acceptability of patients' participation in either the mHealth or standard care protocol was high with 75% (41/55) of patients approached agreeing to participate in the study. Of the 14 that declined to participate, 6 felt that they were "too adherent" to participate, with the other 8 refusing over concerns that either the electronic medication tray was "too bulky", that they were "too busy", or that they would have to travel too much. There was 1 patient who consented but withdrew prior to enrollment due to issues with travel. There were 6 subjects did not complete the lead-in phase, 5 for technical reasons relating to poor cellular signal at their home, and 1 subject was withdrawn due to graft failure necessitating a return to dialysis. Of the 34 subjects that completed the lead-in phase, 7 had adherence scores >0.85 and



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were ineligible for randomization and 3 were not enrolled due to full enrollment quota (n=20) being reached. Only 3 subjects declined randomization citing time concerns. Of the 21 subjects randomized, 1 was withdrawn for scheduling conflicts; the remainder completed the second phase of the study. There was 1 participant who experienced technical failure of the medication tray during month 3 and was excluded from medication adherence analyses.

The mHealth group reported high overall satisfaction with the mHealth system (average score 4.8/5 point Likert scale: 1= strongly disagree-5 = strongly agree). The mHealth system was easy for the subjects to learn to use (4.7/5) and easy to use in their home (4.8/5). They also found the system useful for medication and health management (4.3/5).

Physicians of the mHealth subjects received weekly reports via email detailing their patients' adherence rates and average blood pressures. Armed with the information provided, physicians of mHealth patients prescribed more medication changes to anti-hypertensive medications (7 changes in 5 patients) than controls (3 changes in 3 patients).

**Table 1.** Descriptive characteristics of sample.

| | | mHealth (n=9) | Standard Care (n=10) |
|---|---|---|---|
| **Age in years (SE)** | | 42.44 (12.04) | 57.6 (8.28) |
| **Ethnicity** | | | |
| | Black | 6 | 8 |
| | White | 3 | 1 |
| | Hispanic | 0 | 1 |
| **Gender** | | | |
| | Male | 4 | 7 |
| | Female | 5 | 3 |
| **Marital Status** | | | |
| | Never Married | 4 | 1 |
| | Married | 5 | 9 |
| **Income** | | | |
| | <$15,000 | 2 | 2 |
| | $15,000-$29,999 | 2 | 4 |
| | $30,000-$49,999 | 1 | 2 |
| | $50,000-$74,000 | 1 | 1 |
| | No Answer | 3 | 1 |
| **Months since transplant (SE)** | | 6.33 (2.2) | 4.8 (2.6) |
| **Number of Medications (SE)** | | 12.6 (2.7) | 14.9 (4.5) |

## Medication Adherence

### *Screening Period*

The average adherence score for all subjects who completed the screening period was 0.63 (SE=0.18) and ranged from high of 0.94 to low of 0.26, those who scored ≥ 0.85 had an average of .90 (SE=0.31) and those who scored < .85 had an average of 0.57 (SE=0.14). The 3 subjects who were eligible to be randomized but refused to continue into the trial had average score of 0.57 (SE=0.12)

### *Trial Phase*

The mean monthly adherence rates from pre-intervention screening through study completion by treatment group are presented in Table 2. Medication adherence was examined using a 2 (treatment group: mHealth, SC) x 4 (time: pre-intervention, 1, 2, and 3 months) repeated measures analyses of variance (ANOVA). The repeated-measures ANOVA yielded a significant group by time interaction $F_{3,48}$=11.74, $P$<.001, partial $\eta^2$=.42 and a significant main effect for time $F_{3,48}$=32.81, $P$<.001, partial $\eta^2$=.673 suggesting that although there was a significant difference across groups at all visits the magnitude of adherence differences increased after baseline. Post-hoc examination of Bonferroni adjusted confidence intervals revealed that the mHealth group did not differ significantly at baseline but displayed significantly higher medication adherence rates compared to the SC during each month following the pre-intervention screening (all $P$s<.05). It is important to note; 1 subject in the mHealth group was omitted due to technical malfunction with the system at month 3.

### *Resting Blood Pressure*

Resting BP was examined using 2 (treatment group: mHealth, SC) by 4 (time: pre-intervention, 1, 2, and 3 months) repeated measures ANOVA. A significant group by time interaction was observed for systolic BP (SBP), $F_{3,51}$=4.33, $P$=.009, partial



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$\eta^2$=.20. Further post-hoc examination of Bonferroni adjusted confidence intervals revealed that the mHealth group demonstrated significantly lower SBPs compared to the SC control group at months 1 and 3. A display of group separation over time is shown in Figure 3. Groups were not significantly different at baseline or month 2. Results for diastolic blood pressure (DBP) also revealed a significant group by time interaction $F_{3,51}$=4.58, $P$=.006, partial $\eta^2$=.212. Although groups were randomly assigned based on prescreening adherence, 95% confidence intervals revealed DBP values were significantly different at baseline with those randomized to the mHealth group having an average DBP approximately12mmHg higher. Groups were also significantly different at month three with the mHealth group still revealing significantly higher DBP than SC. Overall, the mHealth group showed a non-linear decline in DBP across months 1-3, while the SC group showed an initial increase at month 1, slight reductions at months 2, and ended with a slight increase at month 3. The pattern of changes across groups is shown in Figure 4.

**Table 2. Medication adherence by time across treatment condition** (Bonferroni adjusted 95% confidence intervals[CI]).

| Medication Adherence by Time Across Treatment Condition | mHealth (n=9) | | | Standard Care (n=10) | | |
|---|---|---|---|---|---|---|
| | Mean | SE | CI (95%) | Mean | SE | CI (95%) |
| Baseline | .576 | .048 | .474-.677 | .500 | .046 | .404-.597 |
| Month 1 | .87.4 | .046 | .777-.970 | .533 | .043 | .442-.625 |
| Month 2 | .929 | .040 | .844-1.014 | .587. | 038 | .507-.668 |
| Month 3 | .945 | .037 | .865-1.025 | .574 | .036 | .498-.650 |

**Figure 3.** SBP across time by treatment group (mean with Bonferroni 95% CI).

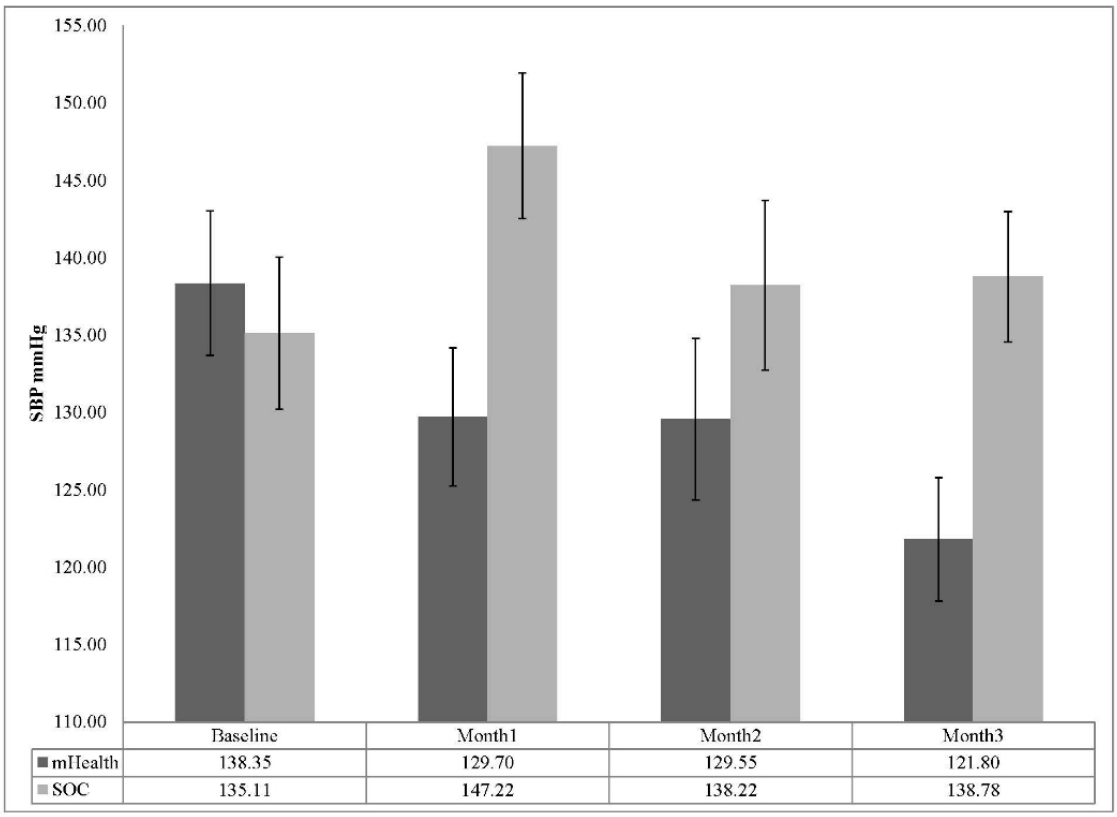




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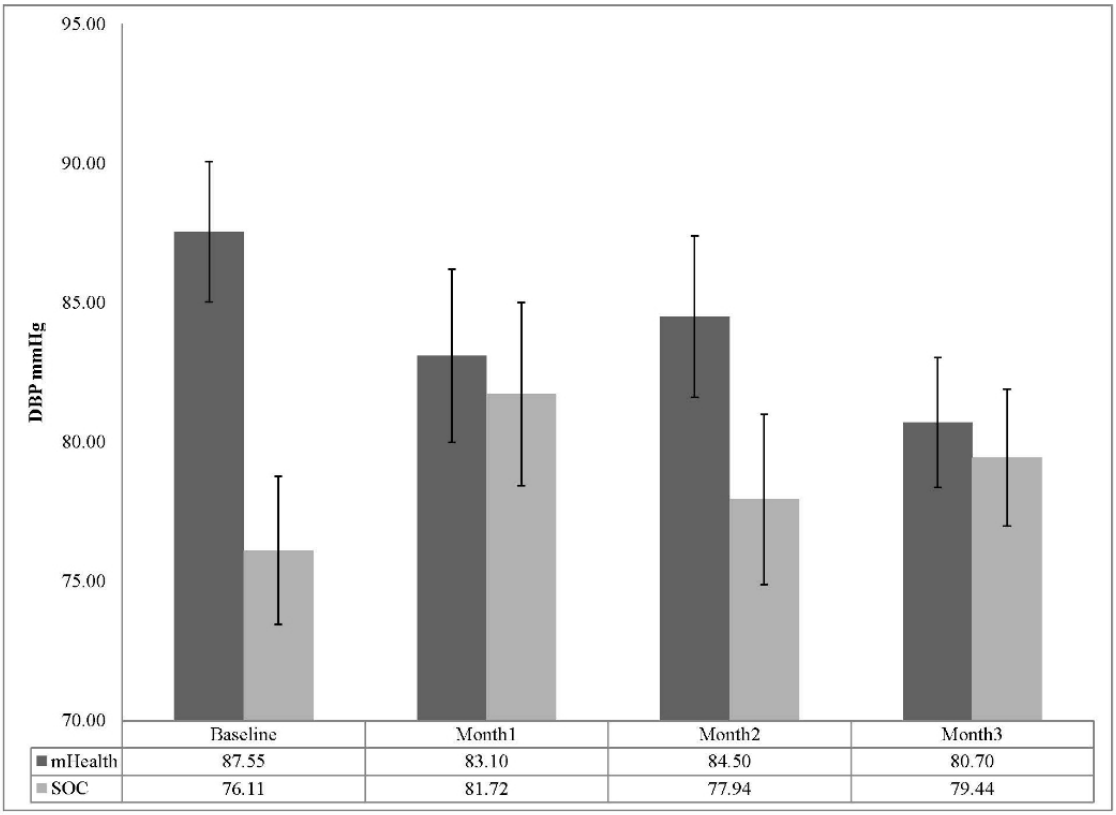
**Figure 4.** DBP across time by treatment group (mean with Bonferroni 95% CI).




## Discussion

### Summary

The development of effective, efficient, and non-intrusive approaches to aid kidney transplant recipients self-management and monitoring is critical to success as limited health care provider resources are increasingly taxed by growing demand. Mobile phone based monitoring is an attractive option due to their ubiquity, connectivity, computational power, portability, and relatively low cost [23,36-38]. Recent studies have supported remote monitoring via mobile health (mHealth) technology as an effective and sustainable strategy for facilitating patient-provider communication, increasing adherence to medical regimens, optimizing control of medical conditions, improving health outcomes, and reducing costs in some chronic illnesses [22,23,36,39-44]. While the evidence is mixed at present as to the cost effectiveness of mHealth technology [45], it seems reasonable to hypothesize that it will become so as the cost of the technology decreases and the long-term health benefits are realized. Furthermore as penetrance of the smartphone technology increases, it seems likely that there will be an increasing demand for this type of health care delivery from consumers.

We employed a patient and provider-centered approach to the development of our theory-driven mHealth prototype that allowed us to deliver a system that was highly acceptable to our target population. Feedback elicited prior to study enrollment from key informant interviews and a formal survey study [24] helped inform the study design and facilitated its acceptability and usability. Seventy-five percent (41/55, 75%) of the patients approached agreed to participate in the trial. Nearly half (6/14) of those who declined did so because they felt that they were already highly adherent to their medication regimen. Only 9% (3/34) of the subjects who completed the lead-in screening phase and were eligible for participation in the trial were unwilling to continue. All 20 of the randomized subjects completed the study. The high rates of participation and device utilization suggest that our subjects found the mHealth system to be useful and easy to use, which was confirmed by their responses on the satisfaction and usefulness survey. We intend on conducting focus groups with providers and patients for guidance in further refinement of the mHealth prototype system.

Our study employed a 1-month lead-in to identify patients with poor adherence prior to randomization. Despite all subjects self-reporting high levels of adherence, 78% of those screened were documented to have adherence rates below the cutoff of 0.85, a relatively liberal standard used by Russell et al [21] for patients on immunosuppressant medications. These findings are consistent with the literature that indicates self-report data overestimates objective measures of medication adherence [46] and that medication non-adherence is a significant problem after renal transplantation [19]. Russell et al used a face-to-face cognitive behavioral medication self-management training program to improve objective adherence from 0.72 to 0.88 over a 6-month trial. This improvement is, to date, the most significant reported in the literature for kidney transplant recipients. Our goal was to achieve a comparable improvement using a simpler mHealth-based approach. While Russell et al's study provided feedback to the patients on a monthly basis there



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was no mechanism to intervene in real time as the MEMS cap adherence data were only available after being downloaded at the time of the monthly clinic visit. In contrast, the MedMinder device provided an opportunity for real time intervention and feedback. The capacity to intervene shortly after a non-adherent event and to provide timely reinforcement and motivational feedback based upon adherence levels is perhaps the most novel and effective aspect of this trial. Should the improvements in medication adherence prove to be sustainable in longer trials, the rather simple and highly acceptable automated mHealth program has the potential to help resolve what has been a very challenging problem in solid organ transplantation.

In addition to monitoring and encouraging medication adherence, our study investigated the effect of our mHealth prototype on BP control. Blood pressure served both as a surrogate marker of adherence and as a meaningful physiologic indicator of the impact of improved adherence. To our knowledge, no prior study in kidney transplant recipients has simultaneously evaluated the impact of a mHealth intervention on both medication adherence and a relevant physiologic parameter. We observed statistically significant and clinically relevant reductions in clinic based systolic blood pressure (SBP) in the mHealth group compared to the SC control group. Previous BP self-monitoring trials have observed significant BP reductions but the degree of reduction observed in the present trial was far greater (eg, SBP reduction at 3 months: average of -20.3 mmHg versus -8 mmHg across previous RCTs [47-49]. Collectively, the degree of sustained BP reductions observed is quite remarkable given the relative simplicity of the mHealth program compared to the multi-modal face-to-face educational and cognitive behavioral skills based approaches used in previous RCTs [47-50]. We anticipated that our mHealth intervention would lead to more timely adjustments to the subjects' antihypertensive medication regimens. This was confirmed as mHealth patients were prescribed more anti-hypertensive medication changes (7 changes in 5 patients) than controls (3 changes in 3 patients). For the 5 subjects in the mHealth group who were not prescribed a medication change, BP substantially improved as their adherence increased. This finding can be interpreted as further evidence that, when managing chronic illnesses, the problem is not necessarily that the prescribed medications are not working, but that the patients are not taking them correctly.

These findings must be evaluated within the context of several limitations of the study. First, all subjects were recruited from a single transplant center which may call into question the generalizability of the findings. However, this center is the sole transplant service provider for the State of South Carolina and has a catchment population of over 4.6 million persons that encompass a wide range of ethnic, educational, and socioeconomic backgrounds. Second, that the randomly assigned groups differed significantly in age and adherence prior to the intervention raises questions about the validity of the conclusions. However, within groups age and adherence were not significantly correlated suggesting that age was not responsible for the differences in adherence and BP between our treatment groups. Third, those who chose to participate in the mHealth based RCT might be predisposed to a more positive attitude toward mHealth and thereby introduce a positive bias. That 75% of those approached agreed to participate suggests that a significant bias toward mHealth is unlikely. Fourth, it cannot be assumed that the subjects' willingness to use the system can be divorced entirely from the fact that the prototype system was freely provided and that they received a small financial reimbursement for their travel costs and time following each clinic evaluation. That many of the subjects asked to continue using the prototype following completion of the trial argues against the financial incentive playing a pivotal role but does not address the question of whether or not they would be as eager to use the mHealth system if it meant spending their own money. Although previous work by this group has documented that nearly 50% of our patient population own smart mobile phones [24], it seems likely that the $45 per month cost of the MedMinder device would prove prohibitive to a large fraction of our patients. Finally, it is important to note that our experiences with the MedMinder devices themselves represent a significant limitation to the broader application of this protocol. We experienced a significant device failure rate of approximately 23%. Without the dedicated attention of our study coordinators and IT personnel, this failure rate would have undoubtedly led to a great deal of patient frustration with the study and poor subject retention.

## Conclusion

To our knowledge, this is the first randomized controlled trial in kidney transplant recipients that has simultaneously examined the use of real time medication reminder and monitoring devices along with wireless measurement of relevant physiological indices to facilitate timely reinforcement based on adherence levels. This study is an early step in our efforts to develop an empirically validated, efficacious, and cost effective mHealth approach dedicated to improving medication adherence, blood pressure control, and minimizing clinical inertia in kidney transplant recipients. In our target population of kidney transplant recipients, our prototype mHealth system was acceptable and resulted in significant improvements in medication adherence and BP control. Although this RCT was not powered to detect an impact on graft function, graft fibrosis, or rejection, the impact on medication adherence and blood pressure control warrant further study. The expected next steps will include a single site efficacy RCT followed by a large-scale multi-site effectiveness RCT with longer follow-up evaluations.

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## Conflicts of Interest

None declared.

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## Abbreviations

**BP:** blood pressure
**DBP:** diastolic blood pressure
**mHealth:** mobile health
**MEMS:** medication event monitoring system
**MUSC:** Medical University of South Carolina
**RCT:** randomized controlled trial
**SC:** standard care control group
**SBP:** systolic blood pressure


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Protocol

# An Internet Intervention to Improve Asthma Management: Rationale and Protocol of a Randomized Controlled Trial

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## Abstract

**Background:** Many studies have shown the effectiveness of self-management for patients with asthma. In particular, possession and use of a written asthma action plan provided by a doctor has shown to significantly improve patients' asthma control. Yet, uptake of a written asthma action plan and preventative asthma management is low in the community, especially amongst adults.

**Objective:** A Web-based personally controlled health management system (PCHMS) called Healthy.me will be evaluated in a 2010 CONSORT-compliant 2-group (static websites verse PCHMS) parallel randomized controlled trial (RCT) (allocation ratio 1:1).

**Methods:** The PCHMS integrates an untethered personal health record with consumer care pathways and social forums. After eligibility assessment, a sample of 300 adult patients with moderate persistent asthma will be randomly assigned to one of these arms. After 12 months of using either Healthy.me or information websites (usual care arm), a post-study assessment will be conducted.

**Results:** The primary outcome measure is possession of or revision of an asthma action plan during the study. Secondary outcome measures include: (1) adherence to the asthma action plan, (2) rate of planned and unplanned visits to healthcare providers for asthma issues, (3) usage patterns of Healthy.me and attrition rates, (4) asthma control and asthma exacerbation scores, and (5) impact of asthma on life and competing demands, and days lost from work.

**Conclusions:** This RCT will provide insights into whether access to an online PCHMS will improve uptake of a written asthma action plan and preventative asthma actions.

**Trial Registration:** Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12612000716864; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=362714 (Archived by WebCite at http://www.webcitation.org/6IYBJGRnW).

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**KEYWORDS**

asthma management; Internet intervention; personalized health record; personally controlled health management system; eHealth; asthma action plan



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## Introduction

### Background

Around 300 million people worldwide currently suffer from asthma [1]. The mortality caused by asthma is significant since a global estimation attributes to this disease about 1 in every 250 deaths [1]. Living with asthma is also difficult. People with asthma report worse health and quality of life than those without asthma [2,3].

Solutions have been developed to help people with asthma cope with their condition [4]. One of the key elements to optimal asthma management is to achieve good control of the disease. To achieve that, patients' knowledge in recognizing asthma symptoms, identifying risk factors, using medication, and managing asthma exacerbations is important. Further, the relationship between patients with asthma and healthcare providers is crucial to develop an efficient asthma self-management plan [5].

One of the most useful tools in facilitating effective asthma self-management is the use of an individualized written asthma action plan, which describes different tailored steps of actions for the patient to follow according to their asthma severity. Written asthma action plans are claimed to be one of the most effective means for asthma self-management in several systematic reviews [6-8]. A Cochrane review by Gibson and colleagues concludes that use of a written asthma action plan, combined with regular visits to the doctor and education about asthma, leads to fewer visits to the emergency department, less hospital admissions, better lung function, and improvement on symptoms [6]. Online social networks and personal health management systems represent an innovative intervention to help patients engage with clinicians, health services, and self-management [9]. Despite strong evidence for the efficacy of written asthma action plans, they are widely under-used. Even after over 20 years of recommendation, only about one in 5 people with asthma have a written asthma action plan [10].

In Australia, the prevalence of asthma is particularly high and represents one of the highest in the world [2,3]. More than 1 in 10 adults and children is estimated to be suffering from asthma, representing more than 2 million Australians [2]. Although prevalence of asthma has declined over the last decade, the mortality caused by this disease remains significant with 411 people reported to have died from asthma in 2009 in Australia. According to a survey from the Australian Council of Asthma Monitoring in 2007 and 2008, only 21.3% of all-age patients with asthma are reported to possess a written asthma action plan [2,3]. This rate dropped to 14.4% when considering a subgroup of people aged 15 years and over [2].

There are a number of explanations for the under-usage of written asthma action plans by patients. Firstly, the diagnosis of asthma may not have been made in primary care where symptoms have been treated, if the disease is not labeled then patients may not be provided with long-term self-management tools [11]. When asthma is properly diagnosed, some health professionals provide patients with oral instruction instead of a formal written asthma action plan [12]. Others may consider asthma action plans as inefficient tools because of a lack of information and a difference of perception of asthma between patients and doctors [13,14]. From the patient's point-of-view, asthma action plans can also be perceived as irrelevant or be under-used because of a passive attitude toward their asthma. This can prevent them from taking personal control of their asthma [15,16]. Finally, another reason could be that patients do not visit healthcare professionals to obtain or to update their asthma action plan, or do not ask for it when they see their general practitioner [15].

For asthma, Internet-based self-management appears to be a promising approach to improve control of this condition [17-21]. The aim of this study is to test a Web-based personally controlled health management system (PCHMS), in supporting consumers with asthma to encourage the uptake and use of a personal written asthma action plan, and to proactively seek self-management advice and schedule planned general practitioner (GP) visits before experiencing an asthma exacerbation. The PCHMS, called *Healthy.me*, has been previously tested with patients undergoing in-vitro fertilization (IVF) [22], in a randomized controlled trial to improve uptake of influenza vaccination [23,24], and amongst university students about help-seeking behaviors for physical and emotional well-being [25,26].

### Study Aims and Hypotheses

Specific hypotheses to be tested in this study are that:

1. Consumers using a Web-based PCHMS with interactive and social features are more likely to follow evidence-based guideline recommendations for asthma management, as measured by the rates of obtaining or updating a written asthma action plan with their GP and the usage rates with the asthma action plan, measured by questionnaires;
2. Use of a PCHMS will contribute to improved asthma control and reduced rates of asthma exacerbation compared to those using only static websites (usual care arm).

## Methods

### Study Design

A randomized controlled trial with a 2-group parallel design (with intervention allocation ratio 1:1) will be used to evaluate the efficacy of the Web-based PCHMS *Healthy.me*, reported in accordance to the 2010 CONSORT statements [27](ACTRN12612000716864). The PCHMS is not part of usual care but aims to improve usual care as measured by compliance to evidence-based guidelines.

- Participants randomized to the *intervention* group will have immediate access to an interactive version of *Healthy.me* with full PCHMS features as described later, from the date they are recruited.
- Participants randomized to the *control* group will receive access to a static webpage, without PCHMS features or any interactive component. This webpage will offer links to Australian information websites about asthma.



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## Participants

Participants meeting eligibility criteria will be invited to use *Healthy.me* for 12 months. Participants will be assigned to intervention (access to *Healthy.me*) or control (access to static website) by random allocation generated by a computerized random-number generator [28]. Participants may be randomly selected to attend a 1-hour interview (or focus group) to discuss their asthma management and feedback at the end of the study. The participant inclusion eligibility criteria are as follows: (1) aged 18 or above, (2) living in Australia at the time of the study, (3) easy access to the Internet and email on a regular basis, (4) doctor diagnosis of asthma, and (5) adequate English reading and written ability. Participants currently enrolled in other trials of *Healthy.me* are excluded.

### *Recruitment Strategy*

The recruitment of participants will be made possible with the assistance of Asthma Foundation Australia, the National Asthma Council Australia, and other consumer groups which have an online presence, to advertise our study using their existing participant engagement methods (ie, electronic newsletters and website). Because the study requires participants who are familiar with the use of the Internet, special emphasis will be given to Internet-based recruitment. Calls for research participants will be made on Google, Facebook, Twitter, and other online/social media on a regular basis, as well as on an online notice board (Gumtree Australia). It will also be possible that some participants will be recruited by others participants (snowballing sampling) via sharing in social networks, and thanks to the "invite a friend" feature they will be able to use on *Healthy.me* website.

Interested participants will be directed to a website with detailed information about the study. All consenting participants (control and intervention) will then be directed to a secure website to complete an eligibility screening survey.

### *Ethical Concerns and Consent*

Ethics approval for this study has been obtained from the University of New South Wales (UNSW) Human Research Ethics Committee (approval no. HC12213), and from the National Research and Evaluation Ethics Committee of the Royal Australian College of General Practitioners (RACGP) (approval no. NREEC 12-005). Eligible participants will complete their written consent form online; the revocation of consent form is also available online.

## Intervention and Control

All participant volunteers responding to the invitation are required to register online by providing consent, completing a 3-minute eligibility questionnaire. Those eligible will then be invited to complete a 10-minute online pre-study survey and to watch a 3-minute online tutorial about *Healthy.me*. All eligible participants will also complete a 5-minute monthly survey during the study and a 10-minute post-study survey at 12 months. The control and intervention arms of the trial run concurrently, meaning that the randomly allocated participants of the trial will be exposed to the same environmental condition (eg, season), and the same background of public health campaigns.

### *Description of Intervention*

*Healthy.me* consists of the following features:

1. *Personal Health Record (PHR)*. Allows for self-recording of medical test results and health measurements.
2. *Pillbox*. Allows for self-recording of current medications and medication adherence.
3. *Schedule, to-do list, and reminders*. An online schedule to self-record and keep track of health-related appointments, to-do items, which sends email reminders, and allows participants to book appointments with their health service providers.
4. *Team*. A feature that allows the self-recording of clinical and non-clinical personnel looking after one's health.
5. *Journeys*. Consumer-specific care pathways that provide knowledge for health service engagement and self-management in an actionable way. These pathways describe the different stages in the management of health conditions that can be used to personalize other PHR sections in the system, and provides advice on what to expect and how to prepare for each stage (Participants in this study will have access to three asthma management journeys with content developed in collaboration with Asthma Foundation NSW, and adapted from its website [29]).
6. *Social communication spaces*. Support rich interaction across the continuum of care between participants and clinicians. The features include: (1) a poll system in which participants will be able to answer simple health-related questions and compare their response with other participants' aggregated and de-identified responses; (2) ability to send and receive email messages with other participants on *Healthy.me*; (3) *diary* which offers a private place (by default but with the possibility to share with other participants) for participants to write down their thoughts and feelings; and (4) forums (moderated by a GP and the research team).
7. *Online appointment booking service.* This feature allows participants to be directly connected by telephone and at no charge with their health professional after clicking on a button. The 3 steps of the protocol are: First, participant clicks on a "book now" graphic button in *Healthy.me* and confirms his/her telephone number as well as health professional's one; Second, participant and health professional receive an automatic ongoing call from the service, and Third, participant and health professional are connected each other and can book an appointment over the phone.

### *Intervention Group and Exposure*

The period of access to *Healthy.me* will vary depending on the date of participant registration (from 9 to 12 months). During the study *Healthy.me* will provide participants in the intervention group with information and forward email reminders about asthma, indications for managing their asthma or other medical concerns, should they wish to use that service.

The intervention will not modify in any way the standard procedures of healthcare provision by GP clinics.



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A pilot study has been conducted with 9 adults including 3 participants with asthma. Issues on system usability, journey content, surveys, study protocol, and advertisement material have been resolved before recruiting participants with asthma to participate in their normal setting.

### *Control*

Participants in the control group will receive only a static webpage with links to external evidence-based materials written for consumers on asthma management available in Australia without the PCHMS features listed previously (ie, myDr.com.au, HealthInSite.gov.au, and asthmaaustralia.org.au), and delayed access to the full interactive version of *Healthy.me* by 12 months.

## Sample Size

A conservative estimate of at least 300 participants with 150 in each arm is needed to detect a 15% point difference in possession rate of a written asthma action plan between the control group (14.4%) and the intervention group (29.4%). This estimate is calculated at 5% level of significance, 80% power (2-sided test), with an anticipated participant dropout rate approximately 25%.

The effect size estimate is based on previous studies using *Healthy.me* assessing the efficacy of Internet-based interventions on the uptake of preventative health actions [23], and on studies with interventions promoting the use of personal asthma action plans [13]. The base rate is the percentage of adults (ie, 15 years and over) with current asthma in Australia and possessing a written asthma action plan, reported in the Australia Centre for Asthma Monitoring analysis of the Australian Bureau of Statistics National Health Survey 2007-2008, and cited in the Australia Centre for Asthma Monitoring 2011 report [2].

## Outcome Measures

The primary measure is the number of participants who have obtained, or have updated, their written asthma action plan with a GP within the 12 months of the study. The secondary outcomes concern actual use rate of the written asthma action plan, number of unplanned visit to healthcare for asthma, usage of *Healthy.me*, asthma symptoms, and competing demands on health and asthma. Please see Table 1 below.



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**Table 1.** Summary of outcome measures.

| Outcome measures | Measurement time points & methods | Time | | |
|---|---|---|---|---|
| | | Baseline | Monthly | Completion |
| **Primary outcome** | | | | |
| Number of participants with a written asthma action plan | Pre and post-study surveys | X | | X |
| **Secondary outcomes** | | | | |
| Number of participants reported using their written asthma action plan, obtained, or updated during the study | Post-study survey | X | | X |
| Rate of planned (non-urgent) visits to a healthcare professional (eg, GP) for routine asthma management | Post-study survey | | | X |
| Rate of unplanned visits to a GP, emergency department, caused by worsening asthma | Post-study survey | | | X |
| Website usage patterns (number and timing of hits, duration of access, uptake of specific functions) of *Healthy.me* | *Healthy.me* system logs | | | X |
| Technology acceptance of *Healthy.me* | Measured via the "Scales for Perceived Usefulness and Perceived Ease of Use" [30] | | | X |
| Asthma control | Measured via "Asthma Control Questionnaire" [31] | | X | |
| Asthma exacerbations | Measured via the "Asthma Exacerbation Questionnaire" [32] | | X | |
| Number of days lost from work or school | Measured via an additional question after the "Asthma Control Questionnaire" [31] | | X | |
| Competing demands on health and asthma | Lists of life priorities and top health issues, monthly made by participants. | | X | |

## Data Collection

Firstly, self-reported responses are collected by use of Internet-based survey, accessed online, or sent to participants via email (Table 2). Surveys will be hosted by "KeySurvey", an in-house survey infrastructure available at UNSW [33]. All completed responses will be stored securely in a server managed by UNSW. These surveys are:

Secondly, during the study, participants' actions on the *Healthy.me* system will be unobtrusively and automatically logged.

Thirdly, a subset of participants (up to 10% of the sample) may be selected, according to their experiences and their patterns of behaviors using *Healthy.me*, for a post-study semi-structured interview/focus group, eliciting their feedback on *Healthy.me* and asthma self-management.

## Analysis Plan

Statistical significance is defined as a *P*-value of less than .05 (determined using a two-tailed test). Data will be collected by online survey software KeySurvey [33] and analyzed using IBM SPSS Statistics 19 [34].

### *Baseline Comparison*

Comparisons of baseline variables between PCHMS group and control group will be conducted using visual inspection, to verify the absence of abnormal measures and data. An assessment of the homogeneity of the variances of distributions from the two groups will be statistically verified before carrying out inferential statistical analyses.

### *Primary Analysis*

Differences in proportions of participants visiting their GP to obtain/update their written asthma action plan during the study will be compared between control and PCHMS groups. All intervention recipients who had the opportunity to use the PCHMS but did not do so will be included in the primary



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analysis (intention-to-treat principle with Last Observation Carried Forward (LOCF) imputation procedure for missing values [35,36]). Differences in participant proportions between control and PCHMS groups will be analyzed using $\chi^2$test or Student's *t*-test. Proportions will be reported with 95% confidence intervals. Adjustments for baseline characteristics and possible confounders, such as age and other demographics [2,3], smoking status [3], and asthma severity [2], will be made through the use of sequential logistic regression [37]. All baseline characteristics, and factors that may affect the written asthma action plan possession rate collected at post study (eg, past possession of an asthma action plan) will be entered at step 1 of the regression; and group allocation (PCHMS vs. control) will be entered at step 2.

### *Secondary and Ancillary Analysis*

Differences in proportions of participants between different groups (eg, control vs. PCHMS) will be examined using $\chi^2$test based on data collected from pre-, monthly, and post-intervention questionnaires, for each of the following activities experienced at least once during the study: (1) visited a GP (or a healthcare professional) for an unplanned asthma visit; (2) used medications or remedy; and (3) experienced performance impairment. Differences in average number of days of absence per participant and differences in score distributions from questionnaires will be compared between control and PCHMS groups using Student's *t*-test or non-parametric statistics. Reasons for receiving (or not receiving) written asthma action plan will be reported using descriptive statistics. Attrition rate for the use of *Healthy.me* will be assessed with system logs. Technology acceptance of *Healthy.me* will be measured via the "Scales for Perceived Usefulness and Perceived Ease of Use" [30,38]. Participants' satisfaction and utilization of Healthy.me will be reported. Cost effectiveness of health service utilization [39] (upon availability and feasibility) will also be considered as well as economic costs from days lost from work/school. If any post-hoc comparison would need to be performed between unplanned groups of participants, a Holm's sequential Bonferroni procedure [40] will be used in order to control a familywise error rate *FWER* inferior or equal to level $\alpha = .05$.

## Study Procedure

Table 3 below summarizes participant procedures in the study. The duration of the study is expected to be 12 months.

Email will be the primary channel to communicate with participants for study information and reminders about survey completion. From the time participants are recruited until study completion, all participants (control and intervention) will receive an email each month to complete a 5-minute survey about their health in the past month. At study completion, all participants will receive an email asking them to complete a post-study survey. In order to ensure the completeness of data collection, there will be 2 follow-up emails sent 5 days apart from each other to remind those who have not completed each survey.

**Table 2.** Surveys used in the study.

| Survey | Purpose |
|---|---|
| Screening survey | Eliciting participants' eligibility criteria. |
| Pre-trial survey | To obtain participants' demographics and experiences of asthma management at study enrolment. |
| Monthly follow-up questions | To obtain participants' self-reported symptoms of asthma (ie, asthma control and exacerbation), impact on work and study due to asthma symptoms, and competing demands and health throughout the study. |
| Post-trial survey (12 months after the beginning of the study) | To obtain participants' state of asthma control and asthma management. For those who receive the PCHMS version of *Healthy.me*, their perceived usefulness of *Healthy.me* will also be assessed. |

**Table 3.** Stages of study procedure.

| Stage of study | Procedure |
|---|---|
| **Online registration** | |
| | Eligibility screening survey |
| | Participant registration, study consent and *Healthy.me* tutorial (self-completed online) |
| **Baseline data** | |
| | Pre-study survey (self-completed online) |
| **Participant follow-up procedures** | |
| | Monthly 5-minute surveys (self-completed online) |
| | Post-study survey (self-completed online) |
| | Patterns of *Healthy.me* use (computer logs and data entered by participants) |



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### *Randomization*

After consent each participant is randomly allocated to the intervention or control group, stratified by gender and level of asthma severity (intermittent vs. persistent), according to a sequence generated by a computerized random-number generator [28] using permutated blocks of 2, 4, and 8. The randomization sequence generation, participant enrolment and group allocation processes in this study are computerized online and do not involve interference from the investigators.

### *Allocation Concealment and Assessment*

Since *Healthy.me* is a behavioral intervention it is not possible to completely blind participants to the intervention. However, allocation of participants is automatically randomized, then coded within the Internet-based survey tool "KeySurvey". The surveys are automatically sent by the system to participants, so investigators involved in the study are blinded to group allocation until completion of the quantitative analyses. The group allocation is revealed to participants only after they consent to participate in the study following completion of the pre-study questionnaire. To minimize contamination of control participants who might interact closely with participants who are part of the intervention group, participants in the intervention group are asked not to share their *Healthy.me* access details with other people.

## Results

The recruitment of participants is ongoing and first results are expected in early 2014. The data collection should be complete by mid-2014.

## Discussion

### Limitations

There are several potential limitations in this study. Firstly, the number of participants meeting inclusion criteria at study completion might be low because the study will focus recruitment only in Australia. The other inclusion criteria such as age, Internet access, and English speaking skills, might be also restrictive for recruiting participant in the targeted population.

Secondly, there is a possible high attrition rates. The study's outcomes will rely on data from participants' self-reports. Due to the long duration of the study, over 12 months, it is possible to observe a high rate of attrition from participants and thus, a significant loss of data. To limit this, all participants will be actively requested to complete questionnaires by receiving monthly reminders via emails. Furthermore, the questionnaires used on a monthly-basis will be easy and convenient complete (short questionnaires with an online completion using multiple-choice questions).

Thirdly, there may not be representative of consumers with asthma. The study may be more appealing to younger participants who are interested or literate in computers, the Internet, or asthma self-management topics. These participants may be more enthusiastic about health and the Internet than the general asthma population.

Fourthly, as this is a pragmatic trial of a multifaceted intervention in a complex environment, it is possible that baseline variables associated with participants might also influence the outcome. For example, having a prior history of obtaining a written asthma action plan may predict future planned visits to GP, independent of any additional intervention. We will identify potential baseline variables that might influence outcomes, including age and smoking status, and test for unequal variance in the distribution of these variables in the intervention and control populations.

### Concluding Remarks

Most of the features used in the study have been recently tested in a *Healthy.me* trial on help-seeking behaviors for physical and emotional well-being in a university student population [25]. The results of that study have shown that some bundles of features could lead to behavioral changes in university health service utilization and reported help-seeking for physical and/or emotional concerns. These results were consistent with theoretical expectations of behavioral changes generated from the use of features in *Healthy.me*. Particularly, the Health Belief Model (HBM) provides insights on how information may be transformed into action when informational cues in the environment are linked to action [41]. In the present study, we expect that the use of the online appointment booking service will be significantly associated with visits to health professionals, and consequently with a high rate in obtaining an asthma action plan. Another lever of behavioral change in accord with the principle of self-monitoring, may be operate thanks to features which encourage self-refection and self-awareness, such as the Personal Health Record, the Pillbox, the Diary, and the Poll [42]. In addition, the social and interactive features used in *Healthy.me* (Forums, Poll, Message) should play an important role in minimizing attrition and in promoting utilization of the platform amongst participants during the 12 months of the study [9].

Our design of the present randomized controlled trial (RCT) focuses on the comparison of outcomes that unequivocally reflect a change in consumer behavior, and takes into account the complexity of intervention. Results of this study will offer new insights about the utility of a Personally Controlled Health Management System (PCHMS) for consumer engagement with e-health services and self-management. Our findings will provide specific answers to whether using a Web-based PHCMS, containing information and self-management tools that facilitate consumers to engage with health services, will improve the uptake of preventive asthma management actions such as the possession and use of a written asthma action plan.



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## Authors' Contributions

Study conceptualization: AL, EC, STL, SD, AA; Study design: AL, AA, SD, STL, EC; Journey design: AA, AL, SD, STL, EC; First draft: AA, AL; Draft revision: AA, AL, SD, STL, EC.

## Conflicts of Interest

The university and some of the researchers involved in this project could in the future benefit from any commercialization of *Healthy.me* or its technologies.

## Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [43].

[PDF File (Adobe PDF File), 988KB - resprot_v2i2e28_app1.pdf ]

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## Abbreviations

**GP:** general practitioner
**HBM:** Health Belief Model
**IVF:** in-vitro fertilization
**LOCF:** Last Observation Carried Forward
**PCHMS:** personally controlled health management system
**RCT:** randomized controlled trial
**UNSW:** University of New South Wales

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Original Paper

# South Asian Heart Risk Assessment (SAHARA): Randomized Controlled Trial Design and Pilot Study

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## Abstract

**Background:** People of South Asian origin suffer a high burden of premature myocardial infarction (MI). South Asians form a growing proportion of the Canadian population and preventive strategies to mitigate the risk of MI in this group are needed. Prior studies have shown that multimedia interventions are effective and feasible in inducing health behavior changes among the obese, smokers, and among those who are sedentary.

**Objective:** Among at-risk South Asians living in Canada, our objectives are to determine: (1) the feasibility of a culturally tailored multimedia intervention to induce positive behavioral changes associated with reduced MI risk factors, and (2) the effectiveness and acceptability of information communicated by individualized MI and genetic risk score (GRS) reports.

**Methods:** The South Asian HeArt Risk Assessment (SAHARA) pilot study enrolled 367 individuals of South Asian origin recruited from places of worship and community centers in Ontario, Canada. MI risk factors including the 9p21 genetic variant status were provided to all participants after the baseline visit. Participants were randomly allocated to receive a multimedia intervention or control. The intervention group selected health goals and received personalized health messages to promote adherence to their selected goals. After 6 months, all participants had their MI risk factors repeated. The methods and results of this study are reported based on the CONSORT-EHEALTH guidelines.

**Results:** The mean age of participants was 53.8 years (SD 11.4), 52.0% (191/367) were women, and 97.5% (358/367) were immigrants to Canada. The mean INTERHEART risk score was 13.0 (SD 5.8) and 73.3% (269/367) had one or two copies of the risk allele for the 9p21 genetic variant. Both the intervention and control groups made some progress in health behavior changes related to diet and physical activity over 6 months. Participants reported that their risk score reports motivated behavioral changes, although half of the participants could not recall their risk scores at the end of study evaluation. Some components of the multimedia intervention were not widely used such as logging onto the website to set new health goals, and participants requested having more personal interactions with the study team.



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**Conclusions:** Some, but not all, components of the multimedia intervention are feasible and have the potential to induce positive health behavior changes. MI and GRS reports are desired by participants although their impact on inducing sustained health behavior change requires further evaluation. Information generated from this pilot study has directly informed the design of another randomized trial designed to reduce MI risk among South Asians.

**Trial Registration:** ClinicalTrials.gov NCT01577719; http://clinicaltrials.gov/ct2/show/NCT01577719 (Archived by WebCite at http://www.webcitation.org/6J11uYXgJ).

***(JMIR Res Protoc 2013;2(2):e33)*** doi:10.2196/resprot.2621

**KEYWORDS**

multimedia; South Asians; health; risk; assessment; randomized; trial

## Introduction

### Background

Myocardial infarction (MI) due to coronary artery disease (CAD) remains a major cause of death globally [1]. The rising prevalence of overweight, obesity, and type 2 diabetes is predicted to potentiate the CAD epidemic in developing countries [2]. South Asians, people who originate from the Indian subcontinent, suffer a high burden of premature MI [3,4], and are projected to account for 40% of the global CAD burden by 2020 [5]. More than 1.2 million South Asians live in Canada and are the fastest growing group of non-white Canadians [6]. Our previous study has shown that, compared to white Caucasians in Canada, South Asians suffer a 2.5 times excess prevalence of elevated glucose (dysglycemia), and CAD [7], and develop cardiometabolic risk factors (ie, abnormal glucose and lipids) at significantly lower body mass index (BMI) values [8].

Despite several previous studies showing excess cardiometabolic risk [4,9,10] and increased premature MI among South Asians [11], there is no routine screening process of South Asians for CAD despite the Canadian Cardiovascular Society recommendations to screen “high-risk” groups including South Asians [12]. Therefore, there is a need for routine screening of CAD risk factors in South Asian adults and to develop and test interventions to improve risk factors among South Asians. This is critical because collectively common risk factors (abnormal lipids, elevated glucose, elevated blood pressure, and abdominal obesity) account for over two-thirds of the population attributable risk of MI [4].

Several studies have shown that multimedia interventions to manage risk factors of common disorders and to modify health behaviors are effective [13-19]. Multimedia interventions include use of email messaging, text messaging, video- or computer-based education, and electronic personalized health records, which are attractive because they involve components of goal setting and feedback—key components of health behavior modification, are relatively cost efficient, and have the potential to be scalable to large numbers of individuals [20-25].

The use of MI risk tools to guide risk factor modification in cardiovascular prevention is increasing [26]. More recently the addition of genetic information into these risk tools has been evaluated. This has been made possible by the recent large-scale genetic studies that have identified common genetic variants associated with MI risk. The most robust genetic variant associated with increased risk for MI is a common polymorphism located on the short arm of chromosome 9 (9p21) [27,28]. This genetic variant is common in the general population, with 50% of people carrying one copy of the risk allele, which increases MI by 15-20%, and 25% of the population carrying two copies of the risk allele, which increases MI risk by 30-40% [29]. Further there is evidence to suggest that the MI risk associated with 9p21 may be modified by healthy dietary patterns [30]. While some recent studies have evaluated whether knowledge of genetic risk of a condition influences individuals’ behavior change [31,32], the results remain inconclusive. To our knowledge there have been no multimedia health behavior modification interventions, which have incorporated genetic risk information among South Asians at risk for MI.

### Objective

To address this gap we conducted a pilot study, the South Asian HeArt Risk Assessment (SAHARA) among at-risk South Asians living in Canada, to determine: (1) the feasibility of a culturally tailored multimedia intervention to induce positive behavioral changes associated with reduced MI risk factors, and (2) the effectiveness and acceptability of information communicated by individualized MI and genetic risk score (GRS) reports. Information generated from the SAHARA pilot study will directly inform the design of another randomized trial designed to test the effectiveness of this intervention to reduce MI risk among South Asians.

## Methods

### Study Design and Recruitment

The study is a randomized controlled pilot trial that was approved by the McMaster/Hamilton Health Sciences Research Ethics Board on June 3, 2009 (09-225).

Individuals were recruited from places of worship and community centers in Southwestern Ontario, Canada, during the period from January 16, 2011 to January 29, 2012. Recruitment clinics were setup in these “high-yield” locations at high yield times (following weekly ceremonies and scheduled activities) to maximize enrollment. The study team contacted community leaders in the recruitment locations to obtain permission to inform the congregation about the study, and this was done 1-2 weeks prior to the screening event.



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### Eligibility

Men and women ≥30 years of age of South Asian ancestry, defined as people whose ancestors originate from the Indian subcontinent (India, Pakistan, Bangladesh, and Sri Lanka), were eligible for inclusion in the SAHARA pilot study. All participants were required to have access to email, cell phone with text messaging capability, or a smart phone (ie, a handheld device capable of sending and receiving text messages and searching the Internet such as an iPhone or Blackberry).

### Exclusion Criteria

Individuals who had suffered a previous MI, had coronary artery bypass graft (CABG) surgery, coronary angioplasty, or stroke, who were not permanent residents of Ontario, and who did not have an Ontario health card were excluded.

### Consent and Baseline Data Collection

Written informed consent, including consent to use of the health card number to facilitate future record linkage with health services databases, and to analyze DNA for genetic variants, was obtained from each participant. Information on risk factors including cholesterol status, diabetes, hypertension, current, former, and second-hand exposure to tobacco smoke, diet, physical activity, sedentary behaviors, and psychosocial stress questions was collected. Stages of change information based on Prochaska's model of change [33] were also obtained for diet, physical activity, sedentary behavior, and smoking. Blood pressure (two measures 3 minutes apart using an automated OMRON device), body weight and height (to calculate BMI), waist and hip circumference, and body fat percentage using a digital bioelectrical impedance scale were measured. A 30-mL nonfasting blood sample was collected from all participants, and was processed onsite within 2 hours of collection. The blood samples were analyzed for apolipoprotein A1 and B, HbA1C, and the 9p21 single nucleotide polymorphism (SNP) (rs1333049) genotype using Taqman. All genotypes were in Hardy-Weinberg equilibrium (HWE) for the total sample ($P$>.05). Previous studies have reported a minimal difference in apolipoproteins' levels when comparing fasting to nonfasting levels [34]. The remaining serum and plasma aliquots were placed in long-term storage for future study-related analysis.

### Risk Profile

Using the information collected at the baseline visit, a MI risk report was generated for each participant using the INTERHEART risk score (IHRS; Multimedia Appendix 1, which is a simple and valid risk factor scoring system developed and validated from the INTERHEART case-control study to assess MI risk in adult men and women [35]. This risk model included the following factors: apolipoprotein B-to-A1 ratio, smoking, second-hand smoke exposure, hypertension, HbA1c, abdominal obesity, physical inactivity, diet, and psychosocial factors. As part of the SAHARA pilot study the risk score report was pretested and modified in an easy to understand format that classifies individuals as low (0-9), moderate (10-15), or high (16-48) risk using a color visual display (Figure 1) (also see website [36]). In addition to IHRS, a GRS based on 9p21 genotype information was generated. The GRS was developed, pretested, and modified in an easy to understand format and classifies individuals who have 0, 1, or 2 risk alleles using a color visual display (Figure 2). The contents of the report were pretested in 2 focus groups conducted at a South Asian temple, and modified to the grade 5 reading level.

### Randomization

#### *MyOSCAR-SAHARA*

Approximately 4-6 weeks after the screening visit was completed, participants were sent an email asking them to log onto the secured MyOSCAR-SAHARA website [37], to access their risk score results. If they were eligible for randomization (based on study inclusion criteria), they were prompted to click on a button that took them to a Web portal to be randomized to intervention or control (usual advice) groups using a computer-generated algorithm in OSCAR (Open Source Clinical Applications and Resources)—an open source software project launched by the Department of Family Medicine at McMaster University in Hamilton, ON, Canada, in 2002, designed for the delivery of evidence-based resources and decision support at the point of care for both patients and providers [37]. We used a specially constructed MyOSCAR-SAHARA personalized website to enable study participants' to retrieve their results, and to set goals which triggered a series of goal-tailored health messages they received by email or text message (for screenshots, see Figures 3-7).

Intervention and control groups received the same baseline assessment and usual care while only the intervention group received the study intervention.



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**Figure 1.** IHRS risk report example.

| Risk Factor | Value | Score |
|---|---|---|
| **Age & Sex:** | You are a Female, under 65 years | 0 |
| **Apo B:A1 Ratio** | 0.45 | 0 |
| **Smoking:** | You are a former smoker | 2 |
| **Second hand smoke** | Less than 1 hour of exposure per week | 0 |
| **Diabetes:** | You have diabetes | 6 |
| **Blood Pressure** | 132/75 | 0 |
| *Desirable Blood Pressure: 120/80 mmHg* | | |
| **Waist to Hip Ratio:** *Desirable Waist to Hip Ratio: Less than 0.87* | Waist circumference: 80.10cm Hip circumference: 83.10cm WHR: 0.96cm | 2 |
| **Psychosocial Factors** | | |
| General Stress: | Several periods or permanent stress | 3 |
| Feeling sad or blue for 2 weeks or more in the past 12 months: | No | 0 |
| **Diet** | | |
| Salty foods or snacks one or more times a day: | Yes | 1 |
| Deep fried foods or snacks or fast foods 3 or more times a week: | No | 0 |
| Vegetables one or more times a day: | Yes | 0 |
| Fruit one or more times a day | Yes | 0 |
| Meat and/or poultry 2 or more times a week | No | 0 |
| **Physical Activity** | | |
| Leisure time | Moderate/High exercise | 0 |
| **Your Score** | | **14** |

Your risk score indicates you are in the middle risk tertile (group) for developing heart disease. Please discuss these results with your physician.


**Figure 2.** Genetic risk score. Through your blood work, we looked for a specific SNP in your DNA which has been shown to be a marker for heart attack risk. This SNP is located on chromosome 9, and is known as 9p21. The SNP is not within a gene itself, but is likely closely related to a gene which causes coronary artery disease. The 9p21 SNP has been shown to increase heart attack risk in several different ethnic groups, including South Asians. Based on your blood work, we determined if you did not have this SNP, only had it on one chromosome (inherited from one parent), or had it on two chromosomes (inherited from both parents). Having either one or two copies of this marker increases your genetic risk of having a heart attack.

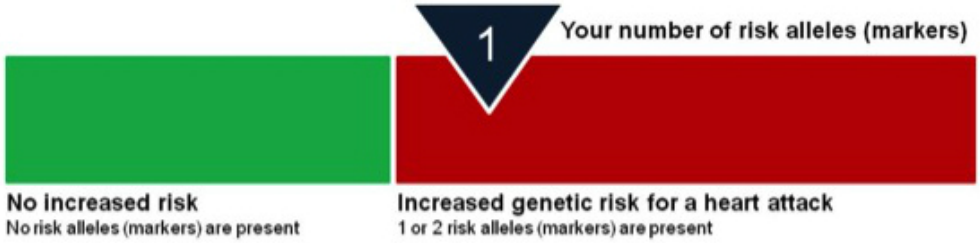




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**Figure 3.** SAHARA home page.

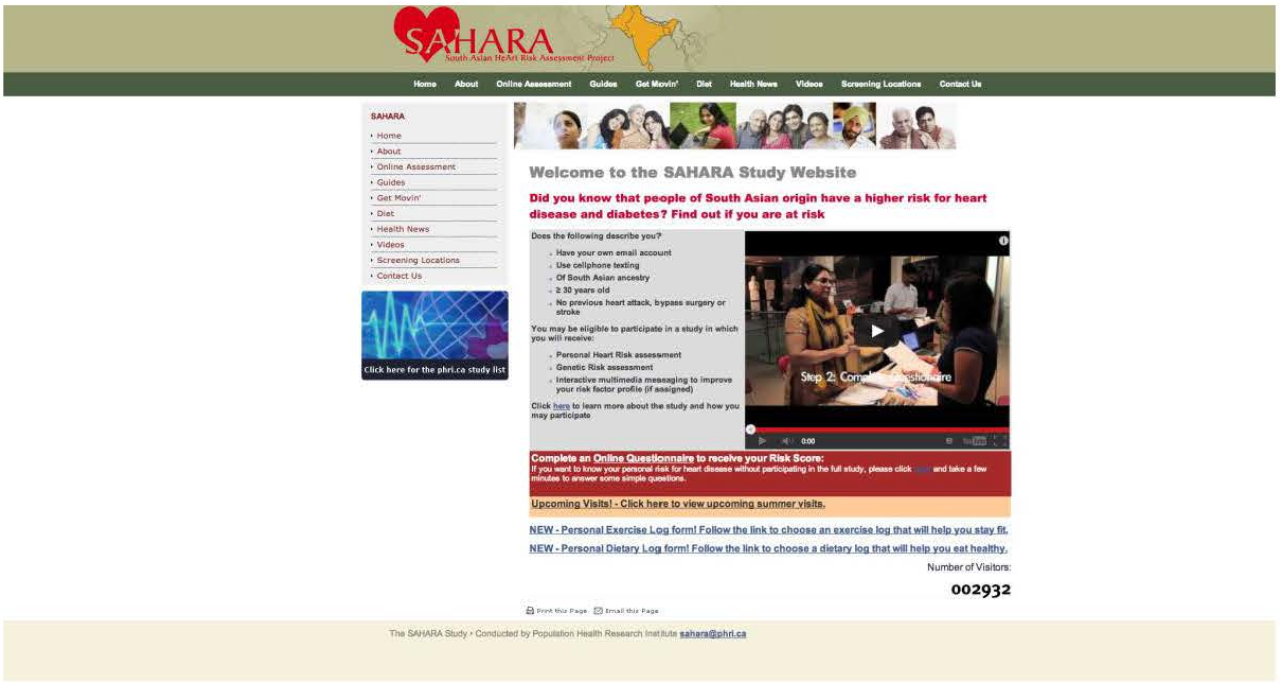


**Figure 4.** Welcome email.

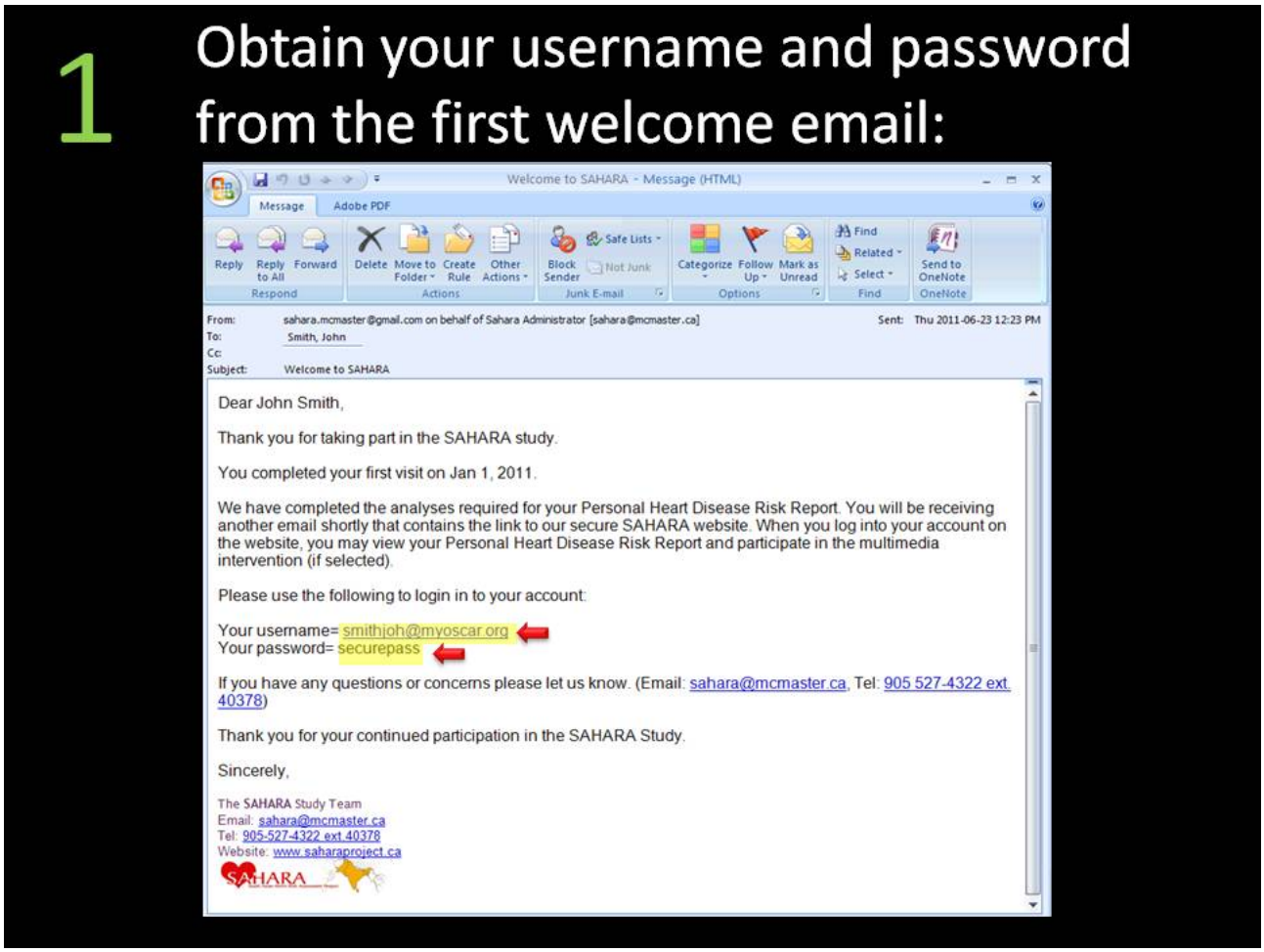




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**Figure 5.** Second welcome email.

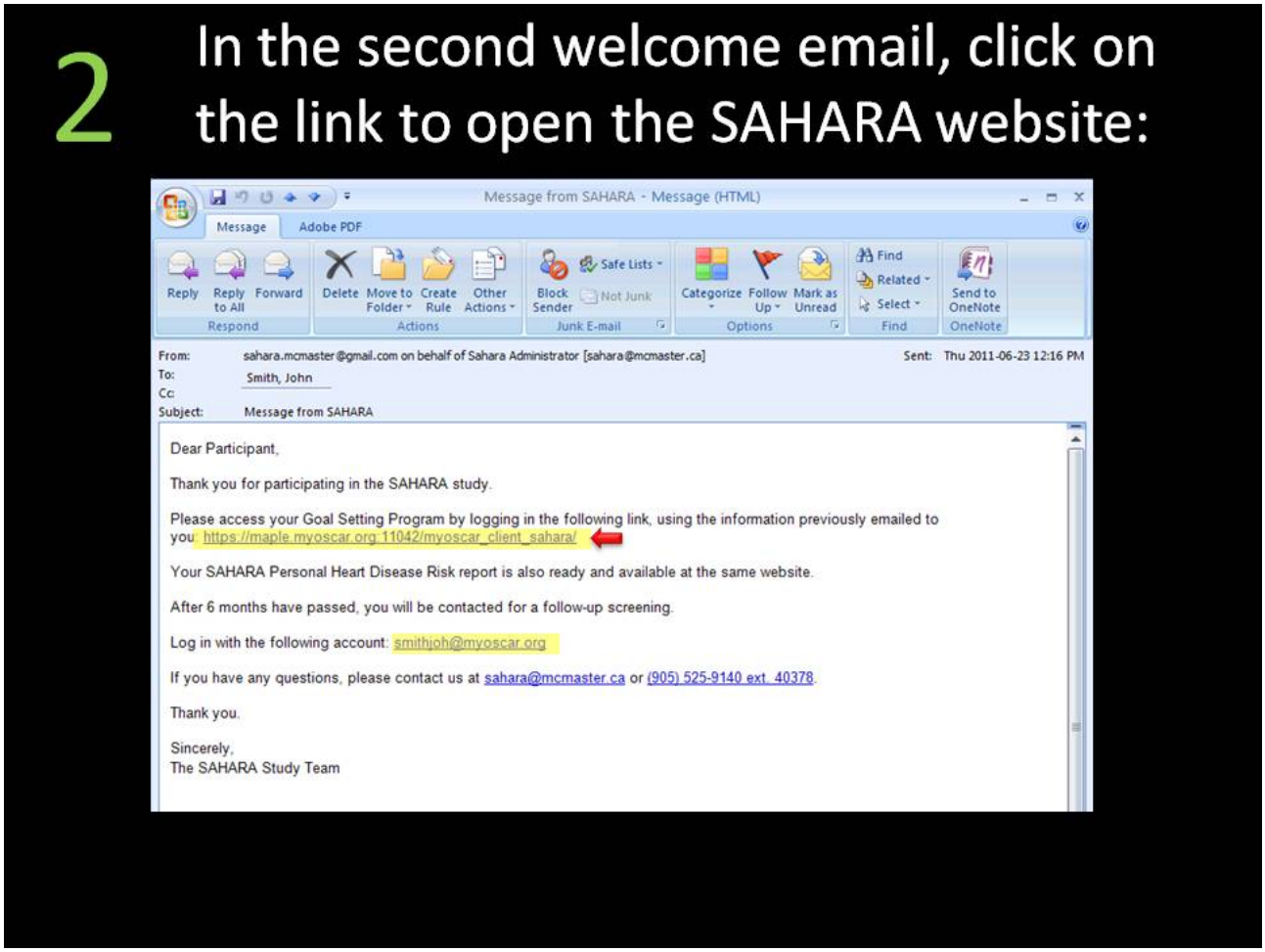


**Figure 6.** MyOSCAR Web login.




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**Figure 7.** SAHARA Web consent and personal health record page.


### *Intervention*

Participants randomized to the intervention were prompted to choose a health goal on the website in the areas of (1) healthy diet, (2) physical activity, (3) reducing sedentary behaviors, and (4) smoking cessation, and were prompted to update their goals weekly on the website. Participants then received health messages via email or text, tailored to their chosen health goal on a daily basis. The messages were based on self-efficacy and social support concepts [38-41] to motivate subjects to make health behavior changes including providing advice and support regarding reduction of energy-dense, nutrient-poor foods (ie, fried, fast foods, sugary beverages, and desserts), advocating increased consumption of fruits and vegetables, encouraging sedentary individuals to minimize sedentary behaviors and increase regular physical activity, and encouraging smokers to quit smoking. Participants were given a choice of methods to receive the health messages by: (1) email sent to an account using a personal computer or a handheld device (eg, BlackBerry, iPhone, or other smartphones), or (2) text message (short message service, SMS) to a handheld device (any cell phone).

In addition to the health messages, a weekly health tip was sent to all intervention participants by email outlining a particular health topic related to healthy lifestyle or an analysis of a recent medical study reported in the press. All of these health messages were then posted on our public website (Figure 3). The components of the intervention are listed in Textbox 1

### *Control*

Participants randomized to the control group were provided with advice on how to interpret their risk report, and if any significantly abnormal results were identified, they were encouraged to discuss them with their family doctor. All participants had access to the SAHARA website that contained health information regarding cardiovascular risk factors from a South Asian perspective [42]. This website includes information on culturally relevant healthy dietary habits, and the health benefits of regular physical activity. The site also includes a frequently asked questions section, and a mechanism for participants to ask our study team study-related questions and receive feedback.

**Textbox 1.** Multimedia intervention components of the SAHARA pilot study.

Components for intervention participants:

- MyOSCAR-SAHARA Goal selection program: a tool which permits participants to select biweekly goals related to improving diet, increasing activity, decreasing smoking, and reducing sedentary behaviors
- Daily health messages—sent via email or text: messages provided tips on how to counter unhealthy habits and maintain healthy ones
- Biweekly reminders to pick a health goal and monitor progress on the goal
- Access to latest health information through personal MyOSCAR-SAHARA account
- Access to healthy living videos, such as yoga and other exercise regimens



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### Website Usage and Adherence to Intervention "Fidelity"

Participants usage of the goal setting website was monitored centrally, and for those participants who did not log on to access their risk score reports or for intervention participants who had not set goals 2 weeks from the time they were prompted by email, a study team member attempted to reach them by telephone to encourage them to access their results and set goals. After 4 weeks if results had not been accessed from the website, a printed MI and genetic risk score report was mailed to participants' home.

### Pilot Study Outcome Measures

The two outcome measures of the pilot study included: First, feasibility of the intervention, defined by: (1) success at transmitting risk score information and health messages via electronic media (website, email, and cell phone), (2) success at participants returning to use the website and set health goals, as this reflects the uptake of the intervention and helps to assess the effect of intervention on health behaviors, and (3) trend in the risk score change to indicate if the intervention leads to progressive health behavior change. Second, effectiveness and acceptability of risk score information was measured by: (1) participants' knowledge of their risk score over time, (2) if this information induced positive behavior change, and (3) participants' satisfaction with the information received.

### Follow-Up

All participants were followed up for a minimum of 6 months after randomization and repeat risk factor assessment was collected at the end of the study. End of study data were collected via face-to-face reassessment at the recruitment sites (238/324, 73.5%) and by telephone or mail (86/324, 26.5%). Repeat HbA1C and apolipoproteins A1 and B were also collected from participants who attended the face-to-face reassessment visit.

The reporting of this study follows the CONSORT-EHEALTH [43] guidelines Multimedia Appendix 2.

## Results

### Summary

Participants (n=412) were screened from 11 centers between January 2011 and January 2012. Among them, 41 were ineligible (5 had cardiovascular disease—CVD, 23 had no email accounts, 13 were missing information required for the risk score, and 4 were eligible but not randomized due to a clerical error), leaving 367 participants randomized into the pilot study. Follow-up data collection occurred between October 28, 2011 and November 11, 2012. The median time of follow-up is 280 days with the interquartile range (IQR) of 252-319 days follow-up. As shown in Figure 8, there were 43 participants (21/167, 12.6% and 22/204, 10.8% of the intervention and control group, respectively) who did not complete the follow-up (21 were not contactable and 22 participants withdrew from the study).

### Demographic and Social Characteristics

Participants' characteristics are shown in Table 1. Briefly the mean age is 53.8 years (minimum age=30.0 years, maximum age=82.0 years, and median age=53.0 years), approximately half are women, and the majority of participants are immigrants to Canada. More than half reported speaking English at home, 88.7% (323/364) received more than secondary school education and 69.2% (254/367) are actively employed. More than 52.0% (191/367) are vegetarian; few (4/367, 1.1%) use or are exposed to tobacco, and approximately one-quarter (27.5%, 101/367) engage in regular physical activity. Further, more than 32.0% (117/367) are exposed to more than 2 hours of screen time per day. The mean BMI at baseline is 26.4 (SD 3.5) for men and 26.5 (SD 4.1) for women. Three quarters of participants have one or two risk alleles for the 9p21 genetic variant.

### Risk Factor Information at Baseline and End of Study

Table 2 shows participants' risk factors at baseline and follow-up. Over a quarter of all participants had hypertension and elevated cholesterol at baseline, and 13.8% (44/319) reported having type 2 diabetes. Over two thirds of participants are inactive at leisure time, the mean servings of fruits and vegetables consumed daily are 2 and 3, respectively, and more than 27.1% (86/317) of participants reported having stress and depressive symptoms. Objective study measures including HbA1c (mean 5.9, SD 0.8; apolipoprotein B-to-A1 ratio: mean 0.68, SD 0.18) and waist-to-hip ratio (WHR, men: mean 0.95, SD 0.05; women: mean 0.88, SD 0.07) indicate that the cohort has a moderate risk for MI, with the mean IHRS being 13.0 (SD 5.8).

### Feasibility: Success at Transmitting Messages Via Electronic Media

All participants were required to have an email access (including shared family email if they choose to use this email account) to be eligible for this study. The majority of participants (352/367, 96%) had personal email access (Table 3). Most participants had no difficulty logging into website or viewing their results, although 23% (74/324) reported having some technical problems with the website, which inhibited the risk score report and health messages delivery.

### Success at Participants Returning to Use the Website and Set Health Goals

Participants use of the MyOSCAR-SAHARA website was monitored to determine how many participants logged on to the website to view their risk score reports and in the case of intervention participants, to set health goals. The login to the study MyOSCAR-SAHARA website was low for both groups (82/182, 45.1% of intervention and 115/185, 62.7% of control groups did not logon or used the website only once). The mean number of login attempts of the intervention group mean was 2.64 (SD 3.17, median 2.0) and the control group was 1.63 (SD 2.14, median 1.0). The difference between intervention and control groups login was statistically significant as expected since the intervention group was asked to set goals (Wilcoxon two-sample test, $P$=.0003). Figure 9 shows the frequency of login by intervention and control groups. On average the intervention group selected 1.12 goals (SD 1.67, median 1.0).



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**Figure 8.** Participants' flow diagram.

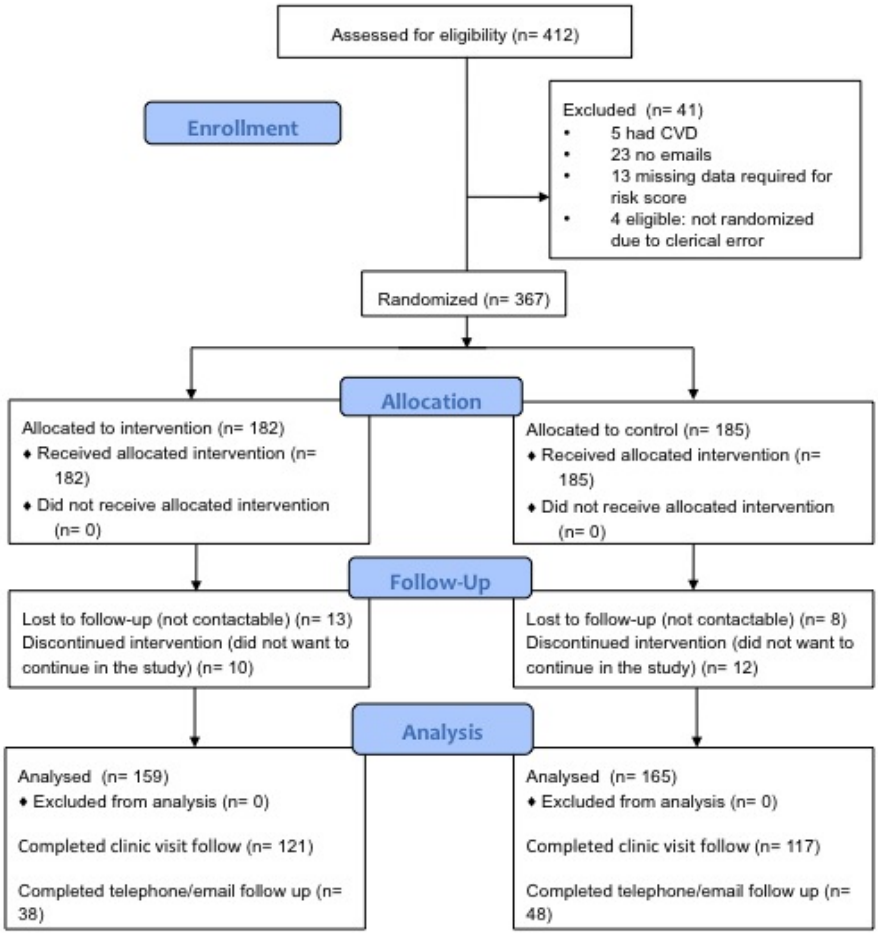




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**Table 1.** Demographic characteristics.

| Characteristics | Overall | Intervention | Control |
|---|---|---|---|
| Number of participants | 367 | 182 | 185 |
| Age in years, mean (SD) | 53.8 (11.4) | 54.6 (11.5) | 53.0 (11.3) |
| Median age (min, max) | 53.0 (30.0, 82.0) | 55.0 (31.0, 81.0) | 53.0 (30.0, 82.0) |
| Male/female (%) | 176 (48.0)/191 (52) | 84 (46.2)/98 (53.8) | 92 (49.7)/93 (50.3) |
| **Ancestral country of origin (%)** | | | |
| India | 327 (89.1) | 163 (89.6) | 164 (88.6) |
| Pakistan | 4 (1.1) | 2 (1.1) | 2 (1.1) |
| Sri Lanka | 4 (1.1) | 2 (1.1) | 2 (1.1) |
| Other | 32 (8.7) | 15 (8.2) | 17 (9.2) |
| Place of birth—Canada, (%) | 9 (2.5) | 1 (0.6) | 8 (4.4) |
| Language spoken at home—English, (%) | 188 (52.2) | 93 (52.0) | 95 (52.5) |
| Married (%) | 337 (92.1) | 167 (91.8) | 170 (92.4) |
| Post-secondary education (%) | 323 (88.7) | 156 (86.7) | 167 (90.8) |
| Employed (%) | 254 (69.2) | 119 (65.4) | 135 (73.0) |
| Household income >CDN$ 60,000/year (%) | 218 (61.6) | 106 (59.6) | 112 (63.6) |
| Alcohol consumption ≥1 drink per day (%) | 23 (6.4) | 11 (6.0) | 12 (6.8) |
| Vegetarian (%) | 191 (52.5) | 90 (49.5) | 101 (55.5) |
| Daily activity mild/none (%) | 266 (72.5) | 125 (69.8) | 141 (77.0) |
| Screen time mean minutes/day (SD) | 140.1 (130.7) | 133.8 (121.5) | 146.3 (139.2) |
| BMI—male, mean (SD) | 26.4 (3.5) | 26.5 (3.6) | 26.4 (3.3) |
| BMI—female, mean (SD) | 26.5 (4.1) | 26.2 (3.7) | 26.8 (4.5) |
| One or two risk alleles of 9p21 (%) | 261 (73.3) | 130 (74.3) | 131 (72.4) |



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**Table 2.** Baseline and follow-up risk factors in intervention and control groups.

| Risk factor | Intervention | | | Control | | |
|---|---|---|---|---|---|---|
| | Baseline | Follow-up | *P* value[a] | Baseline | Follow-up | *P* value[a] |
| Apolipoprotein B/apolipoprotein A1 ratio (SD) | 0.66 (0.19) | 0.67 (0.18) | .42 | 0.70 (0.18) | 0.71 (0.20) | .59 |
| HbA1c (SD) | 5.9 (0.8) | 5.9 (0.8) | .81 | 5.8 (0.8) | 5.9 (0.9) | .01 |
| Self-reported diabetes,[b] n[c] (%) | 31 (20.0) | 36 (23.2) | .03 | 13 (7.9) | 16 (9.7) | .08 |
| Self-reported hypertension, n[c] (%) | 43 (28.1) | 46 (30.1) | .08 | 36 (22.4) | 42 (26.1) | .01 |
| Elevated BP,[d] n (%) | 35 (30.4) | 25 (21.7) | .06 | 31 (27.0) | 22 (19.1) | .08 |
| Mean SBP (SD) mm Hg | 128 (18) | 124 (16) | .008 | 127 (19) | 123 (17) | .003 |
| Mean DBP (SD) mm Hg | 81 (10) | 79 (10) | .006 | 82 (11) | 79 (11) | <.0001 |
| Waist-to-hip ratio—male, mean (SD) | 0.95 (0.06) | 0.96 (0.06) | .68 | 0.95 (0.05) | 0.94 (0.06) | .07 |
| Waist-to-hip ratio—female, mean (SD) | 0.89 (0.07) | 0.88 (0.07) | .12 | 0.87 (0.06) | 0.87 (0.06) | .62 |
| Stress in last year at baseline and in last 6 months at follow-up, n (%) | 48 (30.8) | 29 (18.6) | .001 | 52 (32.1) | 33 (20.4) | .002 |
| Depression for ≥2 weeks in last year at baseline and last 6 months at follow-up, n (%) | 50 (32.3) | 24 (15.5) | .0001 | 36 (22.2) | 16 (9.9) | .0009 |
| Mean servings of fruits/day (SD) | 2.0 (1.2) | 2.0 (1.2) | .90 | 2.0 (1.2) | 1.9 (1.4) | .67 |
| Mean servings of vegetables/day (SD) | 3.0 (1.7) | 2.8 (1.8) | .24 | 3.0 (1.9) | 2.9 (1.9) | .83 |
| Mean servings of deep fried foods/snacks per day (SD) | 0.3 (0.5) | 0.2 (0.2) | .0005 | 0.3 (0.4) | 0.2 (0.4) | .003 |
| Moderate/very active in leisure time, n (%) | 58 (37.9) | 88 (57.5) | <.0001 | 47 (29.0) | 77 (47.5) | <.0001 |
| Self-reported high cholesterol,[c] n (%) | 42 (28.2) | 49 (32.9) | .008 | 37 (22.6) | 44 (26.8) | .008 |
| IHRS[e,f] (SD) | 13.4 (5.8) | 12.0 (5.8) | .002 | 12.6 (5.9) | 11.7 (5.9) | .05 |

[a]Pairwise comparison of data using paired *t*-test for continuous measures and McNemar's test for categorical measures.

[b]Prevalence of events at follow-up includes baseline plus additional new events since baseline. Therefore the prevalence of diabetes, hypertension, and high cholesterol are higher at follow-up.

[c]Number of participants with data available for the specific variable.

[d]Bloodpressure (BP) was measured at baseline and follow-up. Elevated BP is >140/90.

[e]IHRS: INTERHEART risk score.

[f]No significant difference in change between the intervention and control group (*P*=.70).

**Table 3.** Electronic access and reported technical difficulties.

| Baseline | Overall, n=367 n (%) | Intervention, n=182 n (%) | Control, n=185 n (%) |
|---|---|---|---|
| Personal email access | 353 (96.2) | 176 (96.7) | 177 (95.7) |
| Smart phone access | 73 (19.9) | 41 (22.5) | 32 (17.3) |
| Cell phone access | 177 (48.2) | 98 (53.8) | 79 (42.7) |
| Receive and send text messages | 127 (34.6) | 141 (38.5) | 57 (30.8) |
| Check email multiple times per day | 148 (40.3) | 79 (43.4) | 69 (37.3) |
| Participants who completed follow-up | 324 (88.3) | 159 (87.4) | 165 (89.2) |
| Problems accessing results on website | 25 (7.7) | 9 (5.7) | 16 (9.7) |
| Logon difficulties to website | 37 (11.4) | 17 (10.7) | 20 (12.1) |
| Did not receive email with instruction on logon | 11 (3.4) | 4 (2.5) | 7 (4.2) |
| Instructions were unclear | 10 (3.1) | 4 (2.5) | 6 (3.6) |
| MyOSCAR-SAHARA website was difficult to use | 13 (4.0) | 4 (2.5) | 9 (5.5) |
| Total problems with MyOSCAR-SAHARA website | 74 (22.8) | 31 (19.5) | 43 (26.1) |



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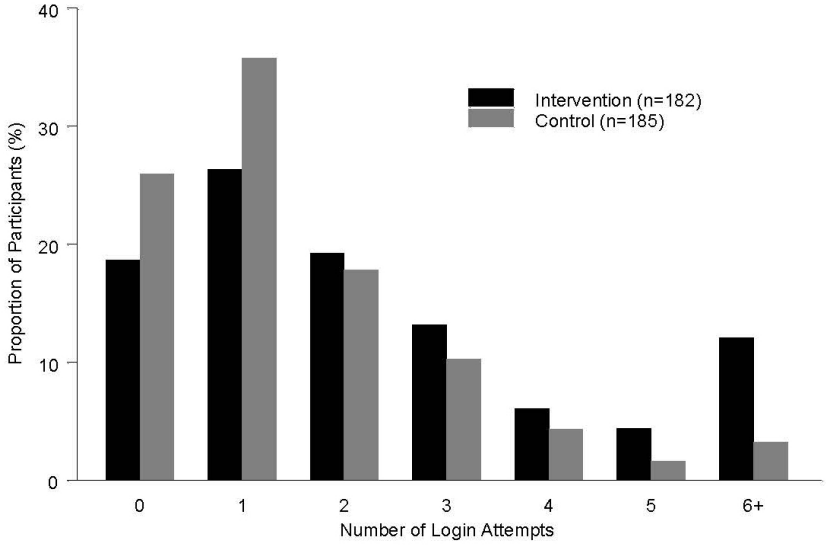
**Figure 9.** Summary of login attempts to website over the course of the pilot study.




## Signal That Intervention Leads to Behavioral Changes

Both the intervention and control group showed a reduction at follow-up in blood pressure, and reported less stress and depression compared to baseline. There was also an improvement in physical activity and reduction in fried food and snacks consumption in both groups at follow-up. Comparing follow-up to baseline score change, the intervention group had a significant reduction in their IHRS score at follow-up (intervention group baseline IHRS: mean 13.4, SD 5.8; follow-up IHRS: mean 12.1, SD 5.9, *P*=.002), and a trend was seen in the control group (baseline IHRS: mean 12.6, SD 5.8; follow-up IHRS: mean 11.7, SD 5.9, *P*=.05) (see Table 2), though these results were not statistically significant.

## Risk Score

### *Risk Report Feedback*

Participants were asked to acquire their risk score reports (IHRS and GRS) following the baseline assessment by logging onto the MyOSCAR-SAHARA website. If they did not retrieve it, it was mailed to their homes. At the end of the study, participants were asked about their knowledge and recall of their risk scores (Tables 4 and 5). Overall while participants reported appreciating receiving their risk information, the recall between baseline and end of study of risk status was low. For example, of 68 participants who were told they were high-risk at baseline, only 11 recalled this correctly (11/68, 16.2%), 17 recalled being moderate risk (17/68, 25.0%), 3 recalled it being low risk (4/68, 4.4%), and 37 could not recall their risk score (37/38, 54.4%) at all. Similarly only 7.3% (5/68) of participants recalled their increased genetic risk score accurately at follow-up (Table 5).

### *Risk Scores and Motivation to Change*

Figure 10 shows individuals reporting that knowledge of their risk for MI could be a motivator to change health behaviors including diet and physical activity. There was a trend (*P*=.06) showing the intervention group as compared to the control group was more likely to agree that the risk score was a motivator for increasing health behaviors especially for physical activity, though these results were not statistically significant (Figure 10).

## Stages of Change

We assessed the stages of change for three main domains: diet, physical activity, and weight loss. Although we also included smoking, only three individuals are current smokers in this sample. Overall, more than 13.9% (51/367) of participants progressed from inactive (precontemplation, contemplation, and preparation) to the active (action, maintenance) stage in diet and physical activity, and 12.5% (46/367) progressed to the active stage in weight loss plans; however, no significant differences were observed between intervention and control groups (Table 6).

## Exit Survey

At the end of the pilot study, feedback from the study participants was obtained by asking all participants about their experiences of participating in the pilot study. The main feedback included: (1) daily messages were too frequent which could potentially lead them to ignore the messages; (2) phone calls to remind participants to login to the study website were too frequent, while others reported that there was not enough in-person contact and would have liked to have a mid-program visit that with more face-to-face contact with the study team; and (3) IHRS and GRS reports should be sent via email and remove the website login component. Most of the participants reported that participation in the SAHARA study was worthwhile for them. Table 7 shows summary of the exit survey.



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**Table 4.** Agreement between MI risk score results and participants recall of risk score at follow-up.

| Actual IHRS score category at baseline | Recall of risk score category at follow-up | | | | |
|---|---|---|---|---|---|
| | Low | Moderate | High | Do not know | Total |
| Low | 47 | 15 | 2 | 63 | 127 |
| Moderate | 11 | 46 | 6 | 59 | 122 |
| High | 3 | 17 | 11 | 37 | 68 |
| Total | 61 | 78 | 19 | 160 | 318 |

**Table 5.** Agreement between genetic risk score results and participants recall of risk score at follow-up.

| Actual GRS score category at baseline | Genetic risk category recall at follow-up | | | |
|---|---|---|---|---|
| | Not increased | Increased | Do not know | Total |
| Not increased (0 risk alleles) | 22 | 6 | 56 | 84 |
| Increase (1 or 2 risk alleles) | 38 | 16 | 172 | 226 |
| Total | 60 | 22 | 228 | 310 |

**Figure 10.** Motivation to change behavior based on risk score reports.

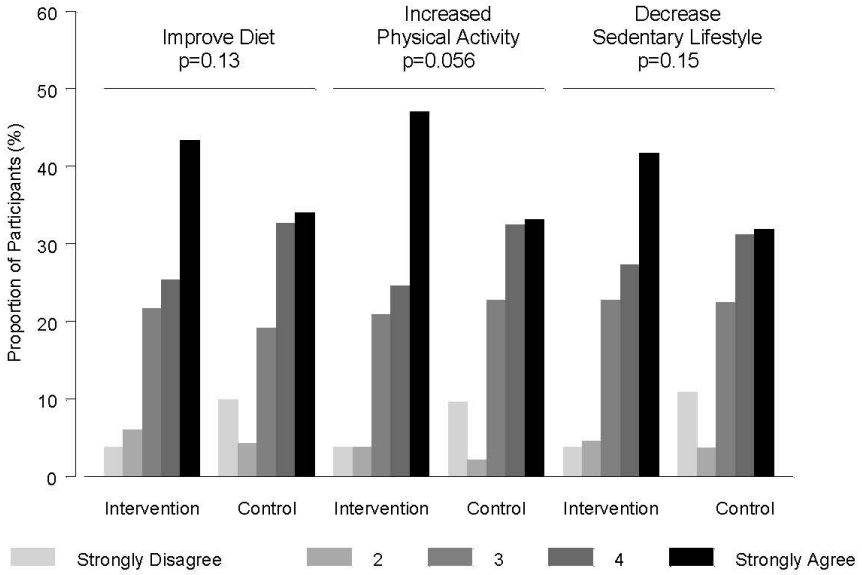


**Table 6.** Stages of change[a]: moving from inactive to active stage by intervention at follow-up.

| Domain | Overall, % | Intervention,% | Control, % | *P* value[b] |
|---|---|---|---|---|
| Diet | 14.9 | 15.7 | 14.1 | 0.69 |
| Weight loss | 12.5 | 13.7 | 11.4 | 0.53 |
| Physical activity | 14.2 | 15.5 | 12.9 | 0.51 |

[a]Stages of change levels: 1=precontemplation, 2=contemplation, 3=preparation, 4=action, 5=maintenance. Inactive=levels 1-3, active=levels 4-5.
[b]These results were obtained from chi-square tests.



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**Table 7.** Exit survey (n=317).

| Rank | Intervention, n (%) | Control, n (%) |
|---|---|---|
| **(A) Did you find participation in SAHARA to be worthwhile?** [a] | | |
| Number of participants | 155 (48.8) | 162 (51.1) |
| Very worthwhile | 75 (48.4) | 78 (48.2) |
| 4 | 47 (30.3) | 45 (27.8) |
| 3 | 24 (15.5) | 19 (11.7) |
| 2 | 8 (5.2) | 10 (6.2) |
| Not at all worthwhile | 1 (0.6) | 10 (6.2) |
| **(B) Did you succeed in setting and achieving your health goals?** [b] | | |
| Number of participants | 153 (48.3) | 157 (49.5) |
| Very successful | 27 (17.7) | 27 (17.2) |
| 4 | 60 (39.2) | 50 (31.9) |
| 3 | 51 (33.3) | 38 (24.2) |
| 2 | 9 (5.9) | 25 (15.9) |
| Not at all successful | 6 (3.9) | 17 (10.8) |

[a]There was no significant statistical difference between intervention and control groups in their view of study participation ($P$=.09; obtained from chi-square tests).

[b]The intervention group reported that they were more likely to be successful in achieving their goals than the control group ($P$=.004; obtained from chi-square tests).

# Discussion

## Principal Findings

We observed that a multimedia health behavior intervention is feasible in a South Asian population at risk for MI. While participants reported being motivated by receiving the risk score information, a number of features of the SAHARA intervention require optimization prior to assessing its effectiveness in MI risk factor reduction.

Most participants had access to email, Internet, and text messages and had no difficulty receiving email or text messages. However, our requirement of participants to proactively logon to the website to receive their risk reports, and to set goals was problematic with 23.9% (88/367) of the study participants reporting technical difficulties. It is likely that this contributed to the low number of goals chosen over the course of the follow-up, and reduced the interventions potential impact on changing health behaviors. In addition, participants received the study messages either by email/text checked on a mobile device or emails checked on a fixed device. These different methods of receiving messages may have also impacted the uptake of the study intervention. The anticipated difference would be based on the fact that the mobile device message would likely be received in real time or close to it, whereas the fixed device message might not be received immediately, although it may reach people when they're more ready to act on the information (ie, they have specifically chosen to sit down at the computer, as compared to a mobile device when the email/text may arrive when the person is doing something else). In this study it is not known the impact of receiving messages via mobile or a fixed device on the intervention uptake and outcome. Despite these technical challenges, the intervention group showed a significant reduction in the IHRS score at follow-up, and were more likely than control subjects to report that their personalized risk scores motivated them to increase their healthy dietary choices, physical activity, and reduce sedentary behaviors. The greater engagement of the intervention group in the study, their receipt of regular messages and reminders to change their health behaviors, may explain this difference.

Based on the participants' feedback from the exit survey, the use of a website health behavior intervention, which requires participants to logon to a website, reduces the chances that participants will be engaged in the study. In our study, 54.9% (100/182) of the intervention group logged onto the website at least twice, which is in keeping with previous studies using Internet-based intervention to aid smoking cessation [44]. A systematic review and meta-analysis of Web-based intervention studies to induce behavioral changes reported that the average logon to website/person/study duration in weeks varies from 2.6 logons/person/32 weeks in a study of depression to 1008 logons/person/36 weeks in a study of HIV. In addition the average time spent on website in minutes per person varied from 4.5 to 45 minutes/person [45]. Furthermore, even when information is sent directly to participants by email, the rate of opening the email is variable. For example in a study of 345 men and women where daily email messages were sent to improve employees' diet and physical activity behaviors in the workplace, only 68.9% (238/345) of the emails were opened by study participants [23], even though all study participants worked in the same office and had a computer at their desk. This is consistent with other studies using Web-based interventions where an uptake of only 62% was reported [46].



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To optimize the uptake of the intervention for the main SAHARA trial we will ask participants to set their goals at the baseline interview, we will remove the logon to website requirement to access risk score reports, and we will deliver the reports directly to participants by emails. These components will be followed by telephone calls and one face-to-face visit mid-way through the study, to ensure receipt and knowledge of risk scores, and to maintain participant interest in the study.

Individuals who participated in this pilot study were at moderate risk of MI based on their baseline IHRS compared to risk score values reported in the validation study [35]. Both the intervention and control groups made some progress in changing their health behaviors and in general participants reported the information they received was useful. Despite participants claiming that their risk reports motivated behavioral changes, half of the participants could not recall their risk report at 6 months. The poor risk score recall may reflect low health literacy (ie, the degree to which individuals can obtain, process, and understand the basic health information) and numeracy (how individuals interpret medical risk information) [47]. However, our sample was of high socioeconomic status, well educated, and we pretested our risk score information in focus groups and presented the information (Figure 2) at the grade 5 reading level. Thus, we attempted to minimize low health literacy and numeracy as possible barriers to understanding risk score information. It is also possible that the active phenomenon of resistance to retain negative information about one's health to maintain an optimistic view of future health was at play. Such views have been described as psychological defense mechanisms [48]; however, it is difficult to confirm if such views hold in the current study. In addition, the low risk score recall may also represent the phenomenon of "unrealistic optimism" whereby individuals display an optimism bias when evaluating own susceptibility to risk [49]. However, this view does not explain the poor recall of low-risk reports.

The low recall rate of health information received, including in face-to-face counseling, is not uncommon. In a large study investigating the recall of health advice given face-to-face to patients (n=3261) who participated in the EuroHeart Failure Survey 12 weeks following discharge, only 57.8% (1885/3261) of patients recalled advice on exercise, 54.9% (1793/3261) recalled advice on diet, 41.9% (1369/3261) recalled advice on smoking, and only 38.9% (1271/3261) recalled advice on alcohol [50]. Nonetheless in our study, participants reported that knowledge of their risk factor and genetic risk score were motivators to improve their health behaviors even if they could not recall their exact risk category. It is possible that recall may vary by the type of information provided to participants, and recall may decrease over time. For example, patients with type 2 diabetes are more likely to recall health recommendations regarding medications than regarding health behaviors [51], and provision of genetic risk information to smokers regarding their risk of lung cancer showed early high recall of risk status yet lower recall with increasing duration of follow-up [52]. We hypothesized that genetic information may motivate behavior change differently than nongenetic health information because of the highly personalized nature of the information [47]. In a recent study among patients with type 2 diabetes who participated in a lifestyle modification trial in which genetic information was provided in a gene score, almost all participants (98%) reported that high-risk genetic results would increase their motivation for lifestyle modification. On the other hand their response to receiving low-risk genetic results varied, with some reporting that low-risk genetic status would decrease their motivation to take on lifestyle changes. However, their reported response has not yet been correlated to their actual change in risk factors as this study is on-going [53]. Future studies, including the main SAHARA trial must assess if provision of genetic risk information is strongly correlated with changes in risk factors and clinical outcomes.

We assessed the stage of change transition over the course of the follow-up. It is known now that the stages of change are not linear and individuals do not progress from one stage to the next as originally proposed [33]. Rather, these stages follow a spiral model with relapses that resets the process back to the precontemplation stage [54]. Despite these challenges, the stages of change model is widely used and accepted as a useful measure to assess motivation to change and the impact of this motivation on achieving the desired behavioral modification [55]. We observed that 25.8% (94/367) of the participants progressed forward in stages of change relating to physical activity, while 18.2% (67/367) regressed in their stages of change. Overall however more than 12.5% (46/367) progressed from the inactive to an active stage at the end of study in all three domains (physical activity, diet, and weight loss). No difference between intervention and control subjects in stages of change transitions was observed.

## Limitations

Our pilot study had a number of strengths, which include recruitment of an apparently healthy population sample of reasonable size, and prospective measurement of health behaviors that included objective measurements (ie, lipid, blood pressure, and anthropometric measurements). Some limitations of our intervention occurred including the technical challenges of logging onto the website, the low rate of logons to set health goals, and relatively poor recall of personal risk at follow-up. Despite these, a significant reduction in the MI risk score was observed in follow-up. In addition the SAHARA study population may not be representative of all South Asians in Canada; however, the socioeconomic characteristics of SAHARA participants are similar to findings from previous health surveys in Ontario [56].

## Modifications to the SAHARA Trial Intervention

We have taken a number of steps to optimize the SAHARA intervention prior to testing its effectiveness in MI risk reduction in a future trial. These changes include: (1) risk reports and randomization status will be emailed directly to participants, (2) the number of health goals participants can focus on has been reduced from 4 to 2, with only one being chosen at one time for a 6-month duration, (3) the duration of follow-up will be extended to 12 months with baseline, 6 months and 12 months face-to-face visits occurring, (4) increasing the frequency of in-person contacts to improve adherence to the intervention and interest in the program, (5) health tips will be tailored to each participant based on the goal selected and their



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readiness to change, and (6) the frequency of messages will be reduced from daily to weekly and sent at a time of day chosen by participants.

## Conclusion

A multimedia intervention is feasible and has the potential to induce positive health behavior changes aimed at reducing MI risk. Information generated from the SAHARA pilot has directly informed the design of the main randomized trial designed to test the effectiveness of a multimedia behavioral intervention to reduce MI risk among South Asians.

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## Conflicts of Interest

The funding sponsor has no role in the conduct or reporting of the study. MyOSCAR-SAHARA was developed by the Department of Family Medicine, McMaster University. Dr Anand holds a Canada Research Chair in Ethnicity and Cardiovascular Disease, Michael G DeGroote Chair Heart and Stroke Foundation Chair in Population Health, and May Cohen Eli Lilly Chair in Womens Health at McMaster University.

## Multimedia Appendix 1

The INTERHEART Risk Score.

[PDF File (Adobe PDF File), 11KB - resprot_v2i2e33_app1.pdf ]

## Multimedia Appendix 2

CONSORT-EHEALTH checklist V1.6.2 [43].

[PDF File (Adobe PDF File), 997KB - resprot_v2i2e33_app2.pdf ]

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## Abbreviations

**BMI:** body mass index
**CABG:** coronary artery bypass graft
**CAD:** coronary artery disease
**GRS:** genetic risk score
**HWE:** Hardy-Weinberg equilibrium
**IHRS:** INTERHEART risk score
**IQR:** interquartile range
**MI:** myocardial infarction MI
**OSCAR:** Open Source Clinical Applications and Resources
**SAHARA:** South Asian HeArt Risk Assessment
**SMS:** short message service
**SNP:** single nucleotide polymorphism
**WHR:** waist-to-hip ratio

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Original Paper

# Low-Intensity Self-Management Intervention for Persons With Type 2 Diabetes Using a Mobile Phone-Based Diabetes Diary, With and Without Health Counseling and Motivational Interviewing: Protocol for a Randomized Controlled Trial

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## Abstract

**Background:** The present study protocol is designed to cover the Norwegian part of the European Union Collaborative Project—REgioNs of Europe WorkINg together for HEALTH (RENEWING HEALTH). Self-management support is an important element of care for persons with type 2 diabetes (T2D) for achieving metabolic control and positive lifestyle changes. Telemedicine (TM) with or without health counseling may become an important technological aid for self-management and may provide a user-centered model of care. In spite of many earlier studies on TM, there remains a lack of consensus in research findings about the effect of TM interventions.

**Objective:** The aim of RENEWING HEALTH is to validate and evaluate innovative TM tools on a large scale through a common evaluation, making it easier for decision makers to choose the most efficient and cost-effective technological interventions. The Norwegian pilot study evaluates whether the introduction of a mobile phone with a diabetes diary application together with health counseling intervention produces benefits in terms of the desired outcomes, as reflected in the hemoglobin A1c level, health-related quality of life, behavior change, and cost-effectiveness.

**Methods:** The present study has a mixed-method design comprising a three-armed prospective randomized controlled trial and qualitative interviews with study data collected at three time points: baseline, after 4 months, and after 1 year. The patients' registrations on the application are recorded continuously and are sent securely to a server.

**Results:** The inclusion of patients started in March 2011, and 100% of the planned sample size is included (N=151). Of all the participants, 26/151 patients (17.2%) are lost to follow-up by now, and 11/151 patients (7.3%) are still in the trial. Results of the study protocol will be presented in 2014.

**Conclusions:** The key goals of this trial are to investigate the effect of an electronic diabetes diary app with and without health counseling, and to determine whether health counseling is important to the continued use of the application and the patients' health competence and acceptability. Research within this area is needed because few studies have investigated the effectiveness of apps used in long-term interventions with this degree of self-management.



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**Trial Registration:** Clinicaltrials.gov NCT01315756; http://clinicaltrials.gov/ct2/show/NCT01315756 (Archived by WebCite at http://www.webcitation/6BTyuRMpH).

***(JMIR Res Protoc 2013;2(2):e34)*** doi:10.2196/resprot.2768

**KEYWORDS**

self-management; empowerment; health-related quality of life; acceptability; type 2 diabetes; lifestyle intervention; complex intervention; mHealth; telemedicine; motivation; health counseling; mixed methods

## Introduction

### Overview

The prevalence of type 2 diabetes (T2D) is increasing throughout the global population [1]. A similar trend is also evident in the Norwegian population, where 192,421 people of the total population (5,063,709) are estimated to have diabetes, with a prevalence of 3.8% [2]. The impact of T2D is serious for both the individual and society with considerable economic costs [1,3]. Although medical competence for treating diabetes is improving and knowledge about treatment and lifestyle factors relating to T2D is substantial, most people with this disease do not achieve metabolic control [4,5], and can therefore experience diabetic complications [6].

The recent Coordination Reform in Norway has reorganized the distribution of health resources with an increased emphasis on the development of services within municipalities [7]. According to the Norwegian guidelines for diabetes, this organizational redirection complies with the current recommendations for the treatment of patients with T2D [8]. Earlier research in Norway indicated a gap between the guidelines and current clinical practice because only one of eight patients reaches the combined goal of control of glycemia, blood pressure, and lipids [9]. However, improvements in primary care for patients with T2D have been observed in Norway in recent years [10].

A systematic review has shown that diabetes self-management education for adults with T2D is effective when delivered in a community context [11]. Lifestyle changes such as increased physical activity and improved dietary habits may influence and improve metabolic control in persons with T2D [12]. To succeed in achieving positive lifestyle changes, the patient must be involved, and self-management support is an important element in the care of persons with diabetes [13] as well as persons with any chronic diseases [14]. Enhancing diabetes self-management strategies has shown promising results for reducing hemoglobin A1c (HbA1c) level in this group, a change that plays an important role in both reducing the risk for developing complications and improving the quality of life [15]. Nurse-delivered combined motivational enhancement therapy and cognitive behavior therapy has been shown to be feasible for adults with poorly controlled type 1 diabetes and can lead to an improvement in HbA1c levels [16]. However, further research is needed for optimizing health outcomes in these settings and for learning how to design more individualized approaches.

The psychological burden on the individual patient caused by the disease must also be recognized. Diabetes care providers such as nurses and physicians must deal with patients' everyday problems in managing diabetes, and some patients may need to seek help from psychosocial specialists [17]. Some earlier research have shown a high prevalence of depression in persons with T2D and an association between depression and poor self-management, poor metabolic control, and diabetic complications [18-20].

When living with and managing a chronic disease at home, telemedicine (TM) has the potential to become an important aid for self-management and may also help ensure a user-centered rather than a biomedically centered model of care [21]. Modern technology combined with psychological interventions can be useful in providing efficient management of diabetes. The TECNOB study is an example of how to use technology and a cognitive behavioral approach in a multidisciplinary telecare intervention for weight loss in obese patients with T2D in inpatient treatment (1 month) and in the continuity of care at home (1 year) [22,23]. Interactive systems that integrate monitoring and personalized feedback functions should be developed [24]. The importance of clarifying the effect of interventions that combine telemonitoring with educational and motivational tools, and those consisting of telemonitoring only, is also of interest [25]. Evaluations of TM interventions for persons with diabetes have mainly focused on the achievement of a clinical outcome in terms of glycemic control [26,27] with a reported trend toward patients achieving better glycemic control [28,29]. Few studies have found improvements in participants' quality of life [24,28-30], but one review investigating the impact of home telehealth interventions on the patients' quality of life and patient satisfaction compared with usual care [29] refers to a study with a single-group design that indicates significant improvements in physical functioning, bodily pain, and social functioning after 1 year of home telehealth [31]. Satisfaction with the new technologies has also been demonstrated, and more complex interventions with definitions of the process of care, and links between patients and professionals, showed better outcomes [30]. It is important to know whether users accept this type of service and the term "acceptability" is often used to indicate the degree to which patients are satisfied with a service and are willing to use it [32]. It is, therefore, recommended to design studies considering the patients' need for technology support [24]. Although diabetes telemonitoring has been shown as an effective approach both for glycemic control and for self-management, more research within this area is needed. Systematic reviews indicate that TM systems can be used effectively for persons with diabetes, although this conclusion is based on weak evidence. Further research should seek to understand how TM may improve diabetes management and enhance educational and self-management interventions [33,34].



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It has, for example, been shown a gap between the evidence-based recommendations and the functionality of the application features used in study interventions for diabetes care [33]. Despite a large number of studies on TM and systematic reviews on the effects of TM, a systematic review of existing reviews raises questions about the quality of the research evidence in terms of the approaches to evaluation and the methodologies used. The authors indicated the need for more focus on patients' perspectives, economic analyses, and TM innovations as complex processes and ongoing collaborative achievements. Formative assessments are also of interest [35]. There is a need for studies to be designed to control for possible mediating variables [28]. It has earlier been shown how positive clinical outcomes might be associated with mediating variables (or process variables) such as intensified provider consultation [36], more active management [37], or cognitive processes [38].

### Aim of the Study

The present study is the Norwegian part of the European Union (EU) Collaborative Project—REgioNs of Europe WorkINg together for HEALTH (RENEWING HEALTH). The aim of this study is to validate and evaluate innovative TM tools on a large scale using a common evaluation method, thereby making it easier for decision makers to choose the most efficient and cost-effective technological aids [39]. The Norwegian study evaluates whether the introduction of personalized and technology-supported self-management with and without health counseling intervention produces benefits in desired outcomes, as reflected in HbA1c level, health-related quality of life, behavior change, and cost-effectiveness.

### Theoretical Framework

In the present study, we perform a self-management intervention focusing on behavior change and the implementation of the evidence-based approach to diabetes self-management education and self-management support [13]. Self-management has been described as "the nature and scope of the ways in which patients state that they need to change to become more active participants in maintaining their health" [14], and the World Health Organization "white paper" has described self-management as a set of cognitive and behavioral self-management skills such as coping skills, goal setting, self-monitoring, environmental modification, self-reward, and arranging social support [40]. The health counseling part of the present study is based on principles from cognitive behavioral therapy, the "Reach Out" problem-solving model [41,42], and motivational interviewing (MI) [43]. The diabetes specialist nurse will use principles of MI such as a person-to-person interview with a client-centered style for eliciting behavior change by helping a patient explore and resolve ambivalence. MI is a refined form of the familiar process of guiding and is a technique that complements the communication skills needed by nurses and other health care workers [43]. The transtheoretical model that provides the diabetes specialist nurse a way of grouping the patients according to their stage of readiness to adopt new behaviors is also used [44,45]. Patients with T2D may have a wide variety of problem behaviors related to diet, physical activity, medication, and smoking. The transtheoretical model focuses on the patient's readiness to change and on the individual's decision making. The model has been used earlier to identify patients with diabetes at different stages of readiness to change to a healthy diet [46]. It has also been used in a successful telephonic intervention to improve diabetes control in urban adults in which patients were grouped according to their stage of change within different lifestyle domains [47]. The diabetes specialist nurse has a role as supporter, helping motivate the patients, although the real work is being undertaken by the patients themselves [41,42]. The term "low-intensity" (intervention) can be seen as a "lower dose" of specific treatment technique that may represent less support from the health personnel (the diabetes specialist nurse in our study) in duration and frequency of contact, and is usually delivered in a nontraditional way such as by mobile phone [41,42].

Glasgow et al [48] documented that it is necessary to include patient-reported psychosocial and behavioral measures in research to address the need for support in persons with diabetes.

## Methods

### Study Design

The study has a mixed-method design comprising a three-armed prospective randomized controlled trial (RCT) and qualitative interviews. The study has been registered with Clinical Trials (NCT01315756). Mixed-method research is a purposeful combination of quantitative and qualitative methods to enrich the material and to obtain a broader understanding of the findings in a study [49]. There are different ways to conduct the investigation and different ways of positioning the involved methods in relation to each other. In our study, the primary outcome measure is based on the findings from the quantitative part, and the qualitative interviews were based on grounded theory to provide us with additional information about the accessibility of the study and the intervention process.

The present study has a longitudinal design, and study data are collected at three time points: Test 1, at the time of inclusion (baseline); Test 2, after 4 months; and Test 3, at the end of the 1-year study. The patients' registrations on the diabetes diary app, called the Few Touch application, are recorded continuously and are transferred securely to a server. The participants in the two intervention groups are using the TM application during the 1-year study (Figure 1); one of these groups additionally receives health counseling during the first 4 months.



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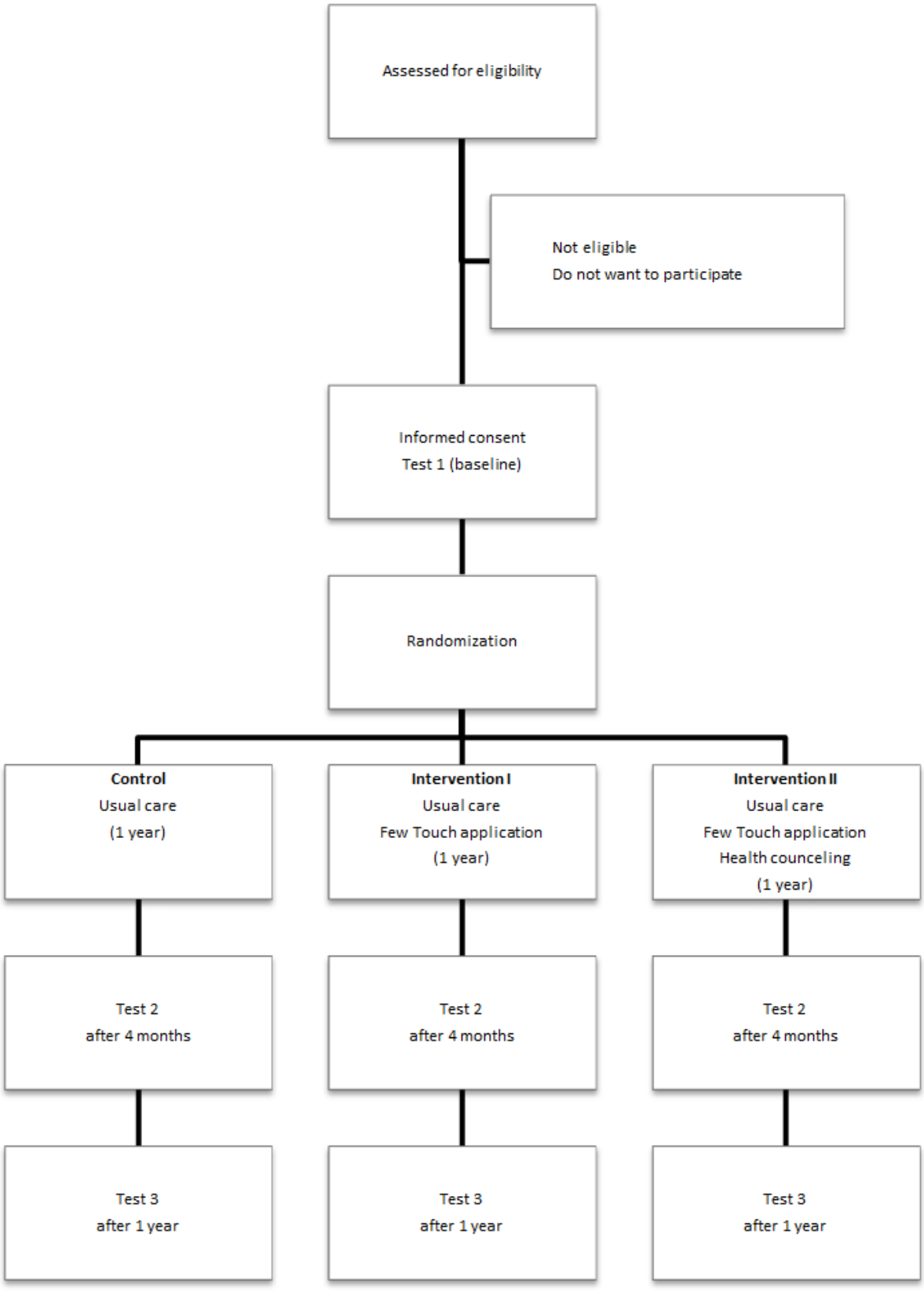
**Figure 1.** Design of the randomized controlled trial.




## Trial Population and Recruitment

Persons with T2D are eligible to participate in the study if they are older than 18 years, were diagnosed with diabetes for more than 3 months before the study inclusion, and have an HbA1c level >7.0%. Patients must be cognitively able to participate, understand, and be able to complete questionnaires in Norwegian language, and be able to use the mobile self-management system provided to the intervention groups. The exclusion criteria are



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any mental or physical conditions that interfere with the protocol.

Patients treated in primary care from both the southern and northern parts of Norway are recruited by their general practitioners (GPs). The GPs obtain recruitment information from the research team and are asked to recruit eligible patients to the study. Patients are also recruited from "diabetes start courses" held by the specialist health care service, which are offered to those newly diagnosed with diabetes in Norway by local public health clinics in municipalities and by advertisement. Patients willing to participate in the study are first given a letter with a brief summary of the study and an invitation to obtain more in-depth information about the study and implications. This information is given both orally and in written form in start-up meetings arranged by the project team. Before entering the study, all patients are required to provide written informed consent about their participation. All patients included must be under the care of a GP who adheres to national guidelines for diabetes care.

## Randomization

Patients who meet our inclusion criteria sign the informed consent form, complete the self-reported questionnaire, and are randomized into one of the three groups through block-randomization in the start-up meeting described above. Randomization is performed through the Center of Randomization at the Unit for Applied Clinical Research at the Norwegian University of Science and Technology in Trondheim, using WebCRF (Case Report Form). Immediately after randomization, the patients are told which group they have been placed. Those placed in the intervention groups are given a mobile phone with the self-management application in the same meeting and taught how to use the phone and the application. Those randomized to both the application and the health counseling group is given information about this intervention at the end of the same meeting. The reason for choosing this procedure is to save time for those who travel a considerable distance to participate.

## Development of the Intervention

### *Overview*

All participants receive usual care by their GP. The patients in the control group receive only usual care. Usual care in Norway is regulated by national guidelines, which include at least one annual visit to a GP. Standard measurements are blood pressure, serum concentrations of lipids and glucose, HbA1c level, and weight and body mass index. The patient's regular visit with a GP includes treatment for elevated blood glucose, blood pressure, and lipids when needed. The GP also emphasizes the importance of lifestyle changes [8].

There are two intervention groups (I+II) in our study. In addition to usual care, the participants in both the intervention groups receive a mobile phone with the diabetes diary app referred to as the Few Touch application, which is a self-help tool comprising five elements that are accessible to the user: (1) food habits registration system, (2) blood glucose data management system, (3) physical activity registration system, (4) personal goal-setting system, and (5) general information system. Blood glucose data are transferred automatically to the mobile phone-based diabetes diary from the blood glucose meter when the user has performed a measurement. Activity data and food habits are entered manually by the user. The users can also set personal goals for physical activity and food habits, access related tips, and look up words and concepts related to their disease.

In addition to the mobile phone, intervention group II also receives theory-based health counseling delivered by a diabetes specialist nurse working at a diabetes outpatient clinic at a university hospital, and with the possibility of support from a dietitian. The health counseling intervention comprises five modules (Table 1) and is delivered over 4 months immediately following the randomization. The nurse sends standardized short messages (using short message service, SMS) a few days before calling to inform the patients of the planned content in the phone conversation. The patients are also able to initiate SMS text messaging to communicate with the diabetes specialist nurse.

**Table 1.** Five modules of the health counseling intervention.

| Module | Module theme |
|---|---|
| Module 1 (intro) | Introduction |
| Module 2 (1st month) | Living with diabetes |
| Module 3 (2nd month) | Goal setting |
| Module 4 (3rd month) | Diet and physical activity |
| Module 5 (4th month) | Looking back and continuing forward |

### *The Mobile Self-Management Tool*

Several projects for designing various mobile self-management systems within diabetes have been conducted at the Norwegian Centre for Integrated Care and Telemedicine in Norway. The T2D tool, the Few Touch application, has been developed together with and tested on 12 patients with diabetes, as described in a previous publication [50]. The app was both designed and tested in close contact with persons with diabetes over a 3-year period. Obtaining constant feedback from participants and having the ability to change the app as needed during the testing-period, helped in making it a user-friendly and practical app. Initial promising results were demonstrated for this user-involved design process involving people with T2D [51].



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### *Health Counseling*

The health counseling intervention given to intervention group II is based on a problem-solving method and is delivered by the nurse through short telephone conversations with the patients. The diabetes specialist nurse supports the patients to (1) assess problems, (2) identify possible solutions, (3) analyze strengths and weaknesses, and the main advantages and disadvantages of each solution, (4) select a solution based on the analyses in the stage 3, (5) plan implementation, (6) implement the solutions, and (7) review the process and outcome. This problem-solving model is an evidence-based low-intensity intervention with a practical and systematic approach. It was developed for counseling and guided self-help for groups of patients in mental health services in the United Kingdom. The model has been described as useful for patients with diabetes and other chronic diseases, and requires less support from the health care provider in terms of duration and frequency of contact [41,42].

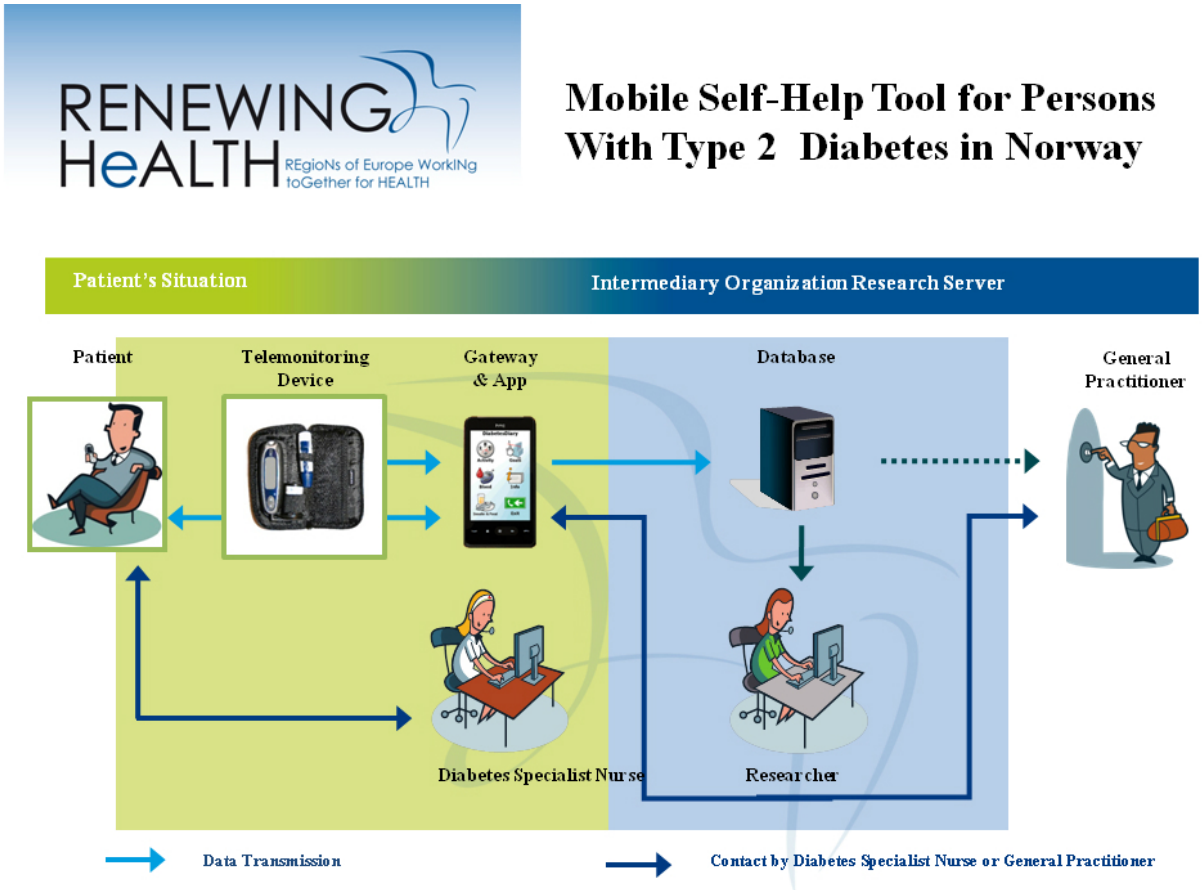
One of the aims of the present study is to activate the patients' motivation toward self-management. In this regard, the MI technique includes the following approaches in the conversation between the patient and the clinician (the diabetes specialist nurse in our study): (1) establishing a collaborative partnership between the patient and the clinician to find a solution, (2) evoking from the patients what they already have in terms of their own motivation and resources for change, and (3) honoring the patients' autonomy about how to live their lives. The clinician has to resist the "righting reflex," understand the patients' motivation, and listen to and empower the patients [43].

To guide the participants in the change process, the nurse assesses the motivational stages [44] for each patient in relation to diabetes-relevant areas and the use of the Few Touch application. The health counseling is based on national guidelines [8], and the intervention as illustrated in Figure 2 is explained in the following text.

At the first stage, patients set goals for what kind of food intake and physical exercise they plan in the next period. Then, the blood glucose level is measured with Bluetooth-enabled glucose meter that transfers blood sugar level data automatically to the mobile phone. Thereafter, patients add food intake and activity manually on the phone application. Accordingly, patients get response from the application on how the individually set goals are met within the defined period.

Parallel to the registration process, the following activities are also carried out. First, patients in the health counseling group have contact with the diabetes specialist nurse in parallel to using the application, where relevant health-related questions and results are discussed. Second, patients in both the intervention groups (I+II), have regular consultations with their physician where they will be able to share their application data, if they choose to do so. Finally, responsibility and control of their data lie with the patients.

**Figure 2.** Pilot drawings.



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### *Information and Training*

Both intervention groups (I+II) are instructed in using the mobile phone-based system. In the first session, they are given a practical presentation of the diabetes diary from the project group, which describes the different details recorded in the diary. This is followed by a session in which the patients try the same functionalities on their mobile phone. They are also given a manual for the use of the mobile phone and the Few Touch application both in a paper-based handbook and on a USB memory stick. The telephone support service is available on weekdays from 9:00 to 15.00 h, when support providers are available to answer questions and help the participants with technical aspects. The patients are also informed through the consent form that the project team might contact them if they are not using the phone at all, which is discovered by lack of registrations on the central database server. Participants in intervention group II who additionally receive the health counseling are given additional training in how to send and receive SMS messages securely to the diabetes specialist nurse or dietitian.

### *Power Analyses*

Power analyses were performed before recruitment to estimate the sample size needed based on the HbA1c level as the primary outcome. Given an effect size of 0.35, a significance level of 5%, a standard deviation of the outcome variable of 0.5, statistical power of 80%, and a two-tailed significance test, the sample size was estimated to be 34 individuals in each group. To compensate for dropouts, the sample was set to 50+50 (two intervention groups), and 50 in the control group. A total of 151 patients were included.

## Evaluation Measures

### *Overview*

Our evaluation is based on the Model for Assessment of Telemedicine (MAST), which is a framework developed for the evaluation of the TM interventions in RENEWING HEALTH [39]. We are also using principles from the complex intervention framework developed by the Medical Research Council in the United Kingdom [52]. We intend to evaluate a large number and variety of outcomes. The consolidated standards of reporting trials (CONSORT) statements for reporting parallel group randomized trials are followed [53,54]. The study data include responses on self-reported questionnaires, logs from the Few Touch application, and data collected from patient journals obtained from the GPs. To assess the representativeness of the sample, we will use data from the general population with and without diabetes from the Nord-Trøndelag Health Study (HUNT 3) in Norway [55]. We will also conduct in-depth interviews with patients and health care providers consecutively. In addition, we will collect data from the technical support service to get knowledge about who are using the service, frequency of use, and what they are asking for. Further, we collect notes from the diabetes nurse taken during the health counseling. The measures in our study are described in detail below.

### *Demographics*

These are self-reported measures and include age, sex, education, cohabitation, marital status, and working status of the participant.

### *Clinical Measures*

Data from the medical records include medication, dosage, treatment period, and adjustments during the study period. Data about height, weight, blood pressure, and waist circumference are also obtained from medical records. Biological data include HbA1c and lipid levels. Frequency of hypoglycemia and comorbidities are self-reported, and late complications such as atrial fibrillation, intermittent claudication, cerebrovascular disease, coronary disease, and microalbuminuria are obtained from the GPs.

## Primary Outcome Measure

The primary outcome is the difference between the control group and the intervention groups regarding change in HbA1c level after 4 months and after 1 year. When possible, HbA1c levels are recorded within 2 weeks before or after the expected date of follow-up (ie, within a 1-month window) [56]. HbA1c level has been shown to vary between 100 laboratories in the United Kingdom and between the various HbA1c assays in use [57]. In the present study, patients are included from different GP offices, and there may be variations in HbA1c levels recorded. To avoid bias potentially introduced through the use of different HbA1c assays, the DCA Vantage Analyzer from Siemens is used when possible.

## Secondary Outcome Measures

### *Short Form-36 for Measuring Health-Related Quality of Life*

This questionnaire contains eight conceptual domains within physical functioning and mental health giving scores of 0-100: (1) physical functioning, (2) role-physical, (3) bodily pain, (4) general health, (5) vitality, (6) social functioning, (7) role-emotional, and (8) mental health [58,59]. It is one of the most frequently applied surveys for measuring health-related quality of life, and its domains are relevant for people with diabetes [60]. The Short Form-36 (SF-36) was included in RENEWING HEALTH to allow comparisons between different regions included in the project and to allow comparisons with norms.

### *Center for Epidemiological Studies Depression Scale for Measuring Depression*

The Center for Epidemiological Studies Depression Scale is a tool for measuring depressive symptoms, but not for diagnosing depression [61]. It assesses the behavioral, cognitive, and affective symptoms of depression, and measures sleep disturbance and loss of appetite, which can be important signs of depression and may have major impact on diabetes management.



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## Behavior Change and Empowerment

### *Health Education Impact Questionnaire (heiQ)*

The Health Education Impact Questionnaire (heiQ) contains 40 questions to measure the effectiveness of patient education and self-management interventions for people with chronic conditions, as well as the patients' health competence. It is an eight-scale questionnaire with the following domains: (1) positive and active engagement in life, (2) health-directed behavior, (3) skill and technique acquisition, (4) constructive attitudes and approaches, (5) self-monitoring and insight, (6) health service navigation, (7) social integration and support, and (8) emotional well-being. The instrument has been proven to be valid and reliable [62]. The instrument has recently been translated to Norwegian, and a psychometrically testing is ongoing.

### *Diabetes Empowerment Scale-Short Form*

The Diabetes Empowerment Scale-Short Form (DES-SF) has eight items related to managing the psychosocial aspects of diabetes, and measures readiness to change and achieve goals [63,64]. The DES-SF has been proven to be valid and reliable, although the short form has not been through a test-retest validation [65]. This instrument has been translated into Norwegian for the present study.

### *Physical Activity*

Measures of physical activity are collected by the same questions as in the HUNT 3 study for comparison purposes with a diabetes sample from the general population. We have also included one question based on the transtheoretical stages of change to assess the respondents' motivation toward physical activity and change in activity level [66].

### *Nutritional Habits*

Measures of nutrition are collected using the same questions as those used by the Cancer Registry of Norway in the Norwegian Colorectal Cancer Prevention study, which collects data about the intake of fruit, vegetables, and fat [67]. Motivation for changing nutritional habits is assessed using a question based on the transtheoretical stages of change [46].

## Patient Acceptability

### *Measurement of the Usability of the Mobile Self-Management Tool*

The usability of the mobile self-management tool FTA Touch application will be measured by the System Usability Scale (SUS) that comprises 10 items to provide a global view of the patients' subjective assessment of usability. The SUS has been found to be a "valuable and robust tool in helping assess the quality of a broad spectrum of user interfaces" [68]. The measure has been used earlier in Norway [50].

### *Assessment of the Patients' Perceptions*

To assess the patients' perceptions about the mobile self-management tool Few Touch application, the patient acceptance questionnaire, Service User Technology Acceptability Questionnaire, used in the Whole Systems Demonstrator program [69] is used in all pilot studies of RENEWING HEALTH. This questionnaire contains 22 items within the following domains: utility of the kit, effect on health status, effects on access to care, effects on health care/social care, privacy, suitability of the kit, and satisfaction with the kit.

### *Patients' Experiences With the Intervention*

We are also integrating a qualitative evaluation with in-depth interviews of consecutive patients at the end of the study. We are using grounded theory [70] and have developed a semistructured interview guide to obtain patients' experiences and their degree of satisfaction with the intervention. Integrating a qualitative approach into this RCT may strengthen the description of its effects. The interviews will be conducted by a researcher who had no earlier contact with the patients. The interviews will continue until saturation of data is achieved.

## Health Care Perspectives

Health Care perspectives will be collected through semistructured interviews with health care professionals, doctors, and nurses in the GP offices and the diabetes outpatient clinics involved in this study. The focus for this evaluation will be facilitators for and obstacles to using the system provided or similar systems.

## Cost-Effectiveness

The objective of the economic study is to analyze whether the interventions in addition to standard care are cost effective compared to standard care alone. The study will be conducted from a societal perspective; all costs and consequences falling on the health service as well as on the patient and their employers will be included. The analysis will include data on investments in the TM app, as well as training costs, cost of maintenance, and technical support. Data on health resource use (such as GP visits, hospital admissions, and contacts with nurses), transportation costs, and costs of foregone production are also collected. Market prices, tariffs, and average wages (including employment costs) will be used as cost weights or unit costs and will be presented alongside resource data. Total costs of the treatment arms will be compared with the benefits of improving the patients' health. Health benefits will be measured in quality-adjusted life years (QALYs). Patient-specific QALYs will be computed from the SF-36 Health Survey by employing an estimated preference-based algorithm developed by Brazier et al [71]. QALYs will be calculated by using under the curve analysis, with linear interpolations between utility scores collected at baseline, 4 months, and 12 months assessments. Incremental cost per QALY will then be calculated and incremental cost-effectiveness ratios will be reported and presented on the cost-effectiveness plane [72].

## Statistical Analysis

Baseline measurements will be presented using descriptive statistics. The participants will be block randomized, and the groups should therefore be equal in age and gender distribution. The groups will be compared with regard to clinically relevant variables to ensure they are comparable. Because of the limited size of the groups, they may differ on some variables and, when such variables are identified, they will be adjusted for in the statistical analyses, for example, by treating them as possible confounders.



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Baseline data will be compared with data from the normal population (HUNT 3 study) to assess whether our sample is representative of the entire population of Norwegian individuals living with diabetes.

The differences in the main outcome between baseline and 4 months and between baseline and 1 year will be compared between the three groups. First, the crude difference will be analyzed using analysis of variance with post hoc tests (differences between groups). The difference between baseline and the following two measurements within each group will be analyzed using a *t* test. When a change in a selected outcome variable is identified, this change will be modeled using linear regression adjusted for possible confounders.

The cost-effectiveness data will be analyzed using standard statistical analyses depending on the distribution of the data. Missing values will be replaced by imputation. Mean values and 95% CI will be reported for each component of resource use as well as for total costs and effectiveness. Sensitivity analyses will be conducted to handle nonsampling variation.

Our study has a longitudinal design and we expect some dropouts. Therefore, we will perform two analyses: one based on intention to treat and another based on the participants who actually participated actively in our study (per protocol).

### Ethical Considerations

The study has been approved by the Regional Ethics Committee. The patients will be guaranteed full confidentiality and are required to provide informed consent to participate in the study. The security associated with the server will ensure the safety of the data. Only anonymous data are sent in an encrypted way over the Internet, and the data will be stored anonymously. There are ethical concerns about clinical trials when some of the patients receive the intervention, while others do not. However, all patients will receive the usual care by their GPs, who will be aware of their patients' participation in the study.

## Results

The inclusion of patients started in March 2011, and 100% of the planned sample size is included (N=151). Of all the participants, 26/151 patients (17.2%) are lost to follow-up by now, and 11/151 patients (7.3%) are still in the trial. Results of the study protocol will be presented in 2014. The aim of this study is to validate and evaluate innovative TM tools on a large scale through a common evaluation, making it easier for decision makers to choose the most efficient and cost-effective technological interventions.

## Discussion

Despite a large number of studies of TM and systematic reviews of the effects of TM, there remains a lack of consensus in research findings [28]. The key elements in this trial are the effect of an intervention that combines a mobile self-management tool with motivational support and the comparison with an intervention comprising TM alone. It is of interest to investigate the effect of the TM application with and without health counseling, and it is reasonable to question whether health counseling is important for the continued use of tools such as those in this study and for patients' health competence and acceptability. One might question whether the health counseling part of the intervention will motivate the patients or whether the repeated phone calls from the diabetes nurse will become more tiresome than supportive and thus unwanted. Research on this question is needed, but to our knowledge, no studies have investigated this thoroughly.

We have chosen to include adult patients of all ages and some not familiar with mobile phones. Our qualitative approach will allow us to search for possible limitations in the use among different groups of patients. This may give us valuable knowledge about how to encourage the use among different groups of patients and how to assess the effects of a low-intensity intervention on different subgroups. Our qualitative approach might also reveal important information in discussions with patients and health personnel about how to integrate self-management tools in the health care system.

The patients included in the study may represent those who are open to new technology and who are willing to participate in a complex intervention; thus, the acceptability to using such devices may be lower in the wider population. It will be important to assess representativeness. In Norway, we have data from large population-based studies that are well suited for comparison purposes. Recruitment to RCTs is also frequently problematic [73,74], and one concern in the present RCT is whether patients who are eligible will be disappointed when they are randomized to the control group and not to an intervention group receiving the Few Touch application or the application together with health counseling. There is reason to question whether an RCT is suited to this type of study when we are recruiting possibly motivated patients to participate in a TM intervention and they may be randomized to the control group. Different designs that are more flexible and clinically useful have been discussed [73], and our study may contribute to this discussion, which is of current interest.

In the present study, we have chosen HbA1c level as the primary outcome. Many people with diabetes have poor understanding of their HbA1c level, and only few remember their actual test results. The level of agreement between perceived glycemic control and actual HbA1c values is also poor [75]. This could be a challenge in our research when the primary outcome is a measure of which many patients may have a poor awareness and understanding. In addition, glycemic control may not be a goal for some patients when they volunteer for the study. However, the patients in the intervention groups will have access to information about their blood glucose measures through the Few Touch application, and one of the intervention groups will additionally receive health counseling to help them attain self-management and diabetes control.

Evaluations of telehealth interventions for persons with diabetes have focused mostly on the achievement of a clinical outcome in terms of glycemic control. Nolte et al [38] performed an in-depth analysis of outcome measures used to evaluate chronic disease self-management programs and found that decisions about the value and efficacy of chronic disease self-management programs should be interpreted with care. There is an important



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difference between clinical measures (eg, HbA1c level) and patient-reported outcomes. The former can be assessed relatively accurately, whereas assessments of patient-reported outcomes have considerably more measurement error and varying degrees of bias caused by question interpretation and personal appraisal. There is a need for further research, qualitative studies in particular, to unravel the cognitive processes and the role of response shift bias in the measurement of change [76]. We will take into account this challenge in our study by using several evaluation-based measures requiring a large amount of personal judgment. Our mixed-method design and inclusion of in-depth qualitative interviews of consecutive patients leaving the study will help us identify their experiences and reflections, and will provide a more comprehensive description of the effects of processes in our evaluation of the intervention.

Another concern in a complex intervention such as ours is the benefit of the attention that all the participants receive during the study period from different persons, for example, the effect from the patients' awareness that they are participants under study (Hawthorne effect) [77]. The intervention groups receive attention from the technical support team during the 1-year use of the tools provided, and all groups may receive attention during the collection of data at the three time points. Finally, the GPs will be aware of "their" patients' participation in a study in which HbA1c is the primary outcome, and this may induce them to provide better treatment. We must avoid the effects of other possible interventions given by these professionals. The possibility that improvements may be caused by intensified provider consultation has been described in a recently conducted review [28], and researchers should be aware of this problem.

Research on barriers to intervention has been requested within diabetes self-management interventions [78] and health research in primary care [79]. Barriers to participation and adoption of TM from the perspective of people who decline to participate or who withdrew early from the trial have been described [80]. We do not have permission from the ethical committee to ask patients who drop out during the study for the reasons. In-depth interviews at the end of the study will, however, give us qualitative data about the patients' views of the intervention's usability and acceptability. We are also using evaluation tools including questionnaires measuring the same topics [68,69], and we are using the heiQ to identify psychosocial barriers to behavior change [62]. Another concern for some participants is that it is a time-consuming intervention because of its technology focus. Patients may choose not to participate in the study because of the time factor, and this may be a limitation to recruitment. It has been shown that recruitment to primary care trials is normally problematic, such as in the United Kingdom [69]. This may also be a problem in Norway, where there is less research in primary care than in specialist care. However, there is little research on how to improve recruitment in primary care studies. It is important to cooperate with health care personnel in the communities when developing an intervention directed toward "their" patients, and where user involvement is of great importance. Politicians and other stakeholders in the communities should both order and participate in research in this area [7]. This should help increase knowledge and competence for developing new and innovative services for health care users and providers.

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## Authors' Contributions

LR and HH drafted the manuscript, and all authors contributed to editing of the final manuscript. All authors have read and approved the final manuscript.

## Conflicts of Interest

None declared.

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## Abbreviations

**EU:** European Union
**GP:** general practitioner
**HbA1c:** hemoglobin A1c
**heiQ:** Health Education Impact Questionnaire
**MAST:** Model for Assessment of Telemedicine
**MI:** motivational interviewing
**QALY:** quality-adjusted life year
**RENEWING HEALTH:** REgioNs of Europe WorkINg together for HEALTH
**SF-36:** Short Form-36
**SMS:** short message service
**SUS:** System Usability Scale
**T2D:** type 2 diabetes
**TM:** telemedicine


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Protocol

# Internet-Based Cognitive Behavior Therapy for Procrastination: Study Protocol for a Randomized Controlled Trial

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## Abstract

**Background:** Procrastination, to voluntarily delay an intended course of action despite expecting to be worse-off for the delay, is a persistent behavior pattern that can cause major psychological suffering. Approximately half of the student population and 15%-20% of the adult population are presumed having substantial difficulties due to chronic and recurrent procrastination in their everyday life. However, preconceptions and a lack of knowledge restrict the availability of adequate care. Cognitive behavior therapy (CBT) is often considered treatment of choice, although no clinical trials have previously been carried out.

**Objective:** The aim of this study will be to test the effects of CBT for procrastination, and to investigate whether it can be delivered via the Internet.

**Methods:** Participants will be recruited through advertisements in newspapers, other media, and the Internet. Only people residing in Sweden with access to the Internet and suffering from procrastination will be included in the study. A randomized controlled trial with a sample size of 150 participants divided into three groups will be utilized. The treatment group will consist of 50 participants receiving a 10-week CBT intervention with weekly therapist contact. A second treatment group with 50 participants receiving the same treatment, but without therapist contact, will also be employed. The intervention being used for the current study is derived from a self-help book for procrastination written by one of the authors (AR). It includes several CBT techniques commonly used for the treatment of procrastination (eg, behavioral activation, behavioral experiments, stimulus control, and psychoeducation on motivation and different work methods). A control group consisting of 50 participants on a wait-list control will be used to evaluate the effects of the CBT intervention. For ethical reasons, the participants in the control group will gain access to the same intervention following the 10-week treatment period, albeit without therapist contact.

**Results:** The current study is believed to result in three important findings. First, a CBT intervention is assumed to be beneficial for people suffering from problems caused by procrastination. Second, the degree of therapist contact will have a positive effect on treatment outcome as procrastination can be partially explained as a self-regulatory failure. Third, an Internet based CBT intervention is presumed to be an effective way to administer treatment for procrastination, which is considered highly important, as the availability of adequate care is limited. The current study is therefore believed to render significant knowledge on the treatment of procrastination, as well as providing support for the use of Internet based CBT for difficulties due to delayed tasks and commitments.

**Conclusions:** To our knowledge, the current study is the first clinical trial to examine the effects of CBT for procrastination, and is assumed to render significant knowledge on the treatment of procrastination, as well as investigating whether it can be delivered via the Internet.

**Trial Registration:** ClinicalTrials.gov: NCT01842945; http://clinicaltrials.gov/show/NCT01842945 (Archived by WebCite at http://www.webcitation.org/6KSmaXewC).

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**KEYWORDS**

procrastination; cognitive behavior therapy; Internet-administered; randomized controlled trial

# Introduction

## Defining Procrastination

Procrastination is defined as "to voluntarily delay an intended course of action despite expecting to be worse-off for the delay" [1]. It involves the postponement of initiating or completing a task or commitment until the last minute, after a predetermined deadline, or indefinitely. Albeit similar to difficulties prioritizing or being self-assertive, procrastination requires an active choice between competing activities, in which one is being avoided in favor of the other [2]. A common explanation for procrastination is based on learning theory and research on motivation and goal setting [3]. According to this perspective, procrastination is the result of an interaction between four variables: (1) expectancy, (2) value, (3) impulsiveness, and (4) time, also known as the procrastination equation [1]. Procrastination is a common behavioral pattern among adolescents and adults, and is presumed to be on the rise because of growing demands on individual responsibility and work flexibility, as well as greater availability of modern information technology [1]. Particularly vulnerable are young people studying at college or university, approximately half of this population suffers from difficulties due to procrastination, compared to 15%-20% in the general public [4]. Procrastination does not only cause problems concerning the task at hand, but has also been related with lower performance in school as well as work, decreased well-being, financial concerns, greater physical and mental illness, and fewer mental health seeking behaviors [5-8]. Both stress and anxiety are common among individuals who procrastinate recurrently, and is correlated with the degree of their difficulties [9,10].

## Procrastination Treatment

Even though procrastination is affiliated with great unrest among those afflicted, research on effective treatment methods is currently lacking. Cognitive behavior therapy (CBT) is often considered the treatment of choice, but since no clinical trials in the field of procrastination have been undertaken to date, its effectiveness is unknown [11]. The assumption that CBT might be beneficial for people suffering from difficulties due to procrastination is therefore primarily based on face validity and singe case studies. However, several of the cognitive and behavioral techniques used with people suffering from procrastination stem from treatment methods that have been proven effective for other psychiatric disorders. Behavioral activation is, for instance, originally developed for depression [12], but is often utilized in situations where a high degree of avoidance is causing great distress and decreased well being [13]. In relation to procrastination, behavioral activation helps the individual change an ongoing behavioral pattern so that tasks and commitments are approached rather than avoided. This usually requires some form of graded exposure considering the fact that procrastination is often reinforced by the unwillingness to experience discomfort [2]. Behavioral experiments can also be used to facilitate a reevaluation of work methods and presumptions regarding one's own ability to achieve certain goals [14], aspects that are often characterized by either exaggerated optimism or pessimism among people who procrastinate [3]. This is often accompanied by other cognitive therapy techniques that aim to modify rigid and dysfunctional thoughts and assumptions that hinder the individual to behave more flexibly [15]. In addition, recent research findings in cognitive neuroscience and industrial psychology stress the importance of creating an effective work environment (eg, inhibiting the use of multitasking, decreasing the number of distractions, and preventing ego-depletion) [16-18]. In CBT this is generally referred to as stimulus control, and is regarded as beneficial for people who are afflicted by certain stimuli in their environment (eg, managing triggers for anxiety or avoiding situations that can cause problem behaviors such as substance abuse or deliberate self-harm) [19].

The effectiveness of specific CBT techniques for procrastination is however uncertain, thus making it unclear what mediates treatment outcome [11]. Since no clinical trials have yet to be carried out, it is not certain whether cognitive therapy, behavioral therapy, or a combination of both, is best suited for the treatment of procrastination. However, a recent meta-analysis indicates that several interventions related to addressing values and rewards, achieving stimulus control, enhancing goal-setting skills, and the utilization of success-spirals, could be beneficial for people suffering from procrastination [3]. Hence, certain CBT techniques, as well as methods from other disciplines, are assumed to be effective in treating procrastination.

## Trial Objectives and Purpose

The aim of this study is to examine the effects of CBT for procrastination, and to investigate whether it can be delivered via the Internet. The study will be based on a self-help book written by one of the authors (AR) [20], which for the purpose of the current research project has been divided into 10 modules that are to be delivered weekly to the participants. There will be two treatment groups used, one with therapist contact and one without, as well as a wait-list control group. It is assumed that the treatment group with therapist contact will be superior to the treatment group receiving no therapist contact since procrastination can be partially explained as a self-regulatory failure. Both treatment groups are presumed to be superior to the wait-list control.

# Methods

## Participants in the Sample

The current study is a randomized controlled trial (NCT01842945) with a total sample size of 150 participants divided into three groups; treatment with therapist contact (50 participants), treatment without therapist contact (50 participants), and wait-list control (50 participants). For ethical reasons the participants in the control group will gain access to the same intervention following the 10-week treatment period, albeit without therapist contact.



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### The Intervention

There will be 10 modules from a self-help book on procrastination administered weekly to the participants via the Internet. These will contain psychoeducation, including information on the mechanisms underlying procrastination, different aspects affecting motivation, the concept of ego-depletion and mental fatigue, as well as a basic rationale of CBT. The modules will also include several techniques commonly used in the treatment of procrastination (eg, behavioral activation, graded exposure, behavioral experiments, identifying and testing rigid beliefs and assumptions, and stimulus control) [3,11,15]. The final module will focus on relapse prevention in order to successfully maintain behavior change [21].

The participants are instructed to study the material and carry out the assignments in each module. This consists of writing down any thoughts and ideas that arise from reading the provided psychoeducation, as well as carrying out different exercises each week (eg, goal-setting, time scheduling, identifying distractions, value clarification, and analyzing behavior patterns. For those participants receiving therapist contact, the completed assignments are retrieved at the end of every week in order to get continuous feedback on their work. This condition is assumed to be superior to those participants that are given each module without therapist contact as procrastination is maintained by difficulties concerning time management and task avoidance [3]. In other words, the presence of an external source of control (ie, a therapist contact) is expected to result in greater treatment outcome, as it will ensure that the participants undertake each module and practice relevant techniques. Similar to homework assignments in traditional face-to-face CBT, which has been found to increase both learning and adherence [22], receiving therapist contact is assumed to improve compliance throughout the treatment period. The feedback from a therapist contact can also be considered a source of positive reinforcement that many participants might lack when working on their day-to-day tasks and commitments [19]. However, even without a therapist contact participants are assumed to gain significant improvement as prior studies of Internet based CBT indicate that also a minimal level of therapist contact can have a positive effect on treatment outcome [23,24].

Internet based CBT has previously been found to be an effective way to administer treatment for several psychiatric conditions [25]. This includes depression [26], social phobia [27], panic disorder [28], generalized anxiety disorder [29], insomnia [30], post-traumatic stress disorder [31], tinnitus [32], and pathological gambling [33] among others. Internet based CBT is considered having several advantages over traditional face-to-face treatment (eg, higher cost-effectiveness, increased accessibility, greater possibility to reach patients in remote locations, and lower attrition rates) [34].

### Control Condition

The participants in the control group will be on a wait-list throughout the 10-week treatment period, and this group is expected to be inferior to the other two treatment groups. For ethical reasons the participants in the control group will gain access to the same intervention following the 10-week treatment period, albeit without therapist contact.

### Sample Size

The current study includes 150 participants randomized into three groups (ie, 50 participants in each group). Since no clinical trials in the field of procrastination have been undertaken, there are no previous effect sizes to take into consideration. However, 50 participants in each group are deemed sufficient to find clinically significant differences.

### Referral and Recruitment

Participants will be recruited through advertisements in newspapers, other media, and on the Internet. Only people residing in Sweden, having Internet access, and suffering from difficulties due to procrastination will be included in the study.

### Inclusion Criteria

Participants will be included in the study if their primary difficulties are caused by chronic and severe procrastination. However, since procrastination is not considered a psychiatric condition there will be no need to utilize diagnostic criteria (ie, Diagnostic and Statistical Manual of Mental Disorders Fourth edition, DSM-IV) [35], or a structured clinical interview (ie, Structured Clinical Interview for DSM-IV) [36]. In order to determine and evaluate the severity of procrastination several primary outcome measures will be used (eg, the Pure Procrastination Scale, PPS; the Irrational Procrastination Scale, IPS; and the Susceptibility to Temptation Scale; STS) [37]. To date, none of the primary outcome measures have clinically established cut-offs. However, greater than 32 points on the IPS have been found to distinguish more severe cases of procrastination (ie, top 25%) [1], and will therefore be used as cut-off for inclusion.

### Exclusion Criteria

In order to be included in the study participants are required to have a Swedish residency, to be at least 18 years of age, and fluent in Swedish, as well as having a computer with Internet access. Participants are not allowed to have an ongoing psychotherapy, and in case of taking psychotropic medication, the dose must have been stabilized for at least three months prior to entering treatment. Psychiatric conditions are not criteria for exclusion as long as procrastination is the primary problem. However, participants with severe depression (> 30 points on the Montgomery Åsberg Depression Rating Scale Self-report version, MADRS-S) [38], suicidal ideation, neuropsychiatric conditions (ie, Attention deficit hyperactivity disorder and Attention deficit disorder) misuse of alcohol or drugs, bipolar disorder, schizophrenia, and psychosis will be excluded from the study.

### Informed Consent

Participation will require a written informed consent.

### Withdrawal

Participation can be withdrawn at any time during the treatment period without specifying a reason behind the decision. In addition, should the condition of a participant deteriorate, supervising clinicians may choose to end the participation



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prematurely and direct the participant to other health care services.

### Safety Monitoring and Reporting

The current study adheres to the Swedish Personal Data Act [39]. The data being stored will be encrypted, and all participants will receive an auto-generated identification code in order to log on to a secure online interface (eg, 1234abcd), thus ensuring the anonymity of the participants during the analysis of the results. All communication with the participants will take place within the secure online interface that requires an electronic identification (ie, Secure Sockets Layer Certificates). Only reminders to log on to the secure online interface will be sent to the participants' private email. At the postassessment, and at all subsequent assessment points, questions probing for adverse events will be used [40].

### Primary Outcomes

Primary outcome measures will be self-assessment of procrastination using a Swedish version of the PPS [37], the IPS [37], and the STS [37]. The PPS features 12 items measuring the prevalence of procrastination, and was originally developed to improve the validity of several different procrastination scales [37]. The items used in the PPS have a reliability of .92, and the PPS shows improved convergent validity with other related measures. The IPS features nine items measuring the degree of irrational delay causing procrastination. The items used in the IPS have a reliability of .91, and the IPS correlates together with the PPS at .96, allowing them to be used as parallel forms and share validation efforts [37]. The STS features 11 items measuring the susceptibility to temptation, which can affect the ability to follow through a task or commitment. The items in the STS have a reliability of .89, and demonstrate correlation with both the PPS and the IPS. However, since none of the primary outcome measures contain established cut-offs, clinical assessment will be used to determine treatment outcome. Participants will complete the primary outcome measures before commencing the treatment period, immediately upon completion of the treatment, and at the 12-month follow-up. Participants, including those on wait-list control, will also complete the IPS each week during the treatment period, allowing continuous measurement and increasing the statistical power.

### Secondary Outcomes

Secondary outcome measures will be self-assessment of depression, anxiety, and quality of life using the MADRS-S [41], Generalized Anxiety Disorder Assessment 7-item (GAD-7) [42], and Quality of Life Inventory (QOLI) [43]. MADRS-S is a self-assessment version of MADRS, and features nine items measuring changes in mood, anxiety, sleeping patterns, appetite, concentration, initiative, emotional engagement, pessimism, and attitude towards life [38]. MADRS is designed to be particularly sensitive to treatment effects, and shows high correlations, from $r$=.80 to .94, between expert ratings and self-reports [44]. GAD-7 features seven items for assessing anxiety, and screening for generalized anxiety disorder. GAD-7 has yielded good internal consistency, Cronbach alpha .92, and a good factorial structure, 69% to 81% of variance explained [42]. QOLI features 32 items concerning 16 areas of life rated by the subject concerning importance and satisfaction. QOLI has yielded good internal consistency, Cronbach alpha between .77 and .89, as well as one month test-retest reliability, from $r$=.80 to .91 [43,45]. Participants will complete the secondary outcome measures before commencing the treatment period, immediately upon completion of the treatment, and at the 12-month follow-up.

### Analysis

The study design will allow multiple comparisons-the two treatment groups, with or without therapist contact, will be compared to the wait-list control (separately and together) at posttreatment. In all subsequent analyses, the treatment groups will include those from the control group later randomized to interventions, which will increase the statistical power. The two treatment groups will be contrasted with the control group. Further, the treatment group with therapist contact (group 1) will be contrasted with the group without therapist contact (group 2). At the 12-month follow-up, within-group comparisons will be made with previous results. A number of statistical analyses will be deployed, all of which will be analyzed by the intention-to-treat approach. Treatment outcomes will be examined using mixed-effect models, Bonferroni-correcting for multiple comparisons. This method is deemed preferable to uni- and multivariate repeated measures of variance [46]. Standard missing data analysis (eg, $t$ tests, chi-square of severity and sex) will be utilized to determine if unexpected missing data due to participant drop out are random or not.

All outcome measures will be completed directly by the participants via an online interface, minimizing the risk of data loss or data distortion [47,48]. Data will be stored encrypted and in unidentifiable form using an auto-generated identification code.

### Ethics

The regional Ethical Board (Dnr 2013/974-3175) has approved the current study. In the application, the following potential ethical issues were addressed. First, great consideration will be taken not to include participants suffering from any other primary diagnosis such as severe depression, suicidal ideation, or other disorders in immediate need of treatment. Should the condition of a participant deteriorate significantly during the treatment period, supervising clinicians may choose to end the participation prematurely and direct the participant to other health care services. Second, no adverse side effects of CBT interventions are assumed to occur. However, this will nonetheless be investigated by asking standard treatment side effects questions at the posttreatment measurements [49]. Third, when using the Internet to communicate and administer interventions, the privacy of the participants is of the greatest importance [50]. As mentioned earlier, participants will therefore use anonymous auto-generated identification codes to interact with a secure online interface, and only reminders will be sent to the participants' private email.



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## Results

### The Current Study

The current study is a randomized controlled trial examining the effects of Internet based CBT for procrastination and is believed to result in several important findings. First, research on procrastination has mainly focused on underlying mechanisms affecting motivation, often involving the study of personality constructs and different demographic variables [3,11]. Although some factors have been found to mediate difficulties due to procrastination (eg, neuroticism, self-efficacy, self-esteem, depression, age, and gender) [15,51-53,54,55], the results are far from consistent and the implications not always clear [3]. Meanwhile, research on the treatment of procrastination is scarce, affecting the possibility of receiving adequate care. CBT is often considered the treatment of choice, even though no clinical trials have yet been carried out [11]. The aim of this study will be to test the effects of CBT for procrastination, thereby generating significant knowledge on what interventions can be used in the treatment of difficulties due to unattended tasks and commitments.

Second, previous research on Internet based CBT has found it to be an effective way to administer treatment for several psychiatric conditions. It is therefore presumed to be beneficial for people suffering from procrastination. The aim of this study will be to investigate whether CBT for procrastination can have a positive effect on treatment outcome if delivered via the Internet, and to test whether or not receiving weekly therapist contact can influence treatment outcome. This is considered highly important as the availability of adequate care is limited, and should it prove effective in alleviating difficulties due to procrastination, it would greatly increase the possibility of receiving treatment regardless of geographic location.

### Trial Status

The recruitment of participants to the current study was completed in August 2013. The treatment period commenced in September for both treatment groups and ends in December the same year. The wait-list control will begin treatment two weeks later and finish in February 2014. Preliminary results will be available later the same month. Follow-up will be carried through 12 months later (ie, December 2014 for the two treatment groups and February 2015 for the control group).

## Discussion

### Summary

To our knowledge, the current study is the first clinical trial to examine the effects of CBT for procrastination, and is assumed to render significant knowledge on the treatment of procrastination. The study also investigates whether Internet based CBT, either with or without support from a therapist contact, can be beneficial for people suffering from difficulties due to procrastination.

### Study Limitations

The current study has some limitations that need to be recognized. First, due to the fact that procrastination is not considered a psychiatric condition there may arise difficulties concerning the evaluation of clinically significant change. In order to assess the effects of the interventions being employed, self-assessments are utilized to determine the severity of procrastination among the participants. However, since none of the primary outcome measures contain clinically established cut-offs, the Reliable Change Index will be used to determine clinical significant change [56]. This might affect the validity and reliability of the results, but is compensated for by the use of secondary outcome measures (eg, MADRS-S, GAD-7 and QOLI), as procrastination often causes great unrest and decreased well being among those afflicted. Second, the use of a Swedish version of the primary outcome measures can also influence the validity of the results, which is why an authorized translator is hired to ensure that no significant loss of meaning is being made during the translation process. Third, another limitation in need of recognition is the involvement of master students in clinical psychology as online therapists. To make up for the students' lack of training and experience, an experienced licensed clinical psychologist and psychotherapist will supervise all involvement in the study.

### Conclusions

Procrastination is a common psychological problem causing major distress, especially among the student population. CBT is deemed the treatment of choice and is evaluated in a clinical trial conducted entirely over the Internet.

### Acknowledgments

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### Authors' Contributions

AR in collaboration with PC designed the study and contributed to its conception. AR drafted the manuscript, which was later reviewed and revised by PC before being approved for publication.



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## Conflicts of Interest

The current study was based on modules from a self-help book authored by one of the authors (AR). The author plans to release this book on the Swedish market during the first half of 2014. Consequently, AR will not be involved in any of the informed consent procedures or analyses of outcome data.

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## Abbreviations

**CBT:** cognitive behavior therapy
**DSM-IV:** The Diagnostic and Statistical Manual of Mental Disorders Fourth edition
**GAD-7:** Generalized Anxiety Disorder Assessment 7-item
**IPS:** Irrational Procrastination Scale
**MADRS:** Montgomery Åsberg Depression Rating Scale
**MADRS-S:** Montgomery Åsberg Depression Rating Scale Self-report version
**PPS:** Pure Procrastination Scale
**QOLI:** Quality of Life Inventory
**STS:** Susceptibility to Temptation Scale


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Protocol

# Evaluating the Efficacy of a Web-Based Program (Diapason) for Informal Caregivers of Patients With Alzheimer's Disease: Protocol for a Randomized Clinical Trial

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## Abstract

**Background:** Informal caregivers (CGs) of patients with Alzheimer's disease are at risk of suffering from psychological and physical weakening. Several psychoeducational interventions have been designed to prevent stress and burden of caregivers. In France, despite health authorities' recommendations, to our knowledge there is no rigorously assessed Web-based psychoeducational program to date.

**Objective:** The objective of our study was to assess the efficacy of a French Web-based psychoeducational program (called Diapason) with an unblinded randomized clinical trial.

**Methods:** In this protocol, 80 informal caregivers of patients followed at Broca Hospital are recruited offline and randomized in the experimental condition (EC) or the control condition (CC). The volunteers in EC have to visit a closed online user group at least once a week and validate one new session of this fully automated Web program, during 12 weeks. Each week a new thematic is added to the website. The participants in the CC receive usual care, and have access to the Diapason program after their participation (6 months). Face-to-face evaluations for both groups are planned every 3 months (M0–M3 and M6). The main objective of this program is to provide CGs with information on the disease process, how to prevent psychological strain (using anticipation and relaxation techniques), and offering a virtual space (forum) to discuss with other caregivers. The primary outcome of this study is the self-perceived stress, while self-efficacy, burden, depression, and self-perceived health status are defined as secondary outcomes. Other variables that might have an impact on the program efficacy are collected.

**Results:** This protocol was accepted for funding. The enrollment began in October 2011, and participants currently recruited will finish their evaluations in January 2014. The results are expected for June 2014.

**Conclusions:** Findings might provide empirical evidence on: (1) the feasibility of an Internet-based program in the French context, (2) the effectiveness of a Web-based program for informal caregivers, and (3) the identification of caregivers who will benefit from this type of intervention.

**Trial Registration:** Clinicaltrials.gov NCT01430286; http://clinicaltrials.gov/ct2/show/NCT01430286 (Archived by WebCite at http://www.webcitation/6KxHaRspL).

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**KEYWORDS**

family caregivers; Alzheimer's disease; Internet; program effectiveness; psychoeducational program; psychological stress; randomized clinical trials

## Introduction

### Background

Informal caregivers (CGs) of patients with dementia have an important role in the prevention of patients' institutionalization. Unfortunately, CGs are prone to high levels of stress and are at higher risk of weakening mental and physical health, lower life expectancy, and lesser economic security than people who are not confronted with such stressful situations [1]. In order to prevent these consequences various programs have been developed for them, which have shown a positive effect on caregivers' burden, depression, or stress [2-4]. Furthermore, several studies have demonstrated the protective role of resilience and coping factors for this population [5].

The new recommendations following French Alzheimer's Plan 2013 [6] underlined the use of Web-based interventions in order to inform and support family caregivers.

### Distance-Based Interventions

There are many reasons for caregivers to use or to prefer a distance intervention instead of a face-to-face one. In fact, CGs spend a lot of their time in care activities, supporting directly (eg, cooking, housekeeping, supervising their loved ones) or indirectly (eg, doing administrative, financial, or logistic management) their relatives. Furthermore, the time requested for caring increases with the disease progression, and finding time for their own respite can be quite difficult. In fact, several CGs fulfill many roles, such as being parent, grandparent, worker, and friend. Finally, some of them live in remote regions and other CGs do not feel at ease with face-to-face interventions or prefer a flexible time/content intervention [7].

Distance interventions, based on information and communications technology (ICT), appeared in the earlier part of the 21st century in order to propose an alternative intervention to caregivers unable to access health centers delivering face-to-face programs. Distant programs have shown a positive effect on self-perceived stress, burden, depression symptoms, and social support of caregivers [7-14].

In the case of caregivers of patients with dementia, several websites exist in France, but these programs have not been, to our knowledge, subjected to a randomized clinical trial.

It is therefore relevant to evaluate the impact of ICT-based or distance-based interventions on the mental and physical health status of caregivers in a controlled experimental study with a French population. It could represent a base for the health care policies and facilitate financial support for these initiatives.

*Diapason* [15] is a fully automated Web-based version of a psychoeducational program, inspired by the group intervention sessions from the geriatric service of Broca Hospital called Aide dans la Maladie d'Alzheimer (AIDMA) program, or in English: Help in Alzheimer's disease. AIDMA was assessed in a previous study including 167 dyads "patient-caregiver" and showed a significant improvement in disease understanding and in the ability to cope with care-recipients' disease [16,17]. The difficulty to schedule and attend all sessions (once per week during 12 weeks) for some of the caregivers was the main reason to adapt the program into an Internet-delivered version. Thus, we have adapted and designed a Web-based program in order to improve the accessibility for caregivers.

The purpose of this article is to present the study protocol of a randomized clinical trial designed to evaluate the efficacy of Diapason, a Web-based psychoeducational program for caregivers of patients with Alzheimer's disease (AD). Our hypothesis is that the Diapason program reduces the caregiver's perceived stress and burden and enhances his/her self-efficacy and self-perceived health. This study protocol has received approval from the French competent authorities (ie, Agence Française de Sécurité Sanitaire des Produits de Santé, Centre de Protection de Personnes–CPP, Commission nationale de l'informatique et des libertés).

## Methods

### Study Design

This is a pragmatic and unblinded randomized controlled trial (NCT01430286) of a Web-based psychoeducational program for the CGs of patients diagnosed with AD. Two parallel groups are compared. The experimental group receives immediate access to a Web-based program, and the comparison group is given the information usually delivered to the patient by the geriatrician during follow-up consultations. In addition to the baseline visit, two follow-up visits at the hospital are planned at 3 and 6 months.

### Participant Eligibility

Eligible participants are informal French-speaking caregivers (family or not, providing care to the patient at least 4 hours per week) of an AD patient diagnosed at the Memory Center of the Broca Hospital, Paris, France, and who meets the criteria in the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition [18] or National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's disease and Related Disorders Association criteria [19]. To be included in the trial, caregivers have to be 18 years or older or to be able to provide an informed consent, to score 12 or over on the Perceived Stress Scale of 14 items (PSS-14) [20] during screening, and to have a computer with an Internet access at home with an email address regularly used. If participants (CGs) are on psychopharmacological treatment or therapy, they are required to keep the same treatment at least two months before inclusion in the protocol.

### Exclusion Criteria

Exclusion criteria include being a professional or paid caregiver, a volunteer suffering from a physical or mental health status incompatible with patient's care, or following another psychoeducational program.



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## Recruitment

Strategies to communicate about the program include flyers and posters in medical waiting rooms of the Memory Center as well as in other places in the Broca Hospital. An information meeting for the hospital staff has been organized before starting the inclusions in order to explain the study protocol. Then, the contact forms are available in every counseling room and in the waiting room.

The participants are recruited either during the follow-up consultation of a patient: (1) the geriatrician/neurologist delivers the general information about the protocol and gives a contact form to fill in and drop off at the Memory Center's reception desk, or (2) the CGs fill in the contact form available in the waiting room and drop it off at the Memory Center's reception desk.

One of the two research psychologists previously trained in the protocol contacts the caregiver, checks his/her eligibility criteria and explains the benefits, constraints, and schedule of the protocol. The psychologist gives an information notice to the caregiver and proposes to contact him/her a few days later. If the caregiver agrees with the protocol and meets the criteria for inclusion, the screening session (M0) is scheduled with the caregiver.

## Randomization

A computer-generated randomization list is used to assign the participants in the experimental condition (EC) group or in the control condition (CC) group after assessment with PSS-14 and all the inclusion and noninclusion criteria are checked. Blocking and stratification by gender and relationship (spouses versus nonspouses) were used to generate the randomization list.

## Interventions

### *Experimental Condition*

The Diapason program is an adapted fully automated computerized version of a psychoeducational program (AIDMA) created by the Geriatric Service of Broca Hospital. Usability of Diapason program was evaluated in a previous experimental study (pre/post). The study involved the assessment of 30 volunteer participants 60 years or older, with various levels of expertise in Internet use, during a guided visit. After modifications and adaptation of the website, the performances of beginners and experts were similar [21].

Diapason is a free password-protected website. Figure 1 shows the home page. The program is run in twelve thematic weekly sessions organized in the following order: (1) caregiver stress, (2) understanding the disease, (3) maintaining the loved ones' autonomy, (4) understanding their reactions–how to recognize behavioral and emotional troubles, (5) coping with behavioral and emotional troubles, (6) communicating with loved ones, (7) improving their daily lives, (8) avoiding fall risks, (9) pharmacological and nonpharmacological interventions, (10) social and financial support, (11) about the future, (12) in a nutshell–a summary of Diapason program.

Globally, these twelve sessions cover the following areas: (1) information about AD diagnosis, symptoms, treatment, and progression, (2) how to cope with stressful situations, and (3) information about socioeconomic support and preventive gestures. A new session is available each week, after the validation of the previous session. Furthermore, the website also contains: (1) relaxation guidelines and training videos (based on Schultz's Autogenic Training and Jacobson's method) [22,23], (2) stories based on testimonials of caregivers, used to show critical situations and possible solutions to manage them (eg, apathy of patient, caregivers' isolation), (3) a glossary for the technical words (eg, neuropsychological assessment, aphasia), (4) stimulation guidelines and entertainment activities to do with the patients, and (5) a forum allowing users to establish contact with other caregivers anonymously, express their concerns, discuss solutions to daily problems, and share their feelings and experiences. The participants use nicknames to protect their privacy. A clinical psychologist takes part in discussions if necessary (ie, aggressive or inappropriate comments).

Participants involved in experimental group have to validate one session per week during 12 weeks (about 10 minutes per session), and complete a satisfaction survey corresponding to each session. During the first evaluation (M0) the participant is trained by a psychologist in how to use the website. At the second visit (M3) the participant is requested to provide the satisfaction paper-based survey filled out.



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**Figure 1.** Home page.


### *Control Condition*

Participants randomized in the CC group receive usual care. It consists of a geriatric semiannual follow-up appointment during which the caregiver obtains illness information from the geriatrician. The volunteers receive the access code to the Diapason website at the end of their participation in the research protocol. Every participant of the CC group is advised to look for more specific help (ie, that of a psychologist or a physician) when he/she feels it necessary and then to report it to the main investigator.

## Measures and Procedures

### *Participant Recruitment*

The physicians of the Memory Center have been informed on the study protocol and have received training in inclusion criteria screening. They provide the caregiver with some information about this study at the end of the consultation with the patient. Then the physician gives a contact form to the volunteers interested in participating in the study. The research psychologist contacts the person, presents the protocol study, and provides the caregiver with the information sheet. When the participant delivers a positive answer, the first visit (M0) at the hospital is scheduled together with the psychologist.

### *Assessment Protocol*

The duration of each visit (M0-M3 and M6) is estimated to 90 minutes. The baseline visit is usually conducted as follows:

1. The research psychologist answers the questions on the information notice and the participant signs the informed consent if he/she agrees.
2. Evaluation with PSS-14 (primary outcome).
3. Randomization if PPS-14 total score is 12 or over.
4. Demographical interview and control questions of caregiver and patient's variables.
5. Assessment of secondary variables (researcher-administered, and then self-administered surveys).
6. The participants randomized in the EC receive the material (weekly paper-based survey, a journey book, and a user's manual of the website) and a personal access code to the website. Then, they are trained on how to use the Web-based program.
7. The CC participants are notified that they will receive a website access at the end of their participation to this protocol (6 months after M0).
8. Planning follow-up visits (M3-M6).

For the CC and EC groups, the assessments at M3 and M6 visits are similar, and go as follows: (1) evaluation of caregiver variables (time spent on caregiving, use of respite resources, stressful events, etc) and patient status (hospitalization or other unexpected event occurred in the last three months), (2) measurements with self-administered scales or administered by an interviewer. The measures used in this RCT are summarized in Table 1.



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**Table 1.** Overview of measures in the baseline and follow-up visits.

| Variables (instruments/measures) | | Administration | M0 | M3 | M6 |
|---|---|---|---|---|---|
| **Caregivers' measures** | | | | | |
| | Self-perceived stress (PSS-14) | [a]ABI | x | x | x |
| | Self-efficacy [b](RSCS) | ABI | x | x | x |
| | Caregiver perception of troubles [c](RMBPC) | ABI | x | x | x |
| | Burden [d](ZBI) | [e]SA | x | x | x |
| | Self-reported health [f](NHP) | SA | x | x | x |
| | Depressive symptoms [g](BDI-2) | SA | x | x | x |
| | Knowledge about illness [h](VAS) | SA | x | x | x |
| | The quality of the relationship with the patient (VAS) | SA | x | x | x |
| | Time spent on caregiving [i](RBC) | Interview | x | x | x |
| | Other sources of stress (ie, work, health status, financial status) (RBC) | Interview | x | x | x |
| | Respite or social help (ie, psychotherapy, associations, technical help, etc) (RBC) | Interview | x | x | x |
| | Time and frequency using the program (website statistics) | Website | x | x | x |
| | Satisfaction towards the program content (weekly paper-based survey filled at home) | Weekly survey (M0-M3 for [j]EC) | x | x | x |
| **Patients' measures** | | | | | |
| | Cognitive status [k](MMSE) | Medical data | x | - | - |
| | Degree of dependency [l](IADL-RBC) | Interview | x | - | - |
| | Duration of symptoms (RBC) | Interview | x | - | - |

[a]ABI=Administered by the interviewer,[b]RSCS=Revised Scale for Caregiving Self-Efficacy, [c]RMBPC=Revised Memory and Behavior Problem Checklist, [d]ZBI=Zarit Burden Interview, [e]SA=Self-administered,[f]NHP=Nottingham Health Profile, [g]BDI-2=Beck Depression Inventory-second version, [h]VAS=Visual Analogical Scale, [i]RBC=Reported by caregiver, [j]EC=Experimental condition, [k]MMSE=Mini-Mental State Examination, [l]IADL=Instrumental Activities of Daily Living

### *Primary Outcome Measure: PSS-14*

Stress perceived by the caregiver is measured by the French version of the Perceived Stress Scale, the version of 14 items from Cohen et al [20], translated into French by Bruchon-Schweitzer in 2002 [24]. The PSS-14 is a widely used self-reported scale evaluating the general appraisal of stress in the last month. It consists of 14 items, with scores ranging from 0 (never) to 4 (very often). This scale has demonstrated a high reliability and validity in several studies [25]. The total score range for this scale is 0-56. Due to numerous roles of caregivers (as mentioned above) and in order to target stress specifically related to a caregiving role, we adapted the instruction of the PSS-14 by proceeding with hetero evaluation and adding the following text in bold: "this scale ask[s] you about your feelings and thoughts about your experience with your relative during the last four weeks." The rest of the instruction is similar to that proposed by Cohen in 1983.

### *Secondary Outcomes Measures Administered by an Interviewer*

#### Self-Efficacy

The Revised Scale for Caregiving Self-Efficacy was validated in 2002 by Steffen et al [26] and translated into French by Marziali and Garcia in 2011 [27]. This scale offers a simple and effective way to evaluate caregivers' self-efficacy on: (1) obtaining respite, (2) controlling upsetting thoughts, and (3) responding to disruptive patient behaviors. Each section has five items arranged from easiest to most difficult (based on research results) [26]. For each item the participants choose a score between 0 and 100, based on their degree of confidence for each situation. This scale should be administered by an interviewer [26].

#### Perceived Behavioral and Cognitive Problems

The Revised Memory and Behavior Problem Checklist [28] is a widely used scale that rates the caregiver's perceived frequency of occurrence of behavioral and cognitive problems and the caregiver's perceived distress facing these problems. It explores 24 situations in which the caregiver estimates: (1) the frequency of situations/problems during the last week, and (2)



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the caregiver's response to each situation/problem. Satisfactory internal consistency coefficients of reliability have been reported (for frequency of behaviors .93 and for reaction .90) [29].

### *Secondary Outcomes Measures Self-Administered*

#### Zarit Burden Interview

The Zarit Burden Interview (ZBI) is a subjective measure of burden that includes 22 items exploring the caregiver's perception and feelings about care situations. There are three factors that could explain 56.3% of global score variance: (1) caregiver's social and personal life, (2) psychological burden, and (3) caregiver's guilt [30]. The score range is 0-88, a higher score indicating a higher burden level.

#### Depressive Symptoms

Depressive symptoms will be evaluated with the second version of Beck Depression Inventory [31]. This widely used scale comprises 21 items, and the total score range is 0-63 [32].

#### Self-Perceived Health

Bucquet et al [33] validated the Nottingham Health Profile in France. We use this scale to evaluate the self-reported morbidity of caregivers. There are 38 items that are grouped in 6 dimensions: (1) physical mobility, (2) social isolation, (3) emotional reactions, (4) pain, (5) sleep, and (6) energy. In the French validation study, weights were calculated using Thurstone's Paired Comparisons [33]. The addition of this item totals a hundred per dimension and corresponds to the percentage of the illness impact perceived by each individual.

### *Additional Measures*

#### Caregivers' Measures

The sociodemographic variables and general information on caregiver situation collected are age, sex, educational level, relationship with the patient (spouse versus nonspouse), current psychopharmacological treatment, current psychosocial services and respite care (daycare centers for the patient, in-home care services, etc), time spent per week with the patient, and their "free time". Moreover, the quality of the relationship with the patient, the caregiver's confidence in his/her ability to cope with the consequences of the disease, and the caregiver's level of knowledge about AD are evaluated with the Visual Analogical Scales.

Participants in the EC complete a satisfaction survey each week, after watching the weekly program. Therefore, qualitative information about perceived utility of this program is obtained during the face-to-face interviews in the visits M3 and M6. Moreover, the frequency and duration of the Web-based program use for each participant is stored and anonymously analyzed at the end of the study.

#### Patients' Measures

The global cognitive status of patients is evaluated with the Mini-Mental State Examination (MMSE) [34] and obtained from the patients' medical file, if the patient accepts it (during follow-up at the Memory Center the patients with AD are evaluated with neuropsychological batteries, including the MMSE evaluation). The degree of dependency from the patient is evaluated by the French version of the Instrumental Activities of Daily Living [35] reported by the caregiver at M0, and the duration of symptoms is also based on the caregivers' report.

### *Data Management and Statistical Analysis*

#### Monitoring/Security Issues

Data are collected via an electronic case-report form, then centralized, and stored on a secured server using the "CleanWEB" system [36]. A monitoring of records is planned every two months and done by an external agent to control the respect of protocol and procedures according to Clinical Best Practices guidelines [37].

#### Ethical Proceedings

This study protocol was submitted to the French ethical CPP and received approval on July 2011. Before they enter the study, all participants receive an information sheet and sign a written consent form.

The study provides equal opportunity to access the program. Caregivers who do not meet the inclusion criteria can access the website and program as external participants. Also, every participant is asked to search another form of help (ie, that of a psychologist or a physician) if he/she feels the need to, and to report it to the main investigator.

#### Sample Size

The sample size has been calculated by the Biostatistics and Epidemiology Department of the Hôtel-Dieu Hospital (Paris). Based on the literature [38], a 6-point difference on PSS-14 scale is expected between EC and CC at the posttest evaluation (M3). With an assumed standard deviation of 9, 40 participants per group should be included to be able to detect such a difference with an 80.0% power (Cronbach alpha=.05; two-tailed).

#### Data Analysis

The Biostatistics and Epidemiology Department of the Hôtel-Dieu Hospital will perform statistical analysis. All the analyses will be conducted according to the intention to treat principle and to handle with missing data; multiple imputations will be used if the missing at random or missing completely at random hypothesis holds. Otherwise sensitivity analysis will be done. No interim analysis will be performed.

A description of the characteristics of the two groups will be performed using percentages for categorical variables and means with standard deviation for quantitative variables. For primary and secondary outcomes, student *t* tests or a Wilcoxon test if required, as well as covariance analysis to take the regression to the mean into account, will be used to compare means between experimental and control groups. Percentages will be compared using chi-square test or Fisher's exact test if required. Calculations will be performed using SAS software.

Qualitative data obtained during visits M3 and M6 from EG participants' perception on the program's utility and satisfaction will be analyzed by Broca's research team, using thematic analysis [39].

Statistical analysis will exclude data from: (1) caregivers performing less than two thirds of the online program



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(participant validates fewer than 8 out of 12 sessions), (2) dropouts due to mental or physical state of the caregiver becoming incompatible with this research protocol.

## Discussion

### Distinctive Features

This study protocol is quite innovative. To our knowledge, it is the first French Web-based program evaluated with a randomized clinical trial. The Diapason program has been conceived to offer a primary access to basic information about the illness progression and practical advice to reduce stress and manage the daily life for Alzheimer's CGs. In coherence with other studies, we are convinced that the Internet for health is an interesting tool to inform and support the isolated CGs [40], at a reduced cost, but with increasing convenience for users [41].

We are interested in evaluating the program effectiveness on self-perceived stress. Although the ZBI is often used to measure the CG stress in the context of dementia [42], the burden construct is relatively complex and not specific enough. In fact, two factor analyses of the ZBI identified three dimensions: (1) personal strain, (2) role strain, and (3) guilt [43], or (1) social impact, (2) psychological burden, and (3) guilt [30]. Based on these results we decided to use a PSS 14-item version and to adapt the main instruction of PSS to caregivers' strain. However, in this protocol we use the ZBI as a secondary outcome, and it would be interesting to compare the results obtained with each of these measurement instruments.

### Strengths of the Study

In our opinion, four main strengths are identifiable in this protocol.

First, since most elderly caregivers (spouses) do not have sufficient experience with the Internet, 30 elderly volunteers participated in the usability tests, which allowed us to modify and adapt the website prior to the present study. The usability tests increase the likelihood of inexperienced Internet users to use Web-based programs and offers access to a widespread population who has never navigated on the Internet because it was considered as too complex or difficult to use.

Second, our Web-based program (Diapason) keeps a structure that is similar to an on-site psychoeducational program, such that it proposes a thematic session weekly. In this way, we control the information viewed by the caregiver according to a specific schedule. In fact, the EC is not completely controlled if the access to the information is determined by the choice of the patient. In our opinion, controlling the order and access to main thematic areas should improve the reliability of results because all the participants receive the same information.

Third, we are aware of the positive impact of social networking and communication between peers for CGs. We did not have enough human resources to offer a virtual presence or face-to-face participation, nevertheless we integrated a forum in the website which enables the CGs to ask and share experiences, feelings, and advice with their peers, with the participation of a psychologist as moderator This initiative represents a first step towards more comprehensive and interactive Web-based initiatives that our team has scheduled to build, optimizing social networking perspectives, as advised by recent works [44,45].

Fourth, we will analyze the data of Web server utilization from each user and compare it with their satisfaction and appraisal of the effectiveness of the program. This objective information will help us to know the system use, and its acceptability. Our purpose with these results is also to identify the "user profiles" with a highest adherence to or benefit from the program. For instance, do spouses or nonspouses benefit more from the program? Is the time spent on the program website associated with the level of stress after the 12 sessions? Or is there minimum time duration of navigation to observe some benefit from the program?

### Conclusions

In conclusion, the results of this study will allow a better targeting of beneficiaries, for whom the intervention will be more efficient. The results will provide strong support to influence health care policies and facilitate the financial support of these initiatives.

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### Authors' Contributions

VCL is the trial manager of the study, contributed to the study design, conception, and preparation of the manuscript. HK contributed to the study design and edited the paper. JDR provided methodological advice, oversaw the adaptation of psychoeducational program, and contributed in the edition of the paper. AR provided statistical and methodological advice, undertook the randomization process, and revised the paper. GL participated in the project group. ASR is the main investigator, contributed to the study concept, to the supervision of the study, oversaw the implementation of the project, and revised the paper. All authors read and approved the final manuscript.



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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [46].

[PDF File (Adobe PDF File), 996KB - resprot_v2i2e55_app1.pdf ]

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## Abbreviations

**AD:** Alzheimer's disease
**AIDMA:** Aide dans la Maladie d'Alzheimer program
**CC:** control condition
**CGs:** Informal caregivers
**CPP:** Centre de Protection de Personnes
**EC:** experimental condition
**ICT:** information and communications technology
**MO:** month 0
**M3:** month 3
**M6:** month 6
**MMSE:** Mini-Mental State Examination
**PSS-14:** Perceived Stress Scale of 14 items
**ZBI:** Zarit Burden Interview

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Original Paper

# Initial Impact of Tailored Web-Based Messages About Cigarette Smoke and Breast Cancer Risk on Boys' and Girls' Risk Perceptions and Information Seeking: Randomized Controlled Trial

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## Abstract

**Background:** Recent evidence indicates a causal link between both active smoking and secondhand smoke (SHS) exposure and breast cancer (BC).

**Objective:** The objective of the present study was to evaluate the initial reactions of girls and boys to tailored Web-based messages that describe the relationship between SHS and BC, using a parallel, single-blinded cluster randomized controlled trial.

**Methods:** This trial was nested within a cycle of an ongoing longitudinal study of 1498 students from 74 secondary schools. Self-reported assessments were used to evaluate the impact of study messages on participants' risk perception and interest in obtaining additional information after participants were randomized by schools to control or intervention groups. The intervention group received a tailored visual message (based on gender and Aboriginal status) about BC and tobacco smoke. The control group received a standard visual message about smoking and cancer.

**Results:** SHS exposure was identified as a BC risk factor by 380/1488 (25.54%) participants, during the preintervention analysis. Compared to the female participants in the control group (491/839, 58.5%), girls who received the intervention (339/649, 52.2%) were 14% more likely to agree that exposure to SHS increased their BC risk (relative risk [RR] 1.14, 95% CI 1.07-1.21). Nonsmoking girls who received the intervention were 14% more likely to agree that starting smoking would increase their BC risk (RR 1.14, 95% CI 1.07-1.21). Compared to the male participants in control group (348/839, 41.5%), boys who received the intervention (310/649, 47.8%) were 10% more likely to agree that girls' exposure to SHS increased their BC risk (RR 1.10, 95% CI 1.02-1.18). Compared to controls, girls who received the intervention were 52% more likely to request additional information about SHS and BC (RR 1.52, 95% CI 1.12-2.06).

**Conclusions:** Brief gender-sensitive messages delivered via the Internet have the potential to increase awareness and to stimulate information seeking about the risk for BC associated with SHS.

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**KEYWORDS**

breast cancer; secondhand smoke; cancer prevention; youth; gender

## Introduction

### Overview

Recently published evidence indicates that there is a causal link between both active smoking and secondhand smoke (SHS) exposure and breast cancer (BC) [1]. In 2009, based on the weight of evidence from a comprehensive review of more than 100 epidemiological studies, as well as toxicology studies and an understanding of biological mechanisms, the Canadian Expert Panel on Tobacco Smoke and Breast Cancer concluded that there was a relationship consistent with causality between active smoking and BC, and between long-term regular exposure to SHS and premenopausal BC [2]. Key support for the increased premenopausal BC risk associated with SHS exposure came from a report on the health effects of environmental tobacco smoke issued by the California Environmental Protection Agency [3]. Based on a meta-analysis of 19 studies, researchers reported a relative risk (RR) of 1.25 (95% CI 1.08-1.44) for BC among all women with regular exposure to SHS [3]. This risk increased to 1.91 (95% CI 1.53-2.39) when the analysis was restricted to studies with more comprehensive SHS exposure assessment [3]. When the meta-analysis was restricted to younger, primarily premenopausal women at diagnosis, they reported RR of 1.68 (95% CI 1.31-2.15) that increased to 2.20 (95% CI 1.69-2.87) when the analysis was restricted to studies with more comprehensive SHS exposure assessment [3].

In addition to reviewing the evidence pertaining to the relationship between regular exposure to SHS and premenopausal BC, the Canadian Expert Panel on Tobacco Smoke and BC also examined findings on the relationship between active smoking and risk of BC. Key epidemiological evidence for the active smoking risk came from 8 large, high-quality cohorts studies with detailed smoking exposure measures, which indicated that early age at smoking commencement, longer duration of smoking before first birth, longer total duration, and greater number of pack-years of smoking were each associated with increased BC risk [2]. In 2011, results from the Harvard Nurses' Health Study cohort were published based on 8772 BC cases, providing the largest and most precise analysis to date [4]. The researchers reported clear, consistent, dose-response evidence that the critical active smoking exposure period was from menarche to first full-term pregnancy, and that BC risk was limited for smoking after the first birth [4]. They also reported increasing risk-factor adjusted RRs, each statistically significant, of 11%, 19%, 21%, and 25% for 1-5, 6-10, 11-15, and ≥16 pack-years of smoking before first birth, respectively [4]. Researchers have also demonstrated that breast tissue in its growth stage, during puberty and first pregnancy, is particularly sensitive to exposure to the carcinogens found in tobacco smoke [5-7]. These findings are especially concerning given current trends in smoking initiation; the average age of smoking a whole cigarette for the first time among Canadian students in grades 6-12 is 13.4 years [8]. Moreover, given that 13% of Canadian boys between the ages of 15 and 19 years smoke, girls are at risk for SHS exposure from their male counterparts [9]. Furthermore, high rates of SHS exposure in Aboriginal communities pose particular challenges for Aboriginal girls, where Aboriginal youths' SHS exposure is twice that of non-Aboriginal youths (27% vs 15%) [10]. To date, however, there have been few efforts to raise awareness of active smoking and SHS as risk factors for BC [11].

Research reveals that there are potential benefits in using youth-friendly approaches to deliver health information and intervention programs that are designed to change youths' smoking behavior [12-15]. One way of addressing these preferences is by developing youth-oriented cancer control initiatives that can be delivered with interactive, socially oriented Web technologies [16-18]. Emerging evidence also indicates that tailoring tobacco control interventions toward adolescents, whereby communications are created based on adolescents' individual characteristics, positively influences their tobacco use behavior [19]. Moreover, research has shown that developing tailored approaches for Aboriginal youth, in particular, is also beneficial [13]. For example, researchers have found that including cultural symbols (eg, feathers) in health promotion messages have been shown to signal the relevance of the health information to Aboriginal people [20].

The use of computer-based systems that facilitate the delivery of tailored interventions has been found to be an effective strategy in prompting changes in smoking behavior [21-24]. By utilizing the interactive capacity of the Internet, computer-based systems have been used by researchers to deliver tailored smoking cessation interventions according to the particular characteristics (eg, gender, cognitive variables, and intention to quit smoking) of each individual [25]. The development of tailored interventions that can be integrated into Web-based delivery systems appears to represent a potentially efficacious means of reducing adolescents' exposure to SHS.

### Conceptual Framework

The teachable moment heuristic proposed by McBride et al [26] is conceptualized as a process of "sensemaking" of naturally occurring transitions or life events (eg, breast development in puberty) that influence people's subjective responses to information (eg, information outlining the increased BC risk associated with SHS exposure) associated with key aspects of these transitions. These responses appear to have the potential to enhance interest in relevant information, as well as motivation to change, acquisition of skills, and self-efficacy, which in turn increase the likelihood of behavior change (eg, reductions in SHS exposure and tobacco use). Within this paradigm, perceptions of one's personal risk play a major role in determining whether the event is significant enough to be a teachable moment that prompts the adoption of preventive health behavior [26]. Because smoking experimentation and uptake typically begin during adolescence, this early stage in boys' and girls' "tobacco careers" may represent a relatively malleable time to alter their tobacco use and exposure behavior. Moreover, puberty is marked with pronounced awareness of physical



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changes, marking girls' transformation into womanhood [27]. These periods of heightened attentiveness to salient health transitions may enhance the cognitive availability of risk perceptions and have been identified as teachable moments for cancer prevention initiatives [26].

The delivery of messages describing the link between tobacco exposure and an increased risk of BC appears to represent an opportunity to take advantage of a naturally occurring teachable moment to promote reductions in tobacco exposure among adolescents. Within the context of cancer prevention, gender has been found to influence responses to teachable moments [28], and there is a growing body of research describing the profound influence of gender on health behavior [29]. Although gender-related factors influencing smoking initiation and patterns of exposure to tobacco have begun to be described, few attempts to develop gender-sensitive tobacco reduction interventions have been made [30].

### Primary and Secondary Hypotheses Being Tested

This study was an application of the teachable moment heuristic. The primary aim of this study was to examine youths' responses to Web-based, gender- and Aboriginal-tailored messages regarding the link between tobacco exposure and risk of BC. We hypothesized that exposure to the tailored messages compared with a general message describing the carcinogenic aspects of tobacco smoke would result in: (1) an increased probability of indicating that tobacco exposure is associated with an increased risk of BC, and (2) an increased probability of opting to receive more information about tobacco exposure and BC. In addition to the aforementioned primary hypotheses, a secondary hypothesis that exposure to the tailored messages would be associated with more time spent viewing the messages was also tested. Each of the hypotheses was adapted to groups defined by their gender (girls and boys) and smoking status (smokers and nonsmokers).

## Methods

### Trial Design

The Supporting Tailored Approaches to Reducing Tobacco (START) study was nested within the longitudinal British Columbia Adolescent Substance Use Survey (BASUS) and is a parallel, single-blinded cluster randomized controlled trial (RCT). Randomization was conducted at the school level prior to enrolment. Students were initially recruited into the BASUS study from 48 participating public secondary schools in British Columbia, Canada. All BASUS participants were 13 years of age or older, able to read and complete a Web-based survey in English, and provided informed consent, as well as written parental consent in schools requiring participants to provide parental consent. In order to prevent the enrolment of ineligible participants (eg, nonstudents), participants were recruited in person in a school environment. After viewing a brief presentation during home room class, eligible students were given an information package that contained a unique login code to set up an account on the survey website. Students completed the Web-based survey during their own time or in some cases in school computer labs during scheduled class time. Each participant received a $25 honorarium in the form of a gift card (mailed to their home address) for participating in each wave of the BASUS survey. School-specific response rates varied from 2% to 100%, with an average of 20%. For the purposes of the START study, schools (n=74) were stratified by the total number of enrolled students and number of self-identified Aboriginal students at each school (based on data from previous waves of the survey). Randomization was based on a random-number generator in MS Excel; the research manager kept the master allocation list in a password-protected computer. From April to June 2011, a subsample of 1498/1593 (94.03%) Wave 4 participants were randomized to either the intervention or the control arm, after meeting general BASUS eligibility criteria, declaring their school, and identifying their gender and Aboriginal status (Figure 1). Although researchers were not blinded to the allocation, the participants were. This study and the longitudinal BASUS study received ethics approval from the University of British Columbia Behavioral Research Ethics Board. The START study was not registered because the research team was unaware of the requirement by medical journals to register all RCTs, including those evaluating nonclinical behavioral responses to brief Web-based messages.

### Harms or Unintended Effects

There are no known harms or unintended effects to receiving either the intervention or control tailored messages.



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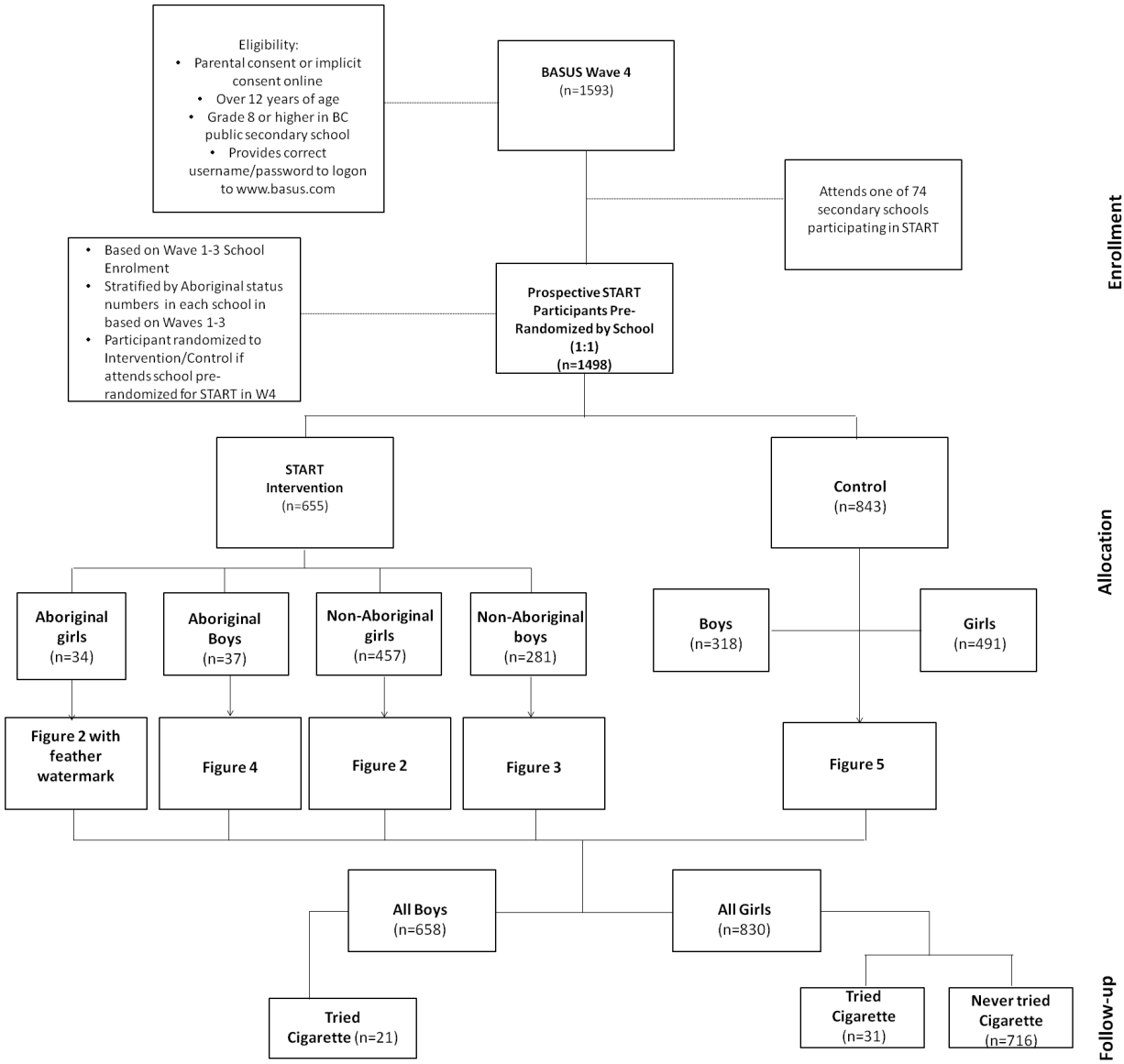
**Figure 1.** Flow diagram for START trial.




## Data Collection

Data collection for this study occurred during Wave 4 of the BASUS survey (April to June, 2011). To reduce contamination through contact with youth in the other experimental conditions, 74 secondary schools, rather than individual participants, were randomized to receive either the control or intervention message. The participants were required to authenticate (log in) using a username and password provided by the research team. Based on their gender and ethnicity, the youth in the intervention group received a tailored message regarding BC and tobacco exposure. The control group received a standard message describing the carcinogenic aspects of tobacco smoke. Immediately after receiving the intervention or control message, participants were given follow-up questions about perceived risk and information seeking.

## Intervention

The Web-based survey was programmed (ie, with the use of skip logic) so that the students in the intervention arm for each target group were presented a group-specific tailored message regarding tobacco exposure as a risk factor for BC and advice on how to minimize this risk. The development of the intervention messages was based on findings from gender- and Aboriginal-specific focus groups held with youth. We shared information about the risk of tobacco exposure and BC with the focus groups, and sought advice about the best way to communicate relevant messages to their respective target groups. Based on the focus group discussions, four messages were developed. The message for girls included images of 4 different girls playfully holding bras, with a printed message stating, “Smoking affects more than your lungs,” followed by, “Cigarette



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smoke, even second hand smoke, puts girls at risk for breast cancer at an early age." The message also included a suggestion for action below the image: "Avoid places where you and your friends are exposed to second hand smoke." The message for boys included an image of 2 boys and 1 girl standing close together in a skateboard park, with a caption stating, "Hey guys, show you care! Respect the girls around you by not exposing them to second hand smoke." The message also included the following information: "Smoking affects more than girls' lungs. Second hand smoke increases their risk of breast cancer at an early age." Both the boys' and girls' messages included a recommendation for smokers: "If you smoke, think about quitting. Do it for yourself and for the girls you know." Examples of the intervention messages are displayed in Figure 2 (girls' intervention message) and Figure 3 (boys' intervention message). The messages for the Aboriginal girls and boys were the same as the non-Aboriginal gender-sensitive messages, except for the addition of a feather motif (eg, see Figure 4). Feathers for Aboriginal people, especially eagle feathers, are ceremonial objects, used as tools for healing, and are treated with great respect [20].

### Control

Students in the control arm in each target group were presented with a generic gender neutral message that cigarette smoke contains carcinogenic agents. This message included an image of a burning cigarette standing alone against a black background, with the message: "Warning, you're not the only one smoking this cigarette. The smoke from a cigarette is not just inhaled by the smoker. It becomes second hand smoke, which contains more than 50 cancer-causing agents." This message content was sourced from Health Canada (Figure 5) [31].

**Figure 2.** Girls' intervention message.




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**Figure 3.** Boys' intervention message.


**Figure 4.** Aboriginal boys' intervention message (the difference compared to Figure 3 is the feather in the background).




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**Figure 5.** Control message.


## Measures

Baseline survey questions were developed to assess the participants' sociodemographic characteristics (eg, age and ethnicity). Question topics also included smoking status, SHS exposure, and knowledge of the link between BC and tobacco. Following the presentation of the tailored intervention messages and the control messages in the survey, the youth were asked questions, tailored to their smoking status, about their perceived risk concerning tobacco exposure as a risk factor for BC. All of the girls were asked about the extent to which they agreed with the following statements: (1) "Being exposed to second hand cigarette smoke increases my risk of getting breast cancer," and (2) "Being exposed to second hand cigarette smoke increases girls' risk of getting breast cancer." The girls who had already tried smoking were also asked about the extent to which they agreed with the statement: "My cigarette smoking increases my risk of getting breast cancer." The girls who had not tried smoking were also asked about the extent to which they agreed with the statement: "If I start smoking it will increase my risk of getting breast cancer." All of the boys were asked about the extent to which they agreed with the statement: "Being exposed to second hand cigarette smoke increases girls' risk of breast cancer." The boys who had tried smoking were asked about the extent to which they agreed with the statement: "Being exposed to my second hand cigarette smoke increases the breast cancer risk of the girls I spend time with."

After the presentation of the messages and the knowledge and risk perception questions, all of the participants were asked, "Would you like to read some more information on the relationship between breast cancer and smoking?" If the participants "clicked" the answer "Yes," they were given further information. The additional information provided to the girls included information about their risk for BC, how smoking and BC are linked, as well as strategies for reducing their risk for BC in relation to tobacco exposure. The information provided to the boys included how SHS puts girls at risk for BC, how smoking and BC are linked, as well as strategies that they could employ to protect girls from SHS exposure.

## Power Analysis

An a priori power analysis was conducted for the START study. This power analysis was based on 4 primary hypotheses for the overall START study being tested using 4 separate two-proportion z-tests to compare the knowledge of the link between cigarette smoke exposure and BC, perceptions of BC risk associated with cigarette smoke exposure, smoking behavior, and stage of change related to avoidance of SHS exposure 6 months after message delivery. Assuming a difference in proportions of 10% and a Bonferroni corrected alpha of .0125 per test (ie, alpha of .05 divided by 4), we estimated that we would need approximately 600 individuals in each group in order to have a 7 power of 0.82. It is important to note that the results presented in this paper are the initial reactions to the messages collected at baseline and not the results for the 6-month follow-up assessment for which the a priori power calculations were developed.

## Statistical Analysis

To check the potential failures in randomization, potential confounders were identified via univariate tests, and any variables found to differ significantly between the treatment and control groups were included as covariates in the subsequent multivariate models. Bivariate analyses of the categorical data were conducted using Fisher's exact test ($P<.05$). A generalized estimating equation was used for all regression models to adjust the standard errors of the parameter estimates for the correlated responses of students within the same school [32]. Adjusted RRs were estimated using a modified Poisson regression, with robust error variance [33], originally proposed by Lee and Chia [34] for binary outcomes [35]. The robust error variance estimator was used because Poisson regression of binary outcomes tends to overestimate the standard errors [33,36]. Analyses were "intention to treat." The statistical analysis was completed with IBM PASW Statistics 19.



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## Results

### Baseline Characteristics

Of the 1593 eligible participants at baseline, 1498 (94.03%) students in 74 schools, aged 13 to 15 years (median of 14 years) participated in the current study. During the course of the study, 10 students had changed to nonstudy schools and were randomized to intervention or control groups on an individual basis. A total of 655/1498 (43.72%) students received the tailored intervention and 843/1498 (56.27%) students received the control message. Table 1 describes the participants' baseline characteristics, patterns of tobacco exposure, and knowledge of the link between SHS and BC. The distributions of gender, age at baseline, family history of BC, intention to try smoking in the future, daily exposure to SHS in the home, as well as parents' and peers' smoking status were found to be significantly different between the treatment and control groups.

### Message Viewing Times in Intervention and Control Groups

The time of the initial display of the message was recorded by the survey system followed by the time of the response to the question immediately following the display of the message. The difference between these two times was treated as the message viewing time. This time includes reading and answering a single demographic question that followed the presentation of the message (ie, "How would you describe your household's financial situation?"). Overall, the mean viewing time was 31 seconds (SD 47) for the boys and 31 seconds (SD 34) for the girls, with median viewing times of 24 seconds for the boys and 25 seconds for the girls. Both the girls and the boys in the intervention group spent significantly more time viewing the messages compared with the viewing time of the control group (girls: mean 36, SD 33 vs mean 28, SD 34, $P<.01$; boys: mean 38, SD 64 vs mean 26, SD 23, $P<.01$).

### Postintervention Perceived Risk of Tobacco Exposure

The girls that received the intervention message were 14% more likely to agree with the statement that being exposed to SHS increased their risk of BC (RR 1.14, 95% CI 1.08-1.20), and the boys were 10% more likely to agree that SHS increased the risk of BC in girls (RR 1.10, 95% CI 1.02-1.18) (see Table 2). The girls who were identified as having never tried tobacco were 14% more likely to agree with the statement that starting smoking would increase their risk of BC (RR 1.14, 95% CI 1.08-1.20). The interaction between intervention group and Aboriginal status was not significant for either boys or girls. Among the boys and girls who smoked, no significant effects were noted.

### Postintervention Information-Seeking Behavior

The girls in the intervention group were 52% more likely to seek more information, after adjusting for covariates (RR 1.52, 95% CI 1.12-2.06), compared with the control group. However, the boys in the intervention group were less likely to seek more information about the link between SHS and BC risk (RR 0.63, 95% CI 0.40-1.0); an adjusted risk ratio could not be obtained for boys likely because few had said they wanted more information (n=69).



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**Table 1.** Participants' sociodemographics and patterns of tobacco exposure.

| General characteristics | | Intervention (n=655)[d] n (%) | Control (n=843)[d] n (%) | Total (N=1498)[d] n (%) |
|---|---|---|---|---|
| **Demographics** | | | | |
| **Gender** [a] | | | | |
| | Male | 310 (47.80) | 348 (41.48) | 658 (44.22) |
| | Female | 339 (52.23) | 491 (58.52) | 830 (55.78) |
| **Age in years** [c] | | | | |
| | 13 | 92 (14.18) | 172 (20.50) | 264 (17.74) |
| | 14 | 351 (54.08) | 480 (57.21) | 831 (55.85) |
| | 15 | 206 (31.74) | 187 (22.29) | 393 (26.41) |
| **Ethnicity** | | | | |
| | Aboriginal | 71 (11.34) | 96 (11.81) | 167 (11.61) |
| | Non-Aboriginal | 555 (88.66) | 717 (88.19) | 1272 (88.39) |
| **Family income (self-reported)** | | | | |
| | Below average | 26 (4.24) | 39 (5.01) | 65 (4.67) |
| | Average | 458 (74.71) | 602 (77.38) | 1060 (76.20) |
| | Above average | 129 (21.04) | 137 (17.61) | 266 (19.12) |
| Family history of breast cancer[a] | Yes | 153 (24.60) | 154 (19.59) | 307 (21.80) |
| **Tobacco smoke exposure** | | | | |
| Has tried smoking tobacco | Yes | 60 (9.20) | 104 (12.40) | 164 (11.00) |
| **Amount smoked in lifetime (of those who tried smoking tobacco), cigarettes** | | | | |
| | Had one or a few puffs | 22 (38.60) | 36 (35.29) | 58 (36.48) |
| | 1-5 | 14 (24.56) | 22 (21.57) | 36 (22.64) |
| | 6-15 | 8 (14.04) | 8 (7.84) | 16 (10.06) |
| | 16-25 | 1 (1.75) | 8 (7.84) | 9 (5.66) |
| | 26-99 | 4 (7.02) | 12 (11.76) | 16 (10.06) |
| | >100 | 8 (14.04) | 16 (15.69) | 24 (15.09) |
| **Age of initiation of tobacco use** | | | | |
| | ≤10 years old | 10 (18.18) | 8 (7.92) | 18 (11.54) |
| | 11 years old | 5 (9.09) | 10 (9.90) | 15 (9.62) |
| | 12 years old | 11 (20.00) | 22 (21.78) | 33 (21.15) |
| | 13 years old | 13 (23.64) | 40 (39.60) | 53 (33.97) |
| | >14 years old | 16 (29.09) | 21 (20.79) | 37 (23.72) |
| **Intention to try smoking in future** [a] **(of those who had not tried smoking tobacco)** | | | | |
| | Definitely yes | 2 (0.35) | 0 (0.00) | 2 (0.17) |
| | Probably yes | 12 (2.11) | 30 (4.26) | 42 (3.30) |
| | Probably not | 122 (21.40) | 157 (22.30) | 279 (21.90) |
| | Definitely not | 434 (76.14) | 517 (73.44) | 951 (74.65) |
| **Secondhand smoke exposure** | | | | |
| Parent(s) smoke[b] | Yes | 146 (25.39) | 239 (32.61) | 385 (29.41) |
| Friends smoke[a] | Yes | 83 (17.29) | 144 (23.00) | 227 (20.51) |



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| General characteristics | | Intervention (n=655)[d] n (%) | Control (n=843)[d] n (%) | Total (N=1498)[d] n (%) |
|---|---|---|---|---|
| Someone smokes in home almost every day[a] | Yes | 60 (9.40) | 107 (13.19) | 167 (11.50) |
| **Past month's exposure to SHS** | | | | |
| | Every day | 20 (3.15) | 35 (4.29) | 55 (3.79) |
| | Almost every day | 70 (11.04) | 79 (9.68) | 149 (10.28) |
| | At least once a week | 153 (24.13) | 236 (28.92) | 389 (26.83) |
| | At least once in the past month | 281 (44.32) | 347 (42.50) | 628 (43.31) |
| | Never | 110 (17.35) | 119 (14.58) | 229 (15.79) |
| Tobacco knowledge: Tobacco identified as a risk factor for breast cancer | Yes | 172 (26.50) | 208 (24.79) | 380 (25.54) |

[a]*P*<.05 (Fisher's exact tests).

[b]*P*<.01 (Fisher's exact tests).

[c]*P*<.001 (Fisher's exact tests).

[d]Total number of responses varies slightly for each variable.



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**Table 2.** Postintervention assessment of perceived risk and information seeking.

| Postintervention assessments | Response[e] | Intervention, n (%) | Control, n (%) | Unadjusted RR (95% CI) | Unadjusted risk difference, % | Adjusted RR[a-d] (95% CI) |
|---|---|---|---|---|---|---|
| **Increase in perceived risk of SHS** | | | | | | |
| My cigarette smoking increases my risk of getting BC (smoking girls) (n=32) | Agree (n=24) | 8 (66.7) | 16 (80.0) | 0.84 (0.56-1.26) | −13.3 | N/A |
| If I start smoking it will increase my risk of getting BC (nonsmoking girls) (n=716) | Agree (n=659) | 306 (98.4) | 353 (87.2) | 1.13[h] (1.08-1.17) | 11.2 | 1.14[h] (1.08-1.20) |
| Being exposed to secondhand cigarette smoke increases my risk of getting BC (all girls) (n=724) | Agree (n=646) | 301 (95.6) | 345 (84.4) | 1.13[h] (1.07-1.19) | 11.2 | 1.14[h] (1.07-1.21) |
| Being exposed to my secondhand cigarette smoke increases the BC risk of the girls I spend time with (smoking girls) (n=31) | Agree (n=22) | 9 (75.0) | 13 (68.4) | 1.13 (0.73-1.77) | 6.6 | N/A |
| **Being exposed to SHS increases girls' risk of getting BC** | | | | | | |
| All girls (n=720) | Agree (n=647) | 303 (95.9) | 344 (85.1) | 1.13[h] (1.07-1.19) | 10.8 | 1.14[h] (1.07-1.21) |
| All boys (n=560) | Agree (n=504) | 261 (93.9) | 243 (87.4) | 1.08[f] (1.02-1.14) | 6.5 | 1.10[g] (1.02-1.18) |
| Being exposed to my SHS increases the BC risk of the girls I spend time with (smoking boys) (n=21) | Agree (n=15) | 7 (77.8) | 8 (66.7) | 1.10 (0.66-1.84) | 11.1 | N/A |
| **Interest in receiving more information** | | | | | | |
| All girls (n=830) | Agree (n=158) | 77 (22.7) | 81 (16.5) | 1.37[f] (1.04-1.82) | 6.2 | 1.52[f] (1.12-2.06) |
| All boys (n=658) | Yes (n=69) | 25 (8.1) | 44 (12.6) | 0.63[f] (0.401-0.997) | −4.5 | N/A |

[a]Relative risk was obtained using a modified Poisson regression (with a robust covariance estimator).

[b]All models included potential confounders (age, family history of BC, intention to smoke in the future, and smoking status of parents and peers).

[c]Ethnicity (Aboriginal status) was initially included to test for an interaction with intervention group and then removed because all interactions were not significant.

[d]The model had problems with convergence due to low cell counts.

[e]*Strongly agree* and *Agree* were collapsed as "agree" and *Strongly disagree* and *Disagree* were collapsed as "disagree," with disagree as the referent response for the calculation of RR.

[f]$P<.05$.

[g]$P<.01$.

[h]$P<.001$.

# Discussion

## Principal Findings

This is one of the first studies to evaluate the delivery of Web-based messages aimed to raise awareness about SHS exposure and BC among youth. The findings of this study indicate that the youth-informed, gender-sensitive messaging approach had positive effects on the awareness of SHS exposure as a risk factor for BC as well as on the information-seeking behavior of girls. Compared with the standard message control group, the girls who received the tailored intervention were 14% more likely to agree that being exposed to SHS increased their risk of BC. The girls who were identified as nonsmokers and received the intervention were also 14% more likely to agree that starting smoking would increase their risk of BC. Finally, compared with the girls in the control group, the girls who received the intervention were 52% more likely to request additional information about the relationship between SHS exposure and BC.

## Limitations

The findings of this study are limited in terms of their generalizability to other types of interventions, other age groups, and other ethnic groups. It is also important to note that due to sample size considerations, we elected to use a single control group that received a standard message. Larger effects would likely have been observed had we had included a third group that served as a no-information control group. Additionally, the relatively small number of Aboriginal participants and adolescents who had tried smoking at the time of the survey may have reduced the statistical power and generalizability of



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the results to these particular groups. The additional number of words in the tailored messages may have contributed to the finding that youth spent significantly more time viewing the tailored messages compared to the standard information control message. Despite these limitations, the results of the present study indicate that brief gender-sensitive messages delivered via the Internet have the potential to enhance awareness of the increased risk for BC associated with SHS exposure, and stimulate additional information seeking about the relationship between smoking and BC, particularly by girls. Although our messages were found to influence youths' risk perceptions and requests for additional information, longitudinal evaluation of the intervention's impact on health behavior (eg, reduced uptake of smoking, reduced exposure to SHS) is needed.

## Conclusions

The use of a positively framed message that promoted the benefits of being smoke free as a way to reduce the risk of BC for oneself, as well as for one's peers, appears to be a promising approach for reaching girls. As previously suggested by Bottorff et al. [27], the juxtaposition of BC with smoking may have been particularly meaningful to girls with a growing interest in women's health issues prompted by physical and social changes marking their transition into womanhood. This period of transition also appears to represent a teachable moment [26] that can be utilized for cancer prevention. Furthermore, the findings support the use of prevention initiatives that normalize smoke-free behavior by linking youths' social aspirations (ie, being a good friend) with smoke-free behavior [37]. By encouraging girls to safeguard their own health, as well as the health of significant others, the tailored messages represent a promising approach to reinforcing nonsmoking girls' smoke-free behavior.

Compared with the standard message control group, the boys who received the intervention were 10% more likely to agree that SHS exposure in girls increased their risk of BC. In addition, exposure to the tailored messages did not elicit further information seeking by the boys. The results align with literature indicating that messaging boys about a young women's health issue is challenging because women (and girls) are traditionally expected to, and often do, look after their own health as well as the health of men rather than vice versa [38]. However, while marginal, the results indicate that a gender-sensitive approach is a promising first step toward successfully raising boys' awareness about girls' increased risk for BC when exposed to cigarette smoke. Awareness of the risk of SHS exposure is important for boys who smoke and may serve to motivate changes in their smoking behavior to protect girls' health.

Adolescents frequently use the Internet to access health-related information; indeed, more than 90% of adolescents have access to the Internet at home and in school [39]. Furthermore, one-quarter of 497 adolescents recently surveyed by Ettel et al. [39] reported modifying their behavior subsequent to accessing health information on the Internet. Web-based health promotion interventions can be tailored and widely delivered to adolescents in a relatively inexpensive and effective manner. Tailoring Web-based messages according to gender, age, and ethnicity has been shown to be effective in several RCTs [40]. For example, in an RCT conducted by Mermelstein [41], adolescents who received 10 group therapy sessions with a Web-based adjunct and proactive phone calls were more likely to report smoking cessation at the 3-month follow-up compared with a control group of adolescents who received only 10 group therapy sessions. A recent meta-analysis found that compared with waitlist controls, online interventions targeting voluntary behavior change demonstrated moderate efficacy, and compared with print materials, they were equally effective but with lower costs and broader reach [42]. The findings from this study add to this body of literature in that they indicate that brief, tailored messages delivered over the Internet can be used to effectively raise awareness among youth about the risks of BC from active smoking and SHS. More generally, our application of the concept of a "teachable moment" to support the timing of this health information further supports the findings of a recent review of Web-based health promotion interventions that emphasized the importance of basing interventions on health behavior theory, including specific behavior change techniques [43].

## Acknowledgments

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [44].

[PDF File (Adobe PDF File), 994KB - resprot_v2i2e53_app1.pdf ]

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## Abbreviations

**BASUS:** British Columbia Adolescent Substance Use Survey
**BC:** breast cancer
**RCT:** randomized controlled trial
**RR:** relative risk
**SHS:** secondhand smoke



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Protocol

# Transplantation and Surgical Strategies in Patients With Neuroendocrine Liver Metastases: Protocol of Four Systematic Reviews

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## Abstract

**Background:** Hepatic metastases of neuroendocrine tumors (NETs) are considered a major prognostic factor associated with significantly reduced survival compared to patients without liver metastases. Several surgical and nonsurgical strategies are present to treat resectable and nonresectable liver metastases, some of which have the potential to cure liver mestatases.

**Objective:** The aims of the four systematic reviews presented in the paper are to determine the effectiveness of liver resection versus nonsurgical treatment of patients with NET liver metastases, to investigate the impact of neoadjuvant and adjuvant treatment options on the tumor-free survival, to assess the role of liver transplantation in patients presenting with unresectable bilateral hepatic metastases, and to evaluate the role of primary tumor resection in presence of unresectable liver metastases.

**Methods:** Literature search was performed on Medical Literature Analysis and Retrieval System Online, Excerpta Medica Database, and the Cochrane Library (Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and Cochrane Central Register of Controlled Trials). No language restrictions were applied. Randomized controlled trials, prospective and retrospective comparative cohort studies, and case-control studies will be used for the qualitative and quantitative synthesis of the systematic reviews. Case series will be only included in a separate database for descriptive purposes.

**Results:** This study is ongoing and presents a protocol system of four systematic reviews that will assist in determining the effectiveness of liver resection versus nonsurgical treatment of patients with NET liver metastases. This study is also assumed to investigate the impact of neoadjuvant and adjuvant treatment options on the tumor-free survival, the role of liver transplantation, and the relevance of primary tumor resection in presence of unresectable liver metastasis.

**Conclusions:** The systematic reviews will show the current evidence based on the effectiveness of surgical strategies in patients with NET liver metastases and serve as basis for clinical practice guidelines.

**Trial Registration:** The systematic reviews have been prospectively registered with the International Prospective Register of Systematic Reviews: liver resection (CRD42012002652); http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42012002652 (Archived by WebCite at http://www.webcitation.org/6LQUqMnqL,). neoadjuvant and adjuvant treatment strategies (CRD42012002656); http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42012002656 (Archived by WebCite at http://www.webcitation.org/6LQVvEHuf). liver transplantation (CRD42012002655); http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42012002655 (Archived by WebCite at



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http://www.webcitation.org/6LQW7WFo3,). resection of the locoregional primary NET (CRD42012002654); http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42012002654 (Archived by WebCite at http://www.webcitation.org/6LQWEIuGe).

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**KEYWORDS**

neuroendocrine tumors; NET; liver resection; adjuvant neoadjuvant; liver transplantation; primary NET; systematic review

# Introduction

## Background

### *Neuroendocrine Tumors*

Neuroendocrine tumors (NETs) developing from neuroendocrine cells can originate almost everywhere in the body [1]. Primary NETs are mainly located in the bronchopulmonary (>25%) and the gastroenteropancreatic system (60%) [2,3]. With an annual age-adjusted incidence of 5.25 cases per 100,000 people, NETs are considered to be rare tumors. Most NETs occur sporadically, whereas a minority of cases may develop due to genetic syndromes such as multiple endocrine neoplasia type 1 [4].

According to their functional behavior, NETs can be subdivided into two categories: functioning NETs and nonfunctioning NETs [5]. Functioning NETs secrete specific products such as biogenic amines and polypeptide hormones and can cause endocrine syndromes such as the carcinoid syndrome. Endocrine syndromes in tumors with portal venous drainage often begin in the presence of liver metastases. Metastases drain active hormones directly into the systemic circulation while the liver metabolizes hormones derived from primary tumors [6,7]. Therefore, functioning tumors are usually detected earlier than nonfunctioning tumors and patients seem to have a better overall survival (OS) [8]. The nonfunctioning NETs may cause local tumor mass-related symptoms or are found incidentally [7,9].

### *Liver Metastases of NETs*

Despite the slow growing nature of NETs, Pape et al reported liver metastases of gastroenteropancreatic NETs in 84.7% of cases at the initial diagnosis [10]. Due to the favorable environment, metastases of NETs are confined to the liver for a prolonged period of time [11]. Hepatic metastases are considered to be a major prognostic factor, associated with a significantly reduced survival compared to patients without liver metastases [12,13]. Furthermore, the metastatic pattern within the liver also has prognostic and therapeutic impact. Frilling et al suggested three different patterns of liver metastases: single metastasis of any size (type 1); isolated metastatic bulk accompanied by smaller deposits, with both liver lobes always involved (type 2); and disseminated metastatic spread, with both liver lobes always involved, single lesion of varying size and virtually no normal liver parenchyma (type 3). This classification is believed to represent differences in biologic characteristics of the tumors, which require different treatment strategies [14].

### *Liver Resection*

A wide array of options is available to treat liver metastases from NETs, which improves the 5-year OS in 60-80% patients who have undergone curative surgery compared to less than 40% untreated patients [15-17]. Surgical interventions contain potentially curative resection of the metastases (R0/R1). If R0/R1 resection is not feasible, a palliative resection is performed in patients suffering from tumor bulk or hormonal symptoms, especially in patients with functioning NETs and who are unresponsive to treatment. However, guidelines suggest that palliative surgery should only be performed if at least 90% of the metastatic bulk can be safely removed [18]. Curative resection can only be achieved in patients with a metastatic pattern type 1, while patients with type 2 or 3 need to be evaluated for other treatment options [14]. Therefore, curative resection is only feasible in less than 20% of patients due to the high rate of diffuse and bilobar spreading of metastases [19]. For patients with a metastatic pattern type 2 or 3, there are several locoregional techniques such as radiofrequency ablation, transcatheter arterial chemoembolization (TACE), and systemically applied therapies (eg, chemotherapy or peptide receptor radionuclide therapy [PRRT]) [17]. The first systematic review intends to compare curative and palliative liver resection versus or in combination with nonsurgical treatment options.

### *Neoadjuvant and Adjuvant Treatment Options*

Disease recurrence after surgical treatment of liver metastases is often observed, even when resection is performed with curative intent [20]. To increase the resectability and to reduce the high rate of metastatic relapse, neoadjuvant and adjuvant treatment options need to be evaluated. According to their treatment modality, neoadjuvant and adjuvant treatment options can be divided into systemic (chemotherapy, biotherapy, and PRRT) and liver-directed therapies (selective internal radiation therapy [SIRT], transcatheter arterial embolization [TAE], and TACE). For the chemotherapeutical strategy, several substances have been used to treat NETs, either as a monotherapy or combined in different regimens [21-23]. Biotherapy for NETs essentially includes treatment with somatostatin analogues, such as octreotide and lanreotide, in order to control hormone-related symptoms [24]. PRRT consists of systemically applied radiolabeled somatostatin derivates that bind specifically to the somatostatin receptor, which is overexpressed in certain NETs and thereby damage the tumor cell [25]. Liver-directed techniques, such as SIRT, TAE, and TACE, make use of the biologic feature that hepatic neoplasms are preferentially supplied via the hepatic artery, whereas normal liver parenchyma is mainly supplied by the portal vein [26,27].

For liver metastases arising from a non-NET primary tumor, the benefit of neoadjuvant and adjuvant strategies combined with liver resection has already been investigated in more detail [28,29]. Nordlinger et al reported that the risk of recurrent disease in patients with liver metastases of colorectal carcinomas



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could be reduced compared to surgical resections alone [29]. Adopting these strategies to the treatment of NET liver metastasis could be a promising option. The second systematic review intends to evaluate whether neoadjuvant and/or adjuvant treatment strategies together with surgical resection are superior to liver resection alone.

### *Liver Transplantation*

Controversy concerning liver metastases from NETs as an indication for liver transplantation arises inter alia from the relatively low number of such patients being transplanted. Moreover, heterogeneous 5-year OS data have been published with ranges between 33% and 96% [16,30]. Therefore, our third systematic review aims to evaluate the possible benefit of liver transplantation as a treatment option for unresectable hepatic metastases of NETs and to define selection criteria to choose patients with the best possible prognosis.

### *Resection of the Primary NET*

Another important question is whether the primary tumor should be removed in presence of nonresectable liver metastases as the answer may improve the outcome. Potential benefits of resection are seen in providing relief from hormonal and local tumor mass-related symptoms [31]. Since evidence is missing, the fourth systematic review aims to answer this question.

### Objective

The purpose of these four systematic reviews is to assess the role of surgical strategies in the management of liver metastases of nets, to evaluate the use of adjuvant and neoadjuvant therapies, to define selection criteria for patients who benefit the most from liver transplantation, and to study the influence of resection of the primary tumor.

## Methods

### Overview

These four systematic reviews dealing with surgical treatment options for NET liver metastases attempt to answer the questions with regard to liver resection in patients with hepatic metastases (see Textbox 1), neoadjuvant and adjuvant treatment strategies (see Textbox 2), liver transplantation in patients with unresectable hepatic metastases (see Textbox 3), and resection of the locoregional primary neuroendocrine tumor (see Textbox 4).

We will report our review findings in accordance with the standards of the Preferred Reporting Items for Systematic reviews and Meta-Analyses [32]. Our reviews were prospectively registered with the International Prospective Register of Systematic Reviews: liver resection (CRD42012002652) [33], neoadjuvant and adjuvant treatment strategies (CRD42012002656) [34], liver transplantation (CRD42012002655) [35], and resection of the locoregional primary NET (CRD42012002654) [36].

The systematic review inclusion and exclusion criteria are listed in Tables 1-4. No language or publication date restrictions were imposed on the literature search. All accessible publications were included. The following study designs will be included for the qualitative synthesis of the systematic review: randomized controlled trials (RCTs), prospective and retrospective comparative cohort studies, and case-control studies. Case series will only be included in a separate database for descriptive purposes. The number of excluded studies and reasons for exclusion will be reported in a flow diagram, according to the PRISMA Statement 2009 (Figure 1) [32].

**Textbox 1.** Questions with regard to liver resection in patients with hepatic metastases from neuroendocrine tumors.

In patients with resectable NET liver metastases, does liver resection with a curative intent (R0/R1) improve outcome (tumor-free survival, overall survival, quality of life) when compared to non-surgical treatment (locally ablative techniques, percutaneous liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, biotherapy)?

In patients with NET liver metastases, does R2 liver resection (debulking) improve outcome (progression-free survival, overall survival, quality of life) when compared to non-surgical treatment (locally ablative techniques, percutaneous liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, biotherapy)?

In patients with NET liver metastases, do locally ablative techniques as an adjunct to R2 liver resection improve outcome (progression-free survival, overall survival, quality of life)?

**Textbox 2.** Questions with regard to neoadjuvant and adjuvant treatment strategies be used together with liver resection for neuroendocrine liver metastases.

In patients with NET liver metastases, does neoadjuvant treatment improve outcome (increase in R0/R1 resectability, tumor-free survival, overall survival, quality of life) after liver resection compared to no neoadjuvant treatment?

In patients with NET liver metastases, does adjuvant treatment improve the outcome (tumor-free survival, overall survival, quality of life) of liver resection as opposed to no adjuvant treatment?

In patients with NET liver metastases, do both neoadjuvant and adjuvant treatment strategies improve the outcome (tumor-free survival, overall survival, quality of life) of liver resection compared to no neoadjuvant and adjuvant treatment?



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**Textbox 3.** Questions with regard to liver transplantation in patients with unresectable hepatic metastases from neuroendocrine tumors.

In patients with non-resectable NET liver metastases, does liver transplantation improve outcome (disease-free / progression-free survival, overall survival, quality of life) as opposed to R2 liver resection (debulking) or non-surgical treatment (locally ablative techniques, percutaneous liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, biotherapy)?

In patients with NET liver metastases, which selection criteria should be used for liver transplantation in order to improve outcome (disease-free survival, overall survival, quality of life)?

In patients with NET liver metastases and consideration for liver transplantation, does a delay (≥6 months) to assess tumor progression before transplanting improve the selection of patients (disease-free survival, overall survival, quality of life) as opposed to early transplantation (<6 months)?

In patients with NET liver metastases listed for liver transplantation, does downstaging (locally ablative techniques, percutaneous liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, biotherapy) improve outcome (tumor-free survival, overall survival, quality of life)?

In patients with non-resectable NET liver metastases, does living donor liver transplantation improve outcome (disease-free survival, overall survival, quality of life) as opposed to deceased-donor transplantation or non-surgical treatment (locally ablative techniques, percutaneous liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, biotherapy)?

Does the outcome of the recipient justify the risk of the donor in the setting of liver transplantation for NET liver metastases?

**Textbox 4.** Questions with regard to resection of the locoregional primary neuroendocrine tumor in the presence of nonresectable liver metastases.

In patients with a pancreatic primary NET and non-resectable liver metastases, does resecting the primary tumor improve outcome (progression-free survival, overall survival, quality of life) when compared to non-surgical treatment (peptide receptor radionuclide treatment, chemotherapy, biotherapy)?

In patients with an intestinal primary NET and non-resectable liver metastases, does resecting the loco-regional primary tumor improve outcome (progression-free survival, overall survival, quality of life) when compared to non-surgical treatment (peptide receptor radionuclide treatment, chemotherapy, biotherapy)?

In patients with a lung primary NET and non-resectable liver metastases, does resecting the primary tumor improve outcome (progression-free survival, overall survival, quality of life) when compared to non-surgical treatment (peptide receptor radionuclide treatment, chemotherapy, biotherapy)?

**Table 1.** Eligibility criteria for review on liver resection [33].

| Study characteristics | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Patient population | Patients with neuroendocrine tumor (NET) liver metastases | Children or adolescents (under the age of 18 years) |
| | Patients who underwent liver resection or nonsurgical treatment (peptide receptor radionuclide treatment (PRRT), chemotherapy, biotherapy) | |
| Intervention: treatment | Liver resection | |
| | Nonsurgical treatment (chemotherapy, biotherapy, locally ablative techniques, radionuclide therapy) | |
| Intervention: comparison | Liver resection vs nonsurgical treatment (chemotherapy, biotherapy, locally ablative techniques, radionuclide therapy) | |
| Outcomes | Primary outcome: overall survival (OS) | Studies that do not report the OS |
| | Secondary outcomes: progression-free survival, quality of life | |
| Study design | Randomized controlled trials | Case reports |
| | Prospective and retrospective comparative cohort studies | |
| | Case-control studies | |
| | Case series | |



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**Table 2.** Eligibility criteria for review on neoadjuvant and adjuvant treatments [34].

| Study characteristics | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Patient population | Patients with neuroendocrine tumor (NET) liver metastases who underwent liver resection with or without neoadjuvant or adjuvant treatment | Children or adolescents (under the age of 18 years) |
| Intervention: treatment | Liver resection | |
| | Adjuvant and neoadjuvant treatment (including radio- and/or chemotherapy) | |
| Comparators: control | Liver resection with neoadjuvant treatment vs liver resection alone | |
| | Liver resection with adjuvant treatment vs liver resection alone | |
| | Liver resection with neoadjuvant and adjuvant treatment vs liver resection alone | |
| Outcomes | Primary outcome: OS | Studies not reporting the OS |
| | Secondary outcomes: tumor-free survival, quality of life, increase in R0/R1 resectability | |
| Study design | Randomized controlled trials | Case reports |
| | Prospective and retrospective comparative cohort studies | |
| | Case-control studies | |
| | Case series | |



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**Table 3.** Eligibility criteria for review on liver transplantation [35].

| Study characteristics | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Patient population | Patients with nonresectable neuroendocrine tumor (NET) liver metastases | Children or adolescents (under the age of 18 years) |
| | Patients who underwent liver transplantation or palliative liver resection or nonsurgical treatment (PRRT, chemotherapy, biotherapy) | |
| Intervention: treatment | Liver transplantation (orthotopic, deceased donor liver transplantation, multivisceral transplantation, living-donor liver transplantation) | |
| | Palliative liver resection | |
| | Nonsurgical treatment (chemotherapy, biotherapy, locally ablative techniques, radionuclide therapy) | |
| | Delay of liver transplantation | |
| | Living-donor liver donation | |
| | Deceased donor liver donation | |
| Intervention: comparison | Liver transplantation vs palliative liver resection vs nonsurgical treatment (chemotherapy, biotherapy, locally ablative techniques, radionuclide therapy) | |
| | Early vs late transplantation | |
| Outcomes | Primary outcome: OS | Studies that do not report the OS |
| | Secondary outcomes: progression free survival, quality of life | |
| Study design | Randomized controlled trials | Case reports |
| | Prospective and retrospective comparative cohort studies | |
| | Case-control studies | |
| | Case series | |



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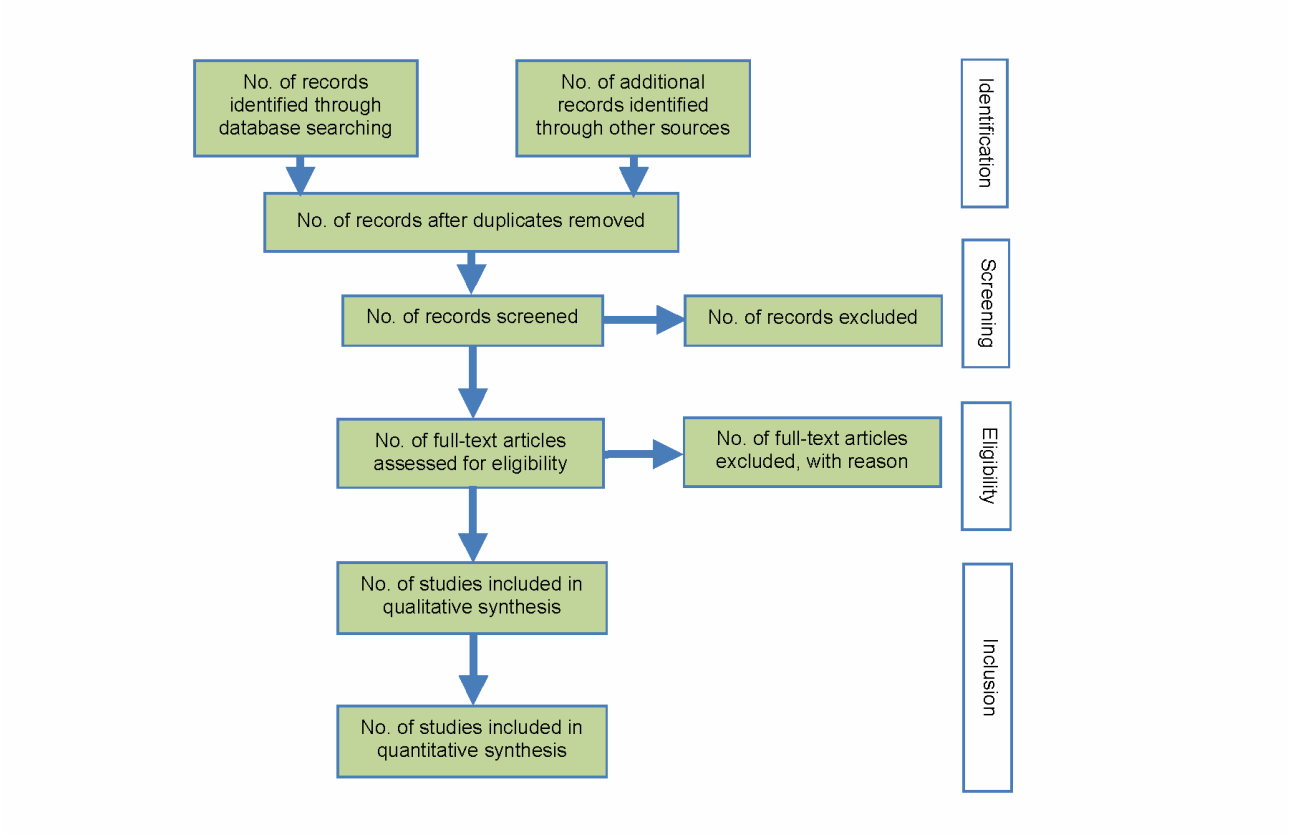
**Table 4.** Eligibility criteria for review on resection of the primary tumor [36].

| Study characteristics | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Patient population | Patients with neuroendocrine tumors and nonresectable liver metastases | Children or adolescents (under the age of 18 years) |
| | Primary tumor located in pancreas, intestine, or lung | |
| | Patients with neuroendocrine tumors and nonresectable liver metastases who underwent resection or nonsurgical treatment of the primary | |
| Intervention: treatment | Resection of the primary tumor | |
| | PRRT | |
| | Chemotherapy | |
| | Biotherapy | |
| Comparators: control | Patients with neuroendocrine tumors and nonresectable liver metastases who received resection of the primary vs nonsurgical treatment of the primary tumor | |
| Outcomes | Primary outcome: OS | Studies that do not report the OS |
| | Secondary outcome: progression-free survival, quality of life | |
| Study design | Randomized controlled trials | Case reports |
| | Prospective and retrospective comparative cohort studies | |
| | Case-control studies | |
| | Case series | |

**Figure 1.** Flow diagram representing the number of excluded studies and reasons for exclusion.



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### Search

Librarians of the Medical Library Careum, University of Zurich, Switzerland, developed the electronic search strategy to query databases and to identify all potentially relevant articles (see Multimedia Appendix 1). The following databases were searched: Medical Literature Analysis and Retrieval System Online, Excerpta Medica Database, and the Cochrane Library (Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and Cochrane Central Register of Controlled Trials). The investigators were provided with an endnote file containing all identified titles and, if available, the corresponding abstracts. Additional articles were retrieved through manual search or scanning of reference lists. Titles and/or abstracts of all identified records were independently screened by 2 members of the review team to ascertain their relevance and to identify studies that potentially meet the inclusion criteria as outlined in Tables 1-4. The full text of each of these potentially relevant studies was then assessed for eligibility. Any disagreement was resolved through discussion with a third review team member. A predefined protocol was used to extract data from the included studies for the assessment of study quality and evidence synthesis.

### Data Extraction

The following parameters will be chosen for data extraction: first author's name, publication year, answering scientific questions, study design, total number of patients, number of patients in the study group, number of patients in the comparison group, type of nonsurgical treatment, age (mean, SD, median), male-to-female ratio, progression-free survival, OS, quality of life (tools), and hazard risk ratio. The Grading of Recommendations Assessment, Development, and Evaluation will be used to grade the quality (level) of evidence and the strength of recommendations [37].

A narrative synthesis of the findings from the included studies will be provided. A quantitative synthesis will be used for studies that are sufficiently homogenous from a clinical (population comparability, interventions, and outcomes) and from a statistical perspective (heterogeneity, eg, $I^2$<50%). It is anticipated that there will be a limited scope for meta-analysis despite a relatively large number of studies due to different outcome measurements of the existing trials as such tumors are rare. However, results from studies using the same type of intervention and comparator with the same outcome measurements will be pooled using a random-effects meta-analysis. In addition, risk ratios for binary outcomes, 95% CI, and two-sided *P* values will be calculated for each outcome.

## Results

This study is ongoing and presents a protocol system of four systematic reviews that will assist in determining the effectiveness of liver resection versus nonsurgical treatment of patients with NET liver metastases. This study is also assumed to investigate the impact of neoadjuvant and adjuvant treatment options on the tumor-free survival, the role of liver transplantation, and the relevance of primary tumor resection in presence of unresectable liver metastasis.

## Discussion

The use of surgical strategies for the treatment of patients with liver metastases from NET is still controversial. An important step toward developing a consensus is to summarize the existing scientific literature.

Regarding liver resection in patients with liver metastases from NETs, Gurusamy et al presented 2 Cochrane Collaboration systematic reviews on liver resection and cytoreductive surgery versus nonsurgical treatments in patients with resectable and nonresectable liver metastases. Publications until July 2008 were included in their reviews. Based on nonrandomized studies, they came to the conclusion that liver resection "appears to be the main stay curative treatment for neuroendocrine liver metastases" [38,39]. Our systematic review will consider data published until 2012.

Regarding neoadjuvant therapies, PRRT seems to be a possible neoadjuvant option in initially unresectable primary NETs, while its benefit in the treatment of NET liver metastases needs to be elucidated [40]. Apart from PRRT, chemotherapy and biologic therapies (eg, octreotide) also need to be evaluated in the neoadjuvant and adjuvant settings.

Liver transplantation is a controversially discussed treatment option in patients with liver metastases from NETs, because it is not clear which patients benefit most from this therapeutic strategy. Máthé et al performed a systematic review to investigate the benefit of liver transplantation for hepatic metastases of pancreatic NETs and grouped patients according to their age (less than 55 years or 55 years or older) and surgical procedure they underwent (pancreatic resection prior to liver transplantation or simultaneous resection). The 5-year OS was found to be significantly different between patients who were less than 55 years of age and had pancreatic resection prior to transplantation compared to patients who were 55 years of age or older and underwent simultaneous resection (5-year OS 61% vs 0%) [41]. Reaching an overall 5-year survival of incredibly 96%, the Milan criteria seem to provide a good foundation for further improvement of the selection criteria [16]. Therefore, and in combination with the scarcity of donor organs, it is crucial to evaluate and define accurate selection criteria for potential transplant recipients to offer these patients the most promising and evidence-based treatment.

Surgical resection of NETs is the treatment strategy whenever a curative intent is anticipated. However, it is not clear whether resection of the primary NET is still beneficial in advanced disease stage presenting with unresectable liver metastases. Bettini et al investigated the role of primary tumor resection in nonfunctioning pancreatic NETs with unresectable liver metastases [42]. OS did not differ significantly, although survival was longer in patients with resected primary tumor. A significant difference in improvement of symptoms in favor of primary resection was observed, although quality of life was not assessed objectively. Therefore, resection was considered as palliative therapy in order to relief symptoms related to primary tumor mass and prevent obstructive complications such as bleeding, acute pancreatitis, or jaundice.



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The four systematic reviews described in this protocol will help to elucidate the role of surgical strategies and serve as a basis for developing clinical practice guidelines.

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## Authors' Contributions

All authors were involved in editing the manuscript and approved the final text of the manuscript.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Results of literature search from Medical Literature Analysis and Retrieval System Online, Excerpta Medica Database, and the Cochrane Library.

[PDF File (Adobe PDF File), 2MB - resprot_v2i2e58_app1.pdf ]

## Multimedia Appendix 2

CONSORT-EHEALTH-checklist V1.6.2 [43].

[PDF File (Adobe PDF File), 986KB - resprot_v2i2e58_app2.pdf ]

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## Abbreviations

**NET:** neuroendocrine tumor
**OS:** overall survival
**PRRT:** peptide radio receptor therapy
**RCT:** randomized controlled trial
**SIRT:** selective internal radiation therapy
**TACE:** transcatheter arterial chemoembolization
**TAE:** transcatheter arterial embolization


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Protocol

# Diagnosis and Prediction of Neuroendocrine Liver Metastases: A Protocol of Six Systematic Reviews

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## Abstract

**Background:** Patients with hepatic metastases from neuroendocrine tumors (NETs) benefit from an early diagnosis, which is crucial for the optimal therapy and management. Diagnostic procedures include morphological and functional imaging, identification of biomarkers, and biopsy.

**Objective:** The aim of six systematic reviews discussed in this study is to assess the predictive value of Ki67 index and other biomarkers, to compare the diagnostic accuracy of morphological and functional imaging, and to define the role of biopsy in the diagnosis and prediction of neuroendocrine tumor liver metastases.

**Methods:** An objective group of librarians will provide an electronic search strategy to examine the following databases: MEDLINE, EMBASE and The Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects). There will be no restriction concerning language and publication date. The qualitative and quantitative synthesis of the systematic review will be conducted with randomized controlled trials (RCT), prospective and retrospective comparative cohort studies, and case-control studies. Case series will be collected in a separate database and only used for descriptive purposes.

**Results:** This study is ongoing and presents a protocol of six systematic reviews to elucidate the role of histopathological and biochemical markers, biopsies of the primary tumor and the metastases as well as morphological and functional imaging modalities for the diagnosis and prediction of neuroendocrine liver metastases.

**Conclusions:** These systematic reviews will assess the value and accuracy of several diagnostic modalities in patients with NET liver metastases, and will provide a basis for the development of clinical practice guidelines.

**Trial Registration:** The systematic reviews have been prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO): CRD42012002644; http://www.metaxis.com/prospero/full_doc.asp?RecordID=2644 (Archived by WebCite at http://www.webcitation.org/6LzCLd5sF), CRD42012002647; http://www.metaxis.com/prospero/full_doc.asp?RecordID=2647 (Archived by WebCite at http://www.webcitation.org/6LzCRnZnO),



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**KEYWORDS**

neuroendocrine tumors (NET); liver metastases; Ki67; mitotic count; genetic signatures; tumor cells; biochemical markers; morphological imaging; functional imaging; systematic review

# Introduction

## Background

### *Neuroendocrine Tumors*

Neuroendocrine tumors (NETs) arise from the diffuse neuroendocrine system and therefore appear widespread over the whole body, especially in the gastrointestinal tract and the bronchopulmonary system [1,2]. NETs secreting hormones lead to a symptomatic disease. Nonsecreting NETs may occur initially asymptomatic or with delayed symptoms due to progressive increase in tumor mass [3,4]. Therefore, differences in functional behavior are the basis of a classification system categorizing functioning and nonfunctioning NETs [4]. Other reported classification systems are based on embryological origin or histopathological findings. In 2010, The World Health Organization (WHO) presented a new classification on the basis of tumor grading using histopathological criteria such as Ki67 index, mitotic count, and presence or absence of necrosis [5].

NETs is a relatively rare disease with an incidence of 1-3 per 100,000 [6,7]. The large range of reported incidence might be due to the fact that NETs often present initially asymptomatic and are often found accidentally or in autopsies [4]. Predominantly, NETs emerge sporadically (>90%) and are traditionally assigned to multiple endocrine neoplasia type 1 (MEN1), neurofibromatosis-type 1 (NF1), and Von-Hippel-Lindau syndrome [1,4]. The clinical picture of NETs spans over different effects of excessive hormone secretion such as hypergastrinemia in Zollinger-Ellison Syndrome (ZES) with hyperchlorhydria, hyperinsulinemia in insulinoma, flushing and diarrhoea in the serotoninergic carcinoid syndrome. In the case of nonsecreting NETs, symptoms present due to the adverse effects of the growing primary tumor or metastases [8].

### *Biochemical Markers*

Hormones secreted from NETs can be used as specific markers for NETs. Moreover, NETs express, store, and secrete characteristic neuronal proteins such as acid glycoprotein chromogranin A (a component of the membrane neurosecretory granula), neuron-specific-enolase (NSE), and synaptophysin [3,9]. These proteins derived from neuronal structures could serve as markers and are even positive in nonfunctioning NETs [1,3]. Since more than one half of NETs are nonsecreting, these proteins play a crucial role [4]. Assessment of different biochemical markers depends on various parameters, such as threshold cut-off level, detecting method of urine, serum or plasma as well as location of the primary tumor or metastases and extension of the disease. Due to the large variety and number of evaluation parameters, it is difficult to compare the studies [10,11].

### *Histopathological Prognostic Markers*

Ki67 is a monoclonal antibody, which was introduced in 1984 by Gerdes et al [11]. It detects a growth rate depending on the nuclear antigen Ki67 which is only expressed during active cell cycle phases (S, G2, and M-phase). Ki67 is completely absent during the resting phase G0. Therefore, cell proliferation is assessed by the immunohistologic presence of Ki67 positive cells per area in stained tissue blocks [11].

For various human neoplasms such as breast, lung, and solid cancers, Ki67 proliferation index has been successfully established as a predictive marker [12,13]. The higher the cell proliferation, the greater is the probability for metastases resulting in decreased patient survival. The primary location of NETs metastases is the liver [14-17]. The occurrence of hepatic metastases is a prognostic factor which strongly influences the survival of patients suffering from NET [18-20].

### *Genetic Signatures and the Presence of Circulating Tumor Cells*

To stratify outcomes in patients undergoing resection of primary NET, a simple scoring system using tumor size, histological grade, nodal metastases, and resection margin status has been introduced [21]. Nevertheless, current classification systems for NETs other than positron emission tomography (PET) fail to predict the clinical course and the response to treatment [22]. The discrepancy might be explained either by an insufficient accuracy of these classification systems or an adaptive NET behavior [23]. These limitations of the pathologic classifications have led to the investigation of other predictive parameters based on genetic signatures as well as the presence of circulating tumor cells [24,25]. These novel predictive parameters have to be included in the classification systems in order to account for the biological behavior, the likelihood for developing metastases as well as the choice of treatment [25].

### *Imaging Methods*

Imaging methods are used to diagnose neuroendocrine tumors (NETs) and their metastases [26]. Beside conventional morphologic imaging methods, functional imaging modalities have been introduced in order to improve accuracy in detecting



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NETs and liver metastases [27]. Functional imaging methods have their limitations with a great impact on a possible therapeutic strategy, where differentiation between pancreatic foci and neighbouring lymph nodes as well as exact demarcation of a suspicious focus to a liver segment is crucial [28]. Advanced techniques such as contrast-enhanced ultrasound may assist in earlier detection of hepatic metastases, and could therefore offer a wider therapeutic range either surgically, with radiofrequency thermal ablation, or with systemic chemotherapy [29].

### *Liver Biopsy*

The most common site of neuroendocrine tumor (NET) metastases is the liver [30]. The presence of hepatic metastases is a strong prognostic factor for the survival of patients with NETs, regardless of the primary tumor site [31]. Histologic examination is the most sensitive diagnostic method and forms the basis for treatment decisions [32]. However, the value of the biopsy for treatment decision making involving primary NETs and their liver metastases is not well defined [33,34].

### Objective

The aim of these six systematic reviews is to assess the predictive value of Ki67 index and other biomarkers, to compare the diagnostic accuracy of morphological and functional imaging, and to define the role of biopsy in the diagnosis and prediction of neuroendocrine tumor liver metastases.

## Methods

### Systematic Reviews

Our reviews were prospectively registered at the International Prospective Register of Systematic Reviews (PROSPERO) with the following IDs: CRD42012002644, CRD42012002647, CRD42012002648, CRD42012002649, CRD42012002650, CRD42012002651.

The above six systematic reviews dealing with the diagnosis and prediction of neuroendocrine liver metastases attempt to address the following questions in Table 1.



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**Table 1.** Scientific questions on diagnosis and prediction of neuroendocrine liver metastases.

| Questions | Sub-questions |
|---|---|
| **Should patients with low Ki67 index be followed up for the detection of liver metastases?** | |
| | In patients with a primary NET, what is the predictive value of Ki67 index, mitotic count, or tumor grading, obtained from the primary tumor, in predicting the development of liver metastases? |
| **Should genetic signatures and the presence of circulating tumor cells be used in the prediction of liver metastases and to inform treatment decisions?** | |
| | In patients with a primary NET, what is the predictive value of genetic signatures obtained from the primary tumor, in predicting the development of liver metastases? |
| | In patients with a primary NET, what is the predictive value of circulating tumor cells obtained from the primary tumor, in predicting the development of liver metastases? |
| | In patients with a primary NET, should genetic signatures be used in the treatment decision (surgery, locally ablative techniques, liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, and biotherapy)? |
| | In patients with a primary NET, should the presence of circulating tumor cells be used in the treatment decision (surgery, locally ablative techniques, liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, and biotherapy)? |
| **Which biochemical markers should be used for detection and post treatment follow-up of liver metastases?** | |
| | In patients with a primary NET, what is the diagnostic accuracy of the available biochemical markers (eg, chromogranin A and B, Serotonin, neuron-specific-enolase (NSE), tumor specific hormones) in detecting liver metastases? |
| | In patients receiving a liver resection, what is the diagnostic accuracy of the available biochemical markers (eg, chromogranin A and B, serotonin, NSE, tumor specific hormones) obtained during follow-up, in detecting recurrent disease or disease progression? |
| **Which morphological imaging modality should be used to assess resectability of liver metastases with a curative intent?** | |
| | In patients with NET liver metastases, what is the diagnostic accuracy of different morphological imaging modalities (US, CT, MRI) in identifying liver lesions and extrahepatic disease? |
| | In patients with NET liver metastases, what is the diagnostic accuracy of different morphological imaging modalities (US, CT, 3D-CT, MRI) in detecting vascular and biliary invasion, in order to assess resectability (R0/R1)? |
| **Which functional imaging modality should be used to assess resectability of liver metastases with a curative intent?** | |
| | In patients with NET liver metastases, what is the diagnostic accuracy of different functional imaging modalities (octreoscan, DOTA-SSTR-PET/CT, F-18 FDG-PET/CT, DOPA PET, etc) in identifying liver lesions? |
| | In patients with NET liver metastases, what is the diagnostic accuracy of different functional imaging modalities (octreoscan, DOTA-SSTR-PET/CT, F-18 FDG-PET/CT, DOPA PET, other) in detecting extra-hepatic disease? |
| **Do we need a biopsy of both the primary and liver metastases for the treatment decision of liver metastases?** | |
| | In patients with a primary NET and synchronous liver metastases, what is the agreement between the biopsy of the primary and the liver metastases with regards to tumor grading? |
| | In patients with metachronous liver metastases, what is the agreement between the biopsy of the primary and the liver metastases with regards to tumor grading? |
| | In patients with liver metastases, what is the agreement between single vs multiple liver biopsies with regards to tumor grading? |
| | In patients with NET liver metastases, do we need additional biopsies from normal parenchyma to detect micrometastases? |

The systematic review inclusion and exclusion criteria are listed in Tables 2-7. There were no restrictions in the literature search regarding the publication language or by publication date. The following study types were included: randomized controlled trials (RCTs), prospective and retrospective comparative cohort and case-control studies and case series (Figure 1).



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**Figure 1.** Prisma 2009 Flow Diagram.

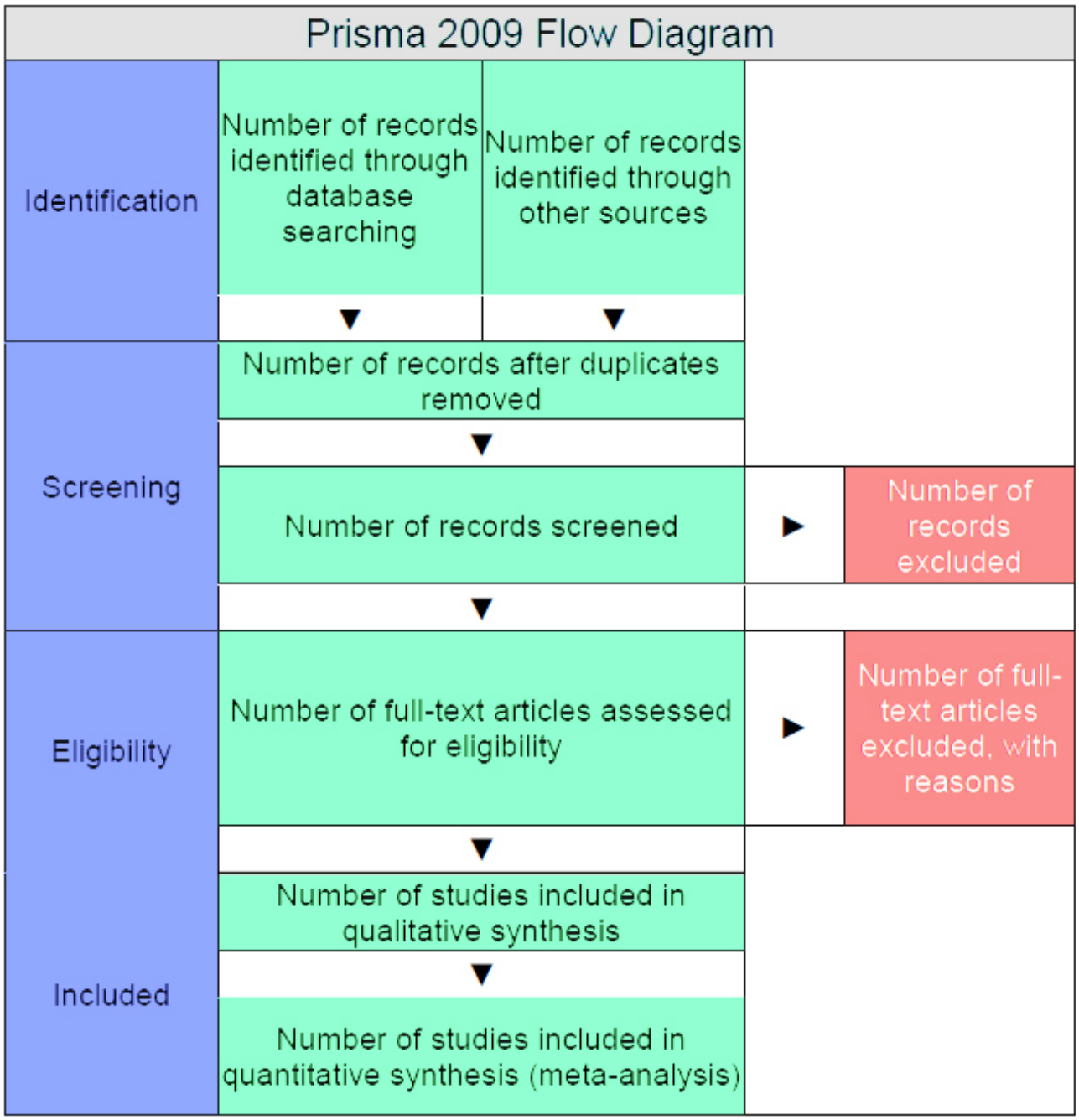




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**Table 2.** Eligibility criteria for review on Ki67 index.

| Study characteristics | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Participants/population | Patients with primary neuroendocrine tumors who were assessed with Ki67 index, mitotic count or tumor grading | Patients over the age of 18 years old |
| Tumor markers | Tumor markers (Ki67 index, mitotic count or tumor grading) must be obtained from the primary tumor | Studies that do not report the predictive value of Ki67 index, mitotic count or tumor grading |
| Study design | Follow-up studies for the development of liver metastases | No follow-up studies for the development of liver metastases |
| | Randomized controlled trials (RCTs) | |
| | Prospective and retrospective comparative cohort studies | Case reports |
| | Noncomparative cohort studies | |
| | Case-control studies | Reviews |
| | Case series | |

**Table 3.** Eligibility criteria review on genetic signatures and the presence of circulating tumor cells.

| Study characteristics | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Participants/population | Patients with primary neuroendocrine tumors | Children or adolescents (under the age of 18 years old). |
| | Patients whose genetic signatures of the primary tumor have been tested or those who have been tested for presence of circulating tumor cells | Animal studies |
| | | Patients with tested genetic signatures only of the metastases |
| | Patients with 18 years of age or older | |
| Test of interest | Gene expression testing of the primary tumor | Gene expression testing of the metastases |
| | Test for circulating tumor cells | |
| Reference standard | The reference standard test will be the presence or absence of liver metastases during follow-up (imaging or histopathology) by presence or absence of a genetic signature or circulating tumor cells | |
| Study design | Cross-sectional studies of any type | Case reports |
| | Cohort studies | |
| Reporting | | Studies that do not report any predictive value |



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**Table 4.** Eligibility criteria for review on biochemical markers.

| Study characteristic | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Participants/population | Patients with primary neuroendocrine tumors and patients who underwent surgery for primary liver tumors with a curative intent and were followed up for the detection of potential liver metastases | Studies that do not report the assessment of resectability (second scientific question) |
| | Patients over the age of 18 years old | Children or adolescents (under the age of 18 years) |
| | | Studies that do not report the diagnostic accuracy (first scientific question) |
| Test of interest | Tests of biochemical markers detecting liver metastases, and for the post treatment follow-up of liver metastases:<br>1) Chromogranin A<br>2) Chromogranin B<br>3) Serotonin<br>4) Tumor specific hormones<br>(Glucose, Insulin, Proinsulin, C-Peptide, Gastrin, Glucagon, Vasoactive Intestinal Peptide, Somatostatin, Neuron Specific Enolase) | |
| Reference standard | The different biochemical markers Chromogranin A and B, Serotonin and tumor specific hormones will be compared | |
| Control | The histopathological diagnosis of the resected specimen or a tumor biopsy will be considered as the reference standard | |
| Study design | Randomized controlled trials (RCTs) | |
| | Prospective and retrospective comparative cohort studies | |
| | noncomparative cohort studies | |
| | Case-control studies | |
| | Case series | |
| Primary outcome | Diagnostic accuracy of the different biochemical markers (sensitivity and specificity) | |
| Secondary outcome | Additional diagnostic accuracy measures of the different biochemical markers (accuracy, positive and negative predictive values, positive and negative diagnostic likelihood ratios, etc) | |



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**Table 5.** Eligibility criteria for review on morphological imaging modality.

| Study characteristic | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Patient population | Patients with liver metastases from neuroendocrine tumors | Children or adolescents (under the age of 18 years) |
| | Patients who underwent liver transplantation or palliative liver resection or nonsurgical treatment (peptide receptor radionuclide treatment, chemotherapy, biotherapy) | |
| Study design | Randomized controlled trials (RCTs) | Case reports |
| | Prospective and retrospective comparative cohort studies | Editorials |
| | Noncomparative cohort studies | Reviews |
| | Case-control studies | |
| | Case series | |
| Reporting | | Studies that do not report the diagnostic accuracy (first scientific question) |
| | | Studies that do not report the assessment of resectability (second scientific question) |
| Test of interest | Computed tomography (CT) | |
| | Magnetic resonance imaging (MRI) | |
| | Ultrasound scanning | |



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**Table 6.** Eligibility criteria for review on functional imaging modality.

| Study characteristic | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Patient population | Patients with NET | Children or adolescents (under the age of 18 years) |
| | Patients with liver metastases | |
| Test of interest | SPECT[a] | |
| | SPECT/CT[b] | |
| | SRS[c] | |
| | $^{123}$I-MIBG-Scintigraphy[d] | |
| | $^{18}$F-FDA-PET[e] | |
| | $^{18}$F-FDG-PET[f] | |
| | $^{18}$F-DOPA PET/CT[g] | |
| | PET/CT[h] | |
| | PET/MRI[i] | |
| | $^{111}$In-SRS[j] | |
| | $^{123}$I-SRS[k] | |
| Study design | Randomized controlled trials (RCTs) | Case reports |
| | Prospective and retrospective comparative cohort studies | |
| | Noncomparative cohort studies | |
| | Case-control studies | |
| | Case series | Reviews |
| Reporting | | Studies that do not report the diagnostic accuracy |
| | | Studies that do not report the assessment of re-sectability |

[a]Single photon emission computed tomography

[b]Hybrid method of single photon emission computed tomography and computed tomography

[c]Somatostatin receptor scintigraphy

[d](123) Iodine-metaiodobenzylguanidine scintigraphy

[e](18) Fluoro-dopamine positron emission tomography

[f](18) Fluoro-2-deoxy-D-glucose positron emission tomography

[g] (18) Fluoro-L-dihydroxyphenylalanine positron emission tomography

[h]Hybrid method of positron emission tomography and computed tomography

[i] Hybrid method of positron emission tomography and magnetic resonance imaging

[j](111) Indium-somatostatin receptor scintigraphy

[k](123) Iodine-somatostatin receptor scintigraphy



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**Table 7.** Eligibility criteria for biopsy of primary and liver metastases.

| Study characteristic | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Patient population | Patients with primary neuroendocrine tumors and/or NET liver metastases | Children or adolescents (under the age of 18 years old) |
| | Patients who underwent a biopsy of the primary and liver metastasis | |
| | Patients who underwent multiple biopsies of the liver metastases and/or healthy parenchyma | |
| Test of interest | Biopsy of primary NET and/or NET liver metastases | Studies that do not report histo-pathological biopsy results |
| Study design | Randomized controlled trials (RCTs) | Case reports |
| | Prospective and retrospective comparative cohort studies | |
| Noncomparative cohort studies | Case-control studies | Reviews |
| | Case series | |
| | Cross-sectional and/or cohort studies | |

### Search

Librarians of the Medical Library Careum, University of Zurich, Switzerland, develop the electronic search strategy to query databases and to identify all potentially relevant articles. The following databases will be searched: MEDLINE, EMBASE and The Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects). The investigators will be provided with an Endnote file containing all identified titles and, if available, the corresponding abstracts. Additional articles will be retrieved through manual search or scanning of reference lists. Titles and/or abstracts of all identified records will be independently screened by two review team members to ascertain their relevance and to identify studies that potentially meet the inclusion criteria outlined in Tables 2-5. The full text of each of these potentially relevant studies will then be assessed for eligibility. Any disagreement will be resolved through discussion with a third review team member. A predefined protocol will be used to extract data from the included studies for assessment of study quality and evidence synthesis.

### Data Extraction

The parameters for data extraction will be the following: first author's name, publication year, answering scientific questions, study design, total number of patients, number of patients in the study group, and number of patients in the comparison group. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) will be used to grade the quality (level) of evidence and the strength of recommendations [35].

A narrative synthesis of the findings from studies included will be provided. A quantitative synthesis will be used for studies that are sufficiently homogenous from a clinical (comparability of populations, interventions and outcomes) and from a statistical perspective (heterogeneity, eg, I2<50%). We anticipate that there will be a limited scope for meta-analysis despite a relatively large number of studies due to the different outcome measurements of the existing trials (ie, since such tumors are rare). However, results from studies using the same type of intervention and comparator, with the same outcome and measurements will be pooled using a random-effects meta-analysis. In addition risk ratios for binary outcomes, 95% confidence intervals and two- sided P values will be calculated for each outcome.

## Discussion

There are several modalities for the diagnosis and prediction of neuroendocrine liver metastases; however, there is a lack of consensual data on the subject. The six systematic reviews described in this protocol will elucidate the role and compare histopathological prognostic and biochemical markers, biopsies of the primary neuroendocrine tumor and NET liver metastases, morphological and functional imaging modalities. They will help to define clinical guidelines.

### Acknowledgments

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### Authors' Contributions

All authors were involved in editing the manuscript and approved the final text of the manuscript.



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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [36].

[PDF File (Adobe PDF File), 984KB - resprot_v2i2e60_app1.pdf ]

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## Abbreviations

**CT:** computed tomography
**E-AHPBA:** European-African Hepato-Pancreato-Biliary Association
**GRADE:** Grading of Recommendations Assessment, Development and Evaluation
**MRI:** magnetic resonance imaging
**NET:** neuroendocrine tumors
**PET:** positron emission tomography
**RCT:** randomized controlled trial
**US:** ultrasound scanning
**WHO:** World Health Organization



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Original Paper

# Exploring eHealth Ethics and Multi-Morbidity: Protocol for an Interview and Focus Group Study of Patient and Health Care Provider Views and Experiences of Using Digital Media for Health Purposes

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## Abstract

**Background:** eHealth is a broad term referring to the application of information and communication technologies in the health sector, ranging from health records to medical consultations (telemedicine) and multiple forms of health education, support, and tools. By providing increased and anytime access to information, opportunities to exchange experiences with others, and self-management support, eHealth has been heralded as transformational. It has the potential to accelerate the shift from traditional "passive patient" to an informed, engaged, and empowered "patient as partner," equipped to take part in shared decision-making, and take personal responsibility for self-managing their illness.

**Objective:** The objective of our study is to examine how people with chronic illness use eHealth in their daily lives, how it affects patient-provider relationships, and the ethical and practical ramifications for patients, providers, and service delivery.

**Methods:** This two-phase qualitative study is ongoing. We will purposively sample 60-70 participants in British Columbia, Canada. To be eligible, patient participants have to have arthritis and at least one other chronic health condition; health care providers (HCPs) need a caseload of patients with multi-morbidity (>25%). To date we have recruited 36 participants (18 patients, 18 HCPs). The participants attended 7 focus groups (FGs), 4 with patients and 3 with rehabilitation professionals and physicians. We interviewed 4 HCPs who were unable to attend a FG. In phase 2, we will build on FG findings and conduct 20-24 interviews with equal numbers of patients and HCPs (rehabilitation professionals and physicians). As in the FGs conducted in phase I, the interviews will use a semistructured, but flexible, discussion guide. All discussions are being audiotaped and transcribed verbatim. Constant comparisons and a narrative approach guides the analyses. A relational ethics conceptual lens is being applied to the data to identify emergent ethical issues.

**Results:** This study explores ethical issues in eHealth. Our goal is to identify the role of eHealth in the lives of people with multiple chronic health conditions and to explore how eHealth impacts the patient role, self-managing, and the patient-HCP relationship. The ethical lens facilitates a systematic critical analysis of emergent ethical issues for further investigation and pinpoints areas of practice that require interventions as eHealth develops and use increases both within and outside of the clinical setting.

**Conclusions:** The potential benefits and burdens of eHealth need to be identified before an ethical framework can be devised.



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**KEYWORDS**

ethics; eHealth; arthritis; multi-morbidity; patient/doctor engagement; self-management; patient role; Internet health; health tools; decision-aids

## Introduction

### Background

eHealth can potentially transform how people live with and manage chronic illness. eHealth is a broad term referring to the application of information and communication technologies in the health sector, ranging from electronic health records to medical consultations (telemedicine) and multiple forms of patient information [1]. We limit eHealth in this study to the technologies used by patients to gather health information and support self-management, specifically, Internet use, decision-making tools, and monitoring systems [2]. "eHealth is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes…a commitment for networked, global thinking, to improve health care…by using information and communication technology" [3]. The Canadian government has invested in this area since 1977 "eHealth is an essential element of health care renewal…Health Canada's priorities and efforts have focused on addressing policy issues and challenges in mainstreaming eHealth services within Canada's health care system and with measuring progress with the deployment and investment of these services" [1].

In 2009, 80% of 30,000 Canadian households and 73% of rural households in Canada used the Internet for personal reasons, while households in British Columbia reported the highest rates (85%). Of the Canadians who used the Internet, 70% used it to "search for medical or health related information," up from 59% in 2007 [4]. A 2010 Pew survey in the United States showed that 74% of 3001 adults over the age of 18 used the Internet, of whom 80% (2065) sought health information [5]. The survey also showed that women are more likely to search for specific diseases and other medical problems, for themselves and others, reflecting their traditional role in family health. A lower percentage of people with chronic illness (n=1488) sought online health information than those who reported a recent experience of an acute episode (n=982) [5]. Fifty-three percent of adults with chronic conditions reported seeking health information online, compared to 62% of adults reporting no chronic conditions. Overall there was high motivation, especially among people living with chronic conditions, to connect with each other on the Internet. These figures suggest a lack of Internet access, rather than a lack of interest in health, as the primary reason for the gap. Those who accessed health information identified positive impacts such as gaining support for self-management and advice about negotiating pathways through care, learning from peers, gaining emotional support, and acquiring advice about treatment options [5]. Fox [5] suggests that this Internet access gap creates a gap in health information for people with chronic illness [5].

### Evidence of eHealth Influence

Given the potential role of eHealth in health care delivery, little evidence is available about how it is influencing patient-HCP relationships. A review of eHealth by Dedding et al [6] and HCP consultation identified five broad areas of impact. Positive impacts include (1) providing a replacement for face-to-face consultations, (2) supplementing existing relationships and forms of care, and (3) creating favorable circumstances for strengthening patient participation. On the other hand, eHealth may disturb the patient-HCP relationship (eg, some providers may feel threatened by patient knowledge and empowerment). Also, it demands more intense and frequent patient participation. Dedding concluded that experiences of patients are diverse, contradictory, and complex and that more research is required. Some evidence reveals a steep increase in patients who take health information found on the Internet into consultations [7,8]. Gauld's telephone survey [7] was based on a nonrepresentative sample of 406 Internet health users in Australia and New Zealand. He found patients increasingly use consultations to understand and confirm their Internet-acquired health information, 52% of Internet users had sought Internet health information alongside consulting their doctors, 40% consulted the Internet prior to their medical meeting, and 50% discussed health information they had found on the Internet with their practitioner. Of these Internet users (n=203), 15% believed their practitioner felt uncomfortable with this, 46% affirmed that it improved their relationship with their practitioner, and over 80% felt that it enhanced their understanding of the Internet-acquired information and treatment plan.

Another major form of Internet health use is found in peer-to-peer support or online forums where people share health concerns, experiences, information, and offer emotional and decision support [9] at all stages of chronic illness. A systematic review of online peer-to-peer support groups failed to show any benefits or harms to participants [10]. Another review of 47 studies concluded that while virtual communities have the capacity to empower consumers and improve service delivery, there is insufficient evidence regarding their effect on health outcomes [11]. The 2010 Pew Internet national survey of 3,000 respondents in the United States noted peer-to-peer help among people living with chronic conditions as a highly significant finding; 23% of Internet users living with a chronic condition reported going online to find others with similar health issues [5]. People can communicate with others in real time, remain anonymous, control the amount of personal information given, and benefit from the empathy of others who understand their fears [12], but there are potential problems such as the quality and trustworthiness of information shared [2]. For example, the stories of others may induce anxieties, offer misleading viewpoints, and inform decisions based on dubious information [13].



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Self-management applications such as electronic devices for self-monitoring chronic conditions (eg, diabetes and asthma) have shown positive clinical effects in systematic reviews, but more evidence is called for [14]. A longitudinal study examined factors that encouraged use of a Web-based resource for monitoring diabetes, positive aspects included gaining feedback from an HCP and being encouraged to actively self-manage, while drawbacks included poor user friendliness [15]. Evidence shows that monitoring may improve patient awareness and adherence to treatments [16,17]. However, while self-monitoring systems are typically regarded as empowering for patients, they may also induce feelings of detachment and lead some patients to become more passive [18]. So, while technically effective, there may be negative impacts [19]. Quantitative research that examined self-monitoring in Type II diabetes found that monitoring could cause anxiety and depression and have a negative impact on quality of life [20]. Likewise, a review on self-monitoring blood pressure indicated it could be harmful to quality of life and encourages people to independently modify their treatment regimens. [21].

Decision aids are designed to inform and support individuals in making health and treatment decisions relevant to them and their illness condition through presenting information, options, and outcomes [22]. Increasingly electronic and interactive, they are regarded as important components of eHealth [2]. One review of 55 clinical trials involving 51 different decision aids showed multiple positive benefits such as encouraging patients to be more actively involved with treatment decisions without causing anxiety [22]. Criticisms have also been aimed at decision aids, in particular that they can be insensitive to the needs of individual patients [23]; this is especially relevant to those with multi-morbidities and complex treatment regimens.

There is some evidence about physician responses to eHealth. Jacobson's review [24] shows that there is resistance from physicians regarding online health information [25,26]. Oncologists displayed skepticism relating to the nature and quality of Internet information and the potential for inducing anxiety or false hope in patients [27]. A focus group study in Canada with 48 family physicians showed the physicians had concerns regarding patients being misinformed by online information, which could cause confusion, distress, and inappropriate self-treatment [28]. Another concern was the time it took to explain Internet information [28,29], which could cause frustrations and tensions in patient-doctor relations [30]. Other studies show significant variation in how specialists respond to patients. There is some evidence that a very small percentage of professionals recommend that their patients use the Internet or refer to the Internet during in-person consultations [31], while some physicians have described the Internet as having a positive effect [32]. In one cross-sectional survey of a nationally representative sample of United States physicians (1050 respondents; response rate 53%), 75% of physicians considered the increase in health information on the Internet to be "a good or very-good thing." Thirty-eight percent (n=399) of physicians believed that bringing Internet information to the consultation was either positive or neutral [29]. A study of male cancer patients suggested that the Internet strengthened the patient-physician relationship, as it prompted discussions about online information [27]. These changes in the patient role have implications for physician training. Bos [33] undertook a review of patient empowerment in 2012 and concluded that HCPs will need training to deal with knowledgeable patients and emerging ethical issues in eHealth [33].

Given the potential of eHealth to transform illness experience and the delivery of care, it may be particularly significant for people with multi-morbidity and associated wide-ranging information and complex self-management needs [34]. The explosion in online health information and support groups, electronic tools, and decision aids aligns with rising trends in self-management of chronic conditions and healthy consumer self-care [35]. Self-management programs for arthritis, diabetes, and other chronic diseases encourage patients to take on an active role and promote individual responsibility in illness management [36,37], and there is evidence to show that self-management programs are associated with positive outcomes [37]. Despite there being a lack of robust evidence [38], eHealth is considered a key tool to extend the reach of self-management programs with the capacity to more successfully align initiatives with patient needs, support and educate individuals to more actively participate in their health management [39], encourage patient-provider partnerships in health care [40], and "empower" people to maintain control of their illness and lives [2]. There is optimism about eHealth's potential to improve health care processes and patient outcomes [41]. The informed patient uses the Internet to seek second opinions, understand symptoms, get support, gain clarification of HCPs' advice, and devise questions for future consultations [42]. Policy documents from Health Canada's Office of Health and the Information Highway and the Department of Health in the United Kingdom also suggest that more informed patients would be empowered and equipped to better manage their health [24,43].

## Aim of the Study

The main aim of this study is to provide a systematic ethical analysis of emerging issues in eHealth regarding its role and impact on chronic illness experience and management. Specific objectives are to:(1) identify, understand, and compare how men and women with multi-morbidity (arthritis plus one or more chronic conditions) use eHealth, both broadly and with particular attention to their gathering of health information, decision-making, and self-management, (2)investigate how eHealth impacts patient-provider relationships, and (3) identify and address ethical ramifications of eHealth for patients, providers, and health service delivery.

Our research will contribute to a better understanding of the role of eHealth in managing multi-morbidity from patient and HCP perspectives. eHealth has been identified as a catalyst for positive and sweeping improvements, but only provisional empirical evidence on how consumers engage with eHealth and conflicting evidence about its impact on patient-provider relationships exists. Focusing on experiences of multi-morbidity, to illuminate issues of use and need, this study will identify and analyze emerging ethical issues of eHealth domains for self-management and patient-provider relationships. Technologies might not deliver their potential if we do not gain



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a comprehensive appreciation of benefits and harms. For example, the study may illuminate how eHealth affects empowerment, autonomy, and equity on individual, interactional, and systems levels in different practice contexts. Distinguishing the salient themes will help to guide further research and begin to identify areas for both patient and HCP support and the implications for decision-making and the patient-HCP relationship.

### Ethical Framework and Study Design

A relational ethics approach is suitable to identify and analyze the potential benefits and harms of a range of eHealth sources and address how far they enhance patient-provider interactions and support genuine decision-making. Moral reasoning can provide a framework to address ethical considerations in eHealth. While drawing on the traditional bioethics principles of autonomy, beneficence, and justice, we adopt a relational approach to understanding the role and ramifications of eHealth. Relational ethics emphasizes context. For example, the traditional conceptualization of autonomy offers an individualistic model of human agency, emphasizing independence and individual competence [44]. Relational autonomy prioritizes interdependence, relationships, social, and structural factors that facilitate or constrain meaningful self-direction [44]. As such, relational ethics is equipped to tackle a range of ethically complex situations arising in eHealth.

Empowerment is claimed as a major benefit of eHealth, but the process of becoming empowered and what this means to patients and HCPs is not well understood. For example, an overemphasis on empowerment may be harmful to patients. If there is a focus on individual patient's ability and desire to be empowered, people may feel responsible for underachievement of outcomes to control a disease or symptoms. This may be especially challenging for those managing multiple diseases with conflicting recommendations and multiple medications for different health problems [45]. A review of eHealth by Dedding et al [6] raises questions about the redistribution of tasks and responsibilities to patients as consumers, and how far this becomes an added burden in daily life [6]. Being self-sufficient and informed may place unrealistic and burdensome expectations on the sickest and exacerbate disadvantage. Some people may resist the new patient role, not have the resources, or lack an HCP who supports their developing empowerment [46,47]. This critical stance mirrors research in sociology about the work of chronic illness and self-management [48], and an ethics perspective on "patient work" [49]. Relational autonomy emphasizes the complex webs of personal and institutional relationships that facilitate real choice and offer ways of respecting another's autonomy. In this way, it addresses the daily life context of patients and the patient-HCP encounter and engages critically with the concept of empowerment and the context in which it emerges and is supported [6].

eHealth poses situations of fundamental moral uncertainty and conflicts between competing values and responsibilities in patient-provider relationships [6]. For example, some providers may find it difficult to relinquish traditional roles and a challenge to gain skills in new partnership-based roles. We do not know how issues of trust and agency are impacted by eHealth. There may be tensions between the development of trust and patient empowerment, which is seen as a major benefit of eHealth as well as prioritized as a policy goal. Interpersonal trust has traditionally been based on imbalance in the medical encounter, the vulnerability of the patient and the specialized knowledge of the HCP [50]. Given the potential shift in the patient-provider relationship, forming a partnership of trust requires knowledge and skills to encourage genuine partnership. For example, traditionally HCPs have been the gatekeepers to health information, but Internet information is an integral part of patient experience. The trust relationship and clinicians' fiduciary responsibility to be beneficent and avoid harm extends to respecting, recognizing, and supporting the patient's perspective and listening to patients as partners. Harm may ensue if patients' skills, experience, and knowledge are devalued [46], which is inconsistent with providers' obligations of fidelity and compassion [51], and their role in providing meaningful support. A relational approach to autonomy will examine the perspectives of both consumers and HCPs in the context of this cultural shift in care and address a range of issues including mutual trust, shared decision-making, and responsibility.

Individuals with poorer health status may also have less access to eHealth tools, so the expansion of eHealth could *exacerbate* health disparities. Even if there is equal access to eHealth resources, its potential benefits may remain beyond reach for some individuals/groups. Access alone, if not accompanied by services, support, and resources designed to reach and appeal to diverse populations, will not automatically improve an individual's eHealth use, or their health outcomes. The concept meaningful access, recognizes that in addition to physical access to eHealth, individuals need the skills and resources to use eHealth tools on a sustained basis. Issues of equity need to be considered regarding disparity in access to skills, education, and opportunities to develop them. Some people live complex lives compromised by illness and face adverse social conditions and personal circumstances that may place constraints on what they can accomplish via eHealth. Multiple disadvantages and vulnerabilities may compound illness and how illness is faced. In this way, structural, personal, and cultural factors may compromise or support optimum use of eHealth. Equity issues also include access to suitable equipment, Internet connections, opportunities for skill development, ongoing technical support, and web content that is appropriate for diverse users. Meaningful access also requires appropriate daily life situations, HCP, and health services support. A relational ethics approach will address issues of access in context, or meaningful access to eHealth and its ramifications.

## Methods

### Two-Phase Study

In this two-phase study, we use a qualitative approach, suitable to investigate process, social settings, human behavior, and examine how individuals make sense of their world. In this study we are guided by grounded theory [52] and narrative [53]. We apply a "social constructionist version" of grounded theory that aims to gain an interpretive understanding of social phenomena [52], emphasizing flexibility, replacing the more



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formulaic approach of original grounded theory [52]. We attempt to construct theory from the data, and will draft an explanatory framework for future study. We also draw on a narrative approach to hear people's storied accounts of their lives and experiences, how they build coherence, and link action with a moral purpose. This helps us recognize the moral themes of accounts. This fits with our focus on the ethics of health care and our overarching framework of relational ethics. In phase one of this study we conducted focus groups to gain insight into a range of perspectives and experiences of eHealth from a range of HCPs and patients. In part, this was a pragmatic choice, because it gave us the opportunity to relatively easily collect data from several perspectives simultaneously. Methodologically, we also wanted to encourage group discussion so that we could explore what people thought, how they thought, and why they thought that way [54]. We are in the process of identifying emergent themes that we will use as a basis for the phase-two interview topic guide for patients and HCPs for in-depth investigation.

## Rationale for Participant Sample

We selected people with arthritis and co-conditions for this study for two reasons-pragmatism and prevalence. We have an established, excellent working relationship with the Arthritis Research Center of Canada. Building on our knowledge base and research relationships enhanced recruitment and study feasibility. Figure 1 shows a screenshot from the Research Centre's Web page. Arthritis is a highly prevalent and serious chronic condition, the leading cause of pain and disability in Canada [55], hampering meaningful activity across life domains. The Canadian Community Health Survey (CCHS), (124,844 respondents, response rate 76%) based on 2007-2008 data, estimated that more than 4.2 million Canadians 15 years and older (16% of the population) had arthritis [55]. The coexistence of other chronic conditions with arthritis was reported as common by the Public Health Agency of Canada, based on the CCHS 2007-2008 data; both men and women frequently reported back problems (42.5%, 41.6%, respectively), high blood pressure (34.7%, 39.1%), heart disease (14.7%, 12.3%), diabetes (14.4%, 13.3%), and mood or anxiety disorders (13.3%, 19.5%) [55]. These coexisting conditions pose problems for individuals, populations, and HCPs, complicating effective treatment and disease management [56]. Multi-morbidity (the presence of two or more co-occurring chronic conditions) becomes more common as populations age, and will rise [57]. Research until very recently has however, tended to focus on single conditions.

Multi-morbidity is increasingly common. A 2003 Canadian study concluded that patients with multi-morbidity seen in family practice were the rule rather than the exception [34]; the province of British Columbia reported that in 2005/2006, 1.3 million patients had 1-3 confirmed chronic conditions and over 92,000 had 4 or more confirmed chronic conditions [57]. Multi-morbidity is associated with high burdens of care and cost [58]. Despite this, our knowledge and understanding of the impact of multi-morbidity for patients and HCPs is poor [59]. Furthermore, despite the explosion of eHealth, we are aware of very little research, if any, on the ethical implications of its role, the impact on self-management, and the patient-HCP relationship in multi-morbidity. Because eHealth is a vast resource for both consumers and HCPs, it is vital to identify its potential benefits and harms, perhaps particularly salient for those who have multi-morbidity and their HCPs who deal with more information and more complex decisions. By using our existing relationships in the arthritis community, we continue to efficiently recruit patients and HCPs with a focus on a common chronic condition as a unifying thread, and concomitantly explore the complexity of multi-morbidity.

**Figure 1.** Arthritis Research Center of Canada screenshot of Web page concerning how technology is used in health care research.




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## Participants and Procedures

We aim to recruit a total number of approximately 60-70 participants for FG discussions and in-depth interviews. This sample comprises an equal number of patients and HCPs. All participants will be adults with self-reported diagnosis of arthritis and one other condition, and use online health resources. This number was considered appropriate on methodological and practical grounds. It is feasible given the time of the research over 18 months; it allows comparisons between groups to identify patterns and range of experiences. Also, because of the amount of data generated in qualitative inquiry, this number still allows for in-depth analysis of data. A purposive sample will be recruited using online groups and listservs, newsletters, websites, posters in clinical settings and offices, word-of-mouth, and community advertising. The inclusion criteria for HCPs are a minimum of 2 years experience working with people with chronic conditions, and who report at least 25% of their caseload has more than one chronic condition. The inclusion criteria for patients are a diagnosis of arthritis (eg, rheumatoid arthritis, ankylosing spondylitis) and at least one additional chronic condition of any duration. For practical reasons, participants live in British Columbia and are able to converse in English. We aim for variation in socio-demographic characteristics including age, gender, geographical location, years of experience and professions (HCP), or disease duration and education (patients). Family members/caregivers of patients will be able to participate in the study.

We planned 8 FGs of 4-8 participants, with patients and HCPs in separate groups–at least four groups with HCPs (including family physicians, specialist physicians, nurses, occupational and physical therapists) and the remainder with patients. The FGs have been and the interviews will be facilitated/conducted by members of the research team experienced in qualitative research (AT and PA). Group discussions lasted approximately 2 hours, plus a short break. For the in-depth interviews we plan to recruit approximately 12 patients and 12 HCPs in order to gain perspectives of both groups (24 interviews in total). Based on our previous qualitative studies on living with chronic conditions, we expect interviews to last approximately 90 minutes. All interview participants will receive a telephone follow-up call of 20-30 minutes that will serve to verify, clarify, and expand on issues discussed.

The audiotaped FGs began by exploring topics, which will be refined and explored further in the interviews. Content focused on forms of eHealth and their impact for self-management and patient-provider relationships, and were organized into three sections. First, broad questions were asked to explore how participants used or viewed eHealth, what kinds of information they needed and preferred, and what sort of decisions they considered making based on eHealth information. Examples of eHealth formats mentioned were: (1) peer-to-peer online support groups, (2) Internet use in general, (3) decision aids, and (4) self-management monitoring devices and applications. The FG guide was arranged around four key areas (1) Devices and types of eHealth used, (2) Details about reasons for use, (3) How eHealth use influenced actions taken including interactions with HCPs, and (4) The benefits and harms/drawbacks of eHealth. (This fourth section probed about ethical issues of eHealth both explicitly and implicitly). Participants were encouraged to compare and contrast their use and views of different types of information and how it related to their experiences. To encourage maximum engagement from all participants, sessions were as relaxed as possible, with refreshments and a comfortable setting (eg, seated in a circle). The facilitator encouraged each participant to contribute to all sections of the topic guide, and to talk to each other and not address themselves solely to the facilitator. In this way focused conversation was fostered rather than questions/answers format. A flip chart was used to note key points and for more focused probing and elaboration. The level of discussion of each issue varied between and within groups. We anticipated that the FG would be unlikely to fully explore all the questions; consequently they were used to generate preliminary data and to identify the most salient topics and findings to inform an interview guide for more in-depth exploration with individuals (see Multimedia Appendix 1 for key FG questions).

## Analysis

An iterative, thematic approach using constant comparative methods is being applied to the data. The audiotaped FG discussion transcripts have been, and the interviews will be, checked against recordings for accuracy and anonymized. We will agree on conceptualizations of relational ethics as an overarching analytic framework. The FG analysis draws on aspects of grounded theory-simultaneous collection and analysis of data, two-step data coding process, constant comparative methods, and memo writing. Three researchers read and annotated a sample of transcripts independently and after discussion agreed on a broad initial coding framework, which will be applied to all transcripts using QSR NVivo7 software. This allows data storage, organization, and constant comparisons within and between transcripts. We will modify and add codes in the light of fresh transcripts and repeated readings. We applied initial themes to all transcripts (eg, building trust). After further analysis higher-level themes will emerge (eg, informed trust, trust wariness). We are identifying both a priori and emerging themes. A summary analysis will provide themes for the interview guide. Interview analysis similarly will follow grounded theory as above. The data generated will be more in-depth and also allow a narrative analysis. We will look for three core narratives-stability, progressive, and regressive [53]. In this way, the analysis is drawn to process, morally informed actions, and decision-making. Applying a relational ethics lens to the dataset, emerging themes include issues related to autonomous decision-making, building trust, hampering trust, building partnerships, taking control, giving control, and sharing responsibility. The ethical analysis will be interpreted in the context of the current literature and e-sources. It will also guide the development of a future more extensive investigation of greater scope (of the most salient eHealth ethical concerns, with a range of people) with patients, clinicians, and caregivers, to assess the transferability of the findings about access, benefits/burdens of eHealth, and communication in consultations.



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### Ethics Approval

We obtained ethics approval for the research from the University of British Columbia Behavioral Research Ethics Board and Vancouver Coastal Health Research Institute. Participants in this study will be provided with a detailed information sheet describing the study and sufficient information to make an informed decision about participation before they give written consent. Participants will be informed they can withdraw from the study at any time.

## Results

This paper presents a protocol of a study in progress, and results are not yet known. The current project status is as follows–Between November 2012 and June 2013 we recruited 36 participants (18 patients, 18 HCPs). The participants attended 7 FGs, 4 with patients and 3 with rehabilitation professionals and physicians. We interviewed 4 HCPs who were unable to attend an FG. Preliminary analysis revealed that patients and HCPs expressed similar views about eHealth, though examples, emphasis, and priorities varied. Analysis is ongoing and findings from the FGs are anticipated by October 2013. Building on the main themes to emerge from this FG phase of the study, we will create topic guides to conduct interviews between October and November 2013. Results from the interviews are anticipated by March 2014.

## Discussion

### Qualitative Studies

Like many qualitative studies, we will gain retrospective accounts of participant experiences. Because we are not asking participants to relay objective facts, but subjective experiences most significant to them, they are likely to recount potent factors, episodes, and processes associated with how they experienced eHealth, multi-morbidity, and clinical encounters, which is our main interest. A well-designed qualitative study is an efficient method for capturing a wide range of experience from the individual's perspective, while minimizing the chance of missing salient factors due to recall bias. Recruiting from British Columbia alone is a potential limitation in terms of generalizability. However, we can estimate how far our findings will be transferable to other settings. Our sampling approach is a practical solution to reach people with arthritis and at least one other condition and HCPs.

### Chronic Illness and eHealth

Surprisingly little research has examined how people with chronic illness use eHealth in their everyday lives, how it affects patient-HCP relationships, or its ethical ramifications for patients, providers, and service delivery. This study examines these issues, drawing on traditional bioethics principles of autonomy, beneficence, and justice within a more recent framework of relational ethics. Internet use is enormously diverse with numerous formats of factual sites, which can be accessed at any time, encouraging rising health consumerism [2]. People increasingly use the Internet to proactively manage their health [30,32]. There is some evidence to show the Internet influences decision-making. In a US survey drawing on a sample of 60,000 households, responses were analyzed from 4764 individuals 21 years and older who self-reported as Internet users. Forty-three point seven percent reported more than one chronic condition, about half of whom indicated Internet use improved their understanding of their chronic conditions and treatments for their chronic condition or other symptoms and treatments. "The percentage indicating effects on decisions about health or health care or on use of the health care system ranged from 7% to 32%" [60]. There are concerns about the quality and quantity of health information on the Internet [2] and we have limited knowledge of how consumers engage with eHealth [2]. Gauld [7] reported that 90% of respondents believed that health information obtained over the Internet was trustworthy, yet only 35% consistently checked the credentials of the information source. Research to date has only begun to tap into the frequency of Internet use and patient-provider communication; more in-depth study of the influence of this information is necessary. One example for further study is to assess whether or not integrating Internet data into the patient-provider consultation lengthens the visit or affects attitudes, communication style, or intervention plans to better understand the role of eHealth information in patient engagement and empowerment. Given the enormous potential eHealth holds for transforming and enhancing health care delivery and self-management, we know relatively little about how eHealth impacts the patient-HCP relationship. We have insufficient evidence of the potential harms and benefits of Internet use for people's health. Gaining evidence as a precursor to introducing costly interventions based on enthusiasm rather than evidence is also an ethical undertaking. Although claims have been made about the potential transformative promise of eHealth for health service delivery [2], more patient-centerd care and complex changes to patient-HCP relationships [51], we have disarmingly little data on its impact in terms of potential benefits and harms and if access gaps equal a gap in health care and self-management support. This situation raises profound ethical issues, which we will examine.

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## Authors' Contributions

AT and CB conceived of the study. AT, CB, and PA designed the study with help from LL and MM. AT drafted the initial version of the manuscript and CB contributed to and commented on all drafts. PA, LL, and MM also commented on versions of the manuscript. All authors read and approved the final manuscript.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

"Notice of decision" document. This contains the reviewer comments from the the Canadian Institutes of health Research (CIHR), who funded this project.

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## Abbreviations

**CCHS:** Canadian Community Health Survey
**FG:** focus group
**HCP:** health care provider


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Proposal

# The Onset of Type 2 Diabetes: Proposal for a Multi-Scale Model

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## Abstract

**Background:** Type 2 diabetes mellitus (T2D) is a common age-related disease, and is a major health concern, particularly in developed countries where the population is aging, including Europe. The multi-scale immune system simulator for the onset of type 2 diabetes (MISSION-T2D) is a European Union-funded project that aims to develop and validate an integrated, multilevel, and patient-specific model, incorporating genetic, metabolic, and nutritional data for the simulation and prediction of metabolic and inflammatory processes in the onset and progression of T2D. The project will ultimately provide a tool for diagnosis and clinical decision making that can estimate the risk of developing T2D and predict its progression in response to possible therapies. Recent data showed that T2D and its complications, specifically in the heart, kidney, retina, and feet, should be considered a systemic disease that is sustained by a pervasive, metabolically-driven state of inflammation. Accordingly, there is an urgent need (1) to understand the complex mechanisms underpinning the onset of this disease, and (2) to identify early patient-specific diagnostic parameters and related inflammatory indicators.

**Objective:** We aim to accomplish this mission by setting up a multi-scale model to study the systemic interactions of the biological mechanisms involved in response to a variety of nutritional and metabolic stimuli and stressors.

**Methods:** Specifically, we will be studying the biological mechanisms of immunological/inflammatory processes, energy intake/expenditure ratio, and cell cycle rate. The overall architecture of the model will exploit an already established immune system simulator as well as several discrete and continuous mathematical methods for modeling of the processes critically involved in the onset and progression of T2D. We aim to validate the predictions of our models using actual biological and clinical data.

**Results:** This study was initiated in March 2013 and is expected to be completed by February 2016.

**Conclusions:** MISSION-T2D aims to pave the way for translating validated multilevel immune-metabolic models into the clinical setting of T2D. This approach will eventually generate predictive biomarkers for this disease from the integration of clinical data with metabolic, nutritional, immune/inflammatory, genetic, and gut microbiota profiles. Eventually, it should prove possible to translate these into cost-effective and mobile-based diagnostic tools.



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**KEYWORDS**

type 2 diabetes; metaflammation; metabolism; computational biology; simulation; physical activity; multiscale modeling; data integration

## Introduction

### Background

Type 2 diabetes mellitus (T2D) is a metabolic disorder of late adulthood and old age, characterized by a decrease in glucose uptake from the blood, resulting in hyperglycemia (high blood sugar levels). In some individuals, this leads to a physiological condition referred to as "insulin resistance" in which the hormone insulin becomes less effective at lowering blood sugar. Insulin resistance can lead to insufficient production of insulin by the pancreatic β-cells and to the clinical condition known as T2D. Both insulin resistance and T2D are associated with obesity, aging, and inactivity [1].

The prevalence of diabetes, and particularly type 2, has increased markedly over the last 50 years in parallel with increasing rates of physical inactivity and obesity. Type 2 diabetes now accounts for about 90% of total cases of diabetes worldwide. As of 2010, there are approximately 285 million people in the world who are diagnosed with T2D compared to around 30 million in 1985 [1]. The figures within the European Union (EU) are equally stark: the World Health Organization states that more than 50 million European citizens are currently affected [2]. The epidemic growth of obesity in Europe, its aging population, and the often sedentary lifestyle of its citizens have led to an explosion in the incidence of T2D. Based on the assumption in this report that approximately 50% of affected people are unaware of their disease, it can be estimated that approximately 60 million people in Europe are likely to be affected by T2D.

An emerging view attributes the main driving forces of diabetes development to chronic energy overload from excess of nutrition, metabolic imbalance, reduction of metabolic flexibility, and inflammation. The role of a pervasive and multi-systemic state of inflammation triggered by the immune system, is also endorsed by 17 clinical trials of therapies that use anti-inflammatory approaches to treat T2D or prediabetic states. Several of these have already reached conclusive results, confirming the role of inflammation in the pathogenesis of T2D [1].

The contributions of mechanisms at the molecular, tissue, and organ levels to the physiological processes that lead from obesity to insulin resistance to the full-blown disease are intertwined in a complex and strongly patient-specific manner, suggesting that T2D must be considered from a personalized and systemic medicine perspective. The multi-scale immune system simulator for the onset of type 2 diabetes (MISSION-T2D) aims to develop personalized diagnostic markers based on the systems view.

In this complex scenario, there is an urgent need for efficient predictive approaches and models, capable of identifying a set of biological characteristics suitable for large-scale, cost-effective screening campaigns that aim to (1) drastically reduce the number of undiagnosed cases; (2) detect T2D at very early stages, at which point the disease appears to be still reversible; and (3) stratify cases in order to predict and, if possible, counteract T2D complications before they start exerting their detrimental effects. Thus, the identification of such a set of metabolic and inflammatory characteristics (ie, model-generated biomarkers and algorithms) and the implementation of their detection on user-friendly, cost-effective devices that can be used by primary care physicians or the patients themselves are the major goals of MISSION-T2D.

From a technical point of view, this study will implement a process workflow to simulate the metabolic and immune responses of tissues, particularly adipose tissues and pancreatic islets, to nutrition intake and metabolic alterations. This model will take into account patient-specificity through parameters derived from metabolic flexibility profiles, lifestyle parameters, nutritional habits and genetic signatures. The integrated modeling platform resulting from the above process will be the basis for a user-friendly diagnostic tool, ultimately developing a mobile app for Android, iOS, or Windows Mobile to be used by physicians for patient-specific intervention, which we will call the "physician assistant", and will be known as "personal coach" by patients to monitor their metabolic health status.

This project is supported by the Virtual Physiological Human (VPH) initiative, which is an EU Framework Seven funded program that aims to develop a framework of computational biomedicine methods and technologies to investigate the human body as a whole [3].

### Type 2 Diabetes as a Systemic Inflammatory Disease

Different interlinked mechanisms participate in the onset of T2D, with pancreatic dysfunction as the major cause. In response to the development of insulin resistance, the specialized cells that are devoted to insulin production (ie, the β-cells in the pancreatic islets) react by increasing their cell mass and amount of insulin secretion (see Figure 1). However, when the functional expansion of islet β-cells fails to compensate for the degree of insulin resistance, insulin deficiency and ultimately T2D may develop. Thus, the onset and progression of T2D are determined by the progressive failure of β-cells to produce sufficient levels of insulin [4,5].

Many insulin-resistant individuals do not become diabetic since their β-cells are able to compensate for the increased demand for insulin. Only about one-third of all people with insulin resistance will develop chronic hyperglycemia and eventually T2D. Progression to disease development involves excessive calorie intake, chronic energy overload, imbalance of metabolic pathways, impairment of metabolic flexibility, and related immune dysfunction. Metabolic flexibility is defined as the capacity to utilize diverse metabolic pathways for the uptake and storage of tissue energy from lipids and carbohydrates. Metabolic flexibility is lost in obese and diabetic individuals [6,7]. Obesity is thought to be among the primary causes of



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T2D, although genetic and epigenetic factors are likely to play an important role.

It has been suggested that a number of possible stress mechanisms (referred to here as "stressors") lead to insulin resistance and β-cell dysfunction, and play a part with them in the development of the full complex T2D phenotype. These include oxidative stress, endoplasmic reticulum stress, deposition of amyloid (ie, insoluble fibrous proteins) in the pancreas, and deposition of ectopic lipid in the muscle, liver, and pancreas [8,9].

All of these stressors can be caused by overnutrition, although it has been difficult to determine which mechanisms are the most important in each tissue, or how much they differ between individuals with T2D. However, it is noteworthy that each of these cellular stressors is thought either to induce an inflammatory response by itself or to be exacerbated by or associated with inflammation [10,11]. Inflammation is a complex, systemic, multi-scale physiological process that is necessary to cope with damaging agents and is fundamental for survival, involving a variety of cells, organs, and systems. The complexity of the inflammatory process escapes reductionist and linear approaches, since it is characterized by nonproportional kinetics as well as by numerous and nested feedback loops [12]. Ultimately, T2D can be conceptualized as being derived from a chronic inflammatory state that is initiated by an excess of nutrients and referred to as metabolic inflammation or metaflammation (see Figure 1). Proof-of-concept clinical studies have demonstrated the potential use of an anti-inflammatory molecule in T2D therapy [13].

The long-term consequences of T2D for most patients are severe. These include both macrovascular complications, including atherosclerosis, cardiovascular diseases, and amputations; and microvascular complications, including retinopathy, nephropathy, and neuropathy.

A number of possible stress mechanisms that are linked to inflammation and have been hypothesized to explain insulin resistance and β-cell dysfunction have already been mentioned. Metaflammation (ie, metabolic inflammation) is the most recent conceptualization in the field of metabolic diseases such as obesity and T2D [14], suggests that the hallmark of these pathologies is a chronic, sterile inflammatory state that is initiated by an excess of nutrients. This, and excessive levels of glucose and free fatty acids (FFAs), stresses the pancreatic islets, and therefore the β-cells and insulin-sensitive tissues such as adipose tissue, liver, and muscle, leading to the local production and release of immune inflammatory mediators such as cytokines and chemokines [1].

The immune system plays a pivotal role in the outbreak of the inflammatory state. Activated immune cells such as macrophages and T-cells invade adipose tissue, which is the site where these inflammatory alterations were first described and have been most studied. Consequently, the adipose tissue alters in response to this inflammation, triggering specific cellular programs that activate multiple signaling networks resulting in the production of a variety of inflammatory compounds. Furthermore, the activation of inflammatory pathways such as nuclear factor κB (NF-κB), protein kinase RNA-activated (PKR) and c-Jun N-terminal kinases (JNKs) pathways also occurs in liver cells, and muscles are deeply influenced by peripheral inflammation.

To summarize, metaflammation is metabolic, moderate, and characterized by local expression of inflammatory mediators. These are induced by stress-sensing cellular mechanisms originated through signaling pathways involving the inhibitor of κB kinases (IKKs) and JNK kinases, and a range of other signaling molecules that have been collectively termed the "inflammasome". This peculiar type of inflammation, unlike the classic inflammatory paradigm, is associated with a reduced metabolic rate**,** activates specialized immune cells, and creates a modified milieu in which an altered composition of immune cells favors a proinflammatory tissue environment that is maintained without apparent resolution (see Figure 1).

There is a second inflammatory component that must be considered: the interaction between the inflammatory process and aging. The aging process itself is accompanied by a chronic low-grade inflammation, which has been termed "inflammaging", a term derived from inflammation and aging. As it is known that insulin resistance and T2D are associated with aging, it is likely that the combination of metabolic-driven and age-driven inflammatory pathways plays a pivotal role in T2D pathogenesis.

Metaflammation has inhibitory effects on insulin action through inflammatory kinases (eg, JNK, IKK, and PKR) in metabolic tissues (eg, adipocytes) and disrupts nutrients and energy metabolism (see Figure 1, right). Metaflammation is also characterized by the activation of the classical pathogen-sensing or immune response pathways by stimulation of the toll-like receptors (TLR) as a result of an excess of nutrients [12] (see Figure 2). This observation suggests that aging-related and metabolic inflammation (inflammaging and metaflammation) can share stimuli and pathogenic mechanisms.

In this context, it is important to note that inflammatory stimuli derived from intestinal bacterial flora (gut microbiota) can make a substantial contribution to inflammaging as well as to metaflammation and obesity. Several studies on animals and humans have shown that populations of gut microbiota differ significantly between average-weight and obese individuals [15]. Moreover, a recent study has shown that the composition of the gut microbitota alters with age, and that there is a correlation between age-related changes in micobiota and increased levels of inflammatory cytokines such as interleukin 6 (IL-6) and interleukin 8 (IL-8) in the plasma [16,17].

Another factor that plays a non-trivial role in maintaining metabolic balance is physical activity. Epidemiological studies suggest that physically active individuals have a 30-50% lower risk of developing type 2 diabetes. Physical activity, measured in terms of exercise intensity (eg, the number of steps walked, kilocalories burned per minute, or metabolic equivalent units) impacts the regulation of body weight, body mass index, insulin resistance and sensitivity, glycemic control, atherogenic dyslipidemia, and inflammation [18].

Taken as a whole, most of the mechanisms that underpin these complex interactions and circuits are still poorly understood.



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An integrated modeling approach such as that proposed in this project is thus necessary to grasp, as well as to model, the complexity of the pathological conditions that lead to T2D.

**Figure 1.** Left: Excessive levels of nutrients, including glucose and free fatty acids, stress the pancreatic islets and insulin-sensitive tissues such as adipose tissue, leading to the local production and release of cytokines and chemokines (eg, IL-1β, TNF, CCL2, CCL3, and CXCL8). Furthermore, production of IL-1 receptor antagonist (IL-1RA) by β-cells is decreased. As a result, immune cells will be recruited, which contribute to tissue inflammation [14]. Right: Hallmarks of metaflammation. The first feature of this type of inflammation in obese individuals is that it originates from signals within metabolic cells such as adipocytes. Second, the metabolic signals trigger inflammatory intracellular signaling pathways that mediate downstream inflammatory responses (eg, JNK, IKK, or PKR pathways). The activation of these mediators induces a low level of chronic inflammation in response to the excess nutrients. Over time, this may induce the recruitment and activation of specialized immune cells [1].

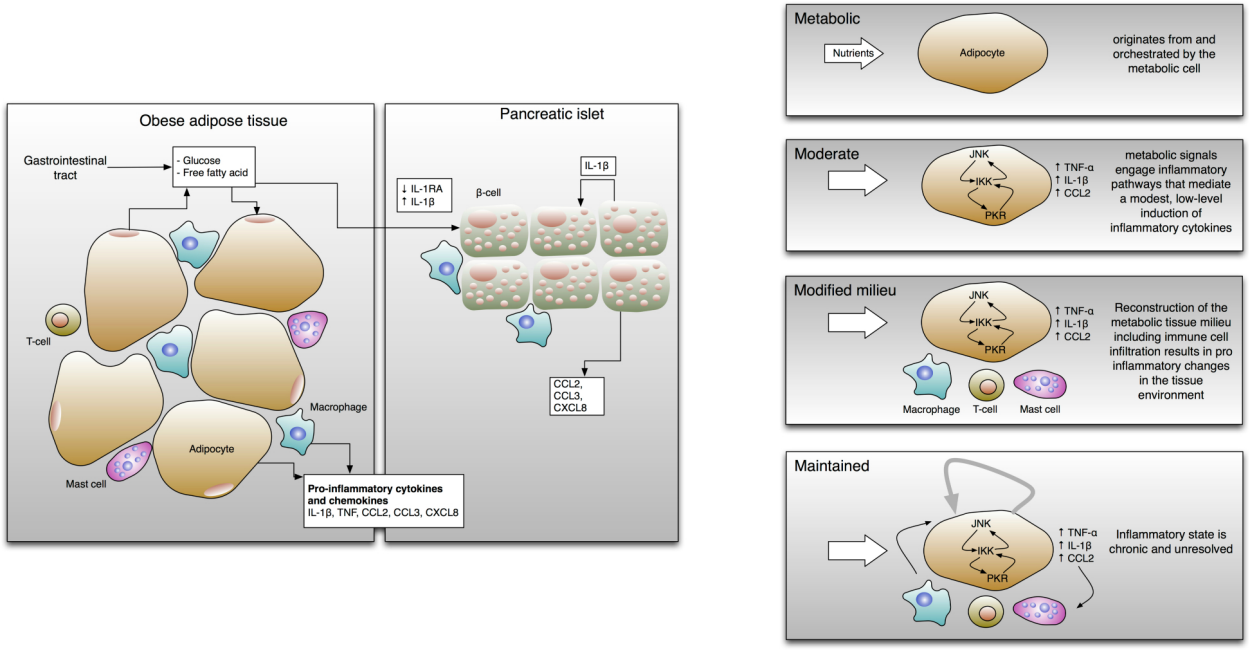
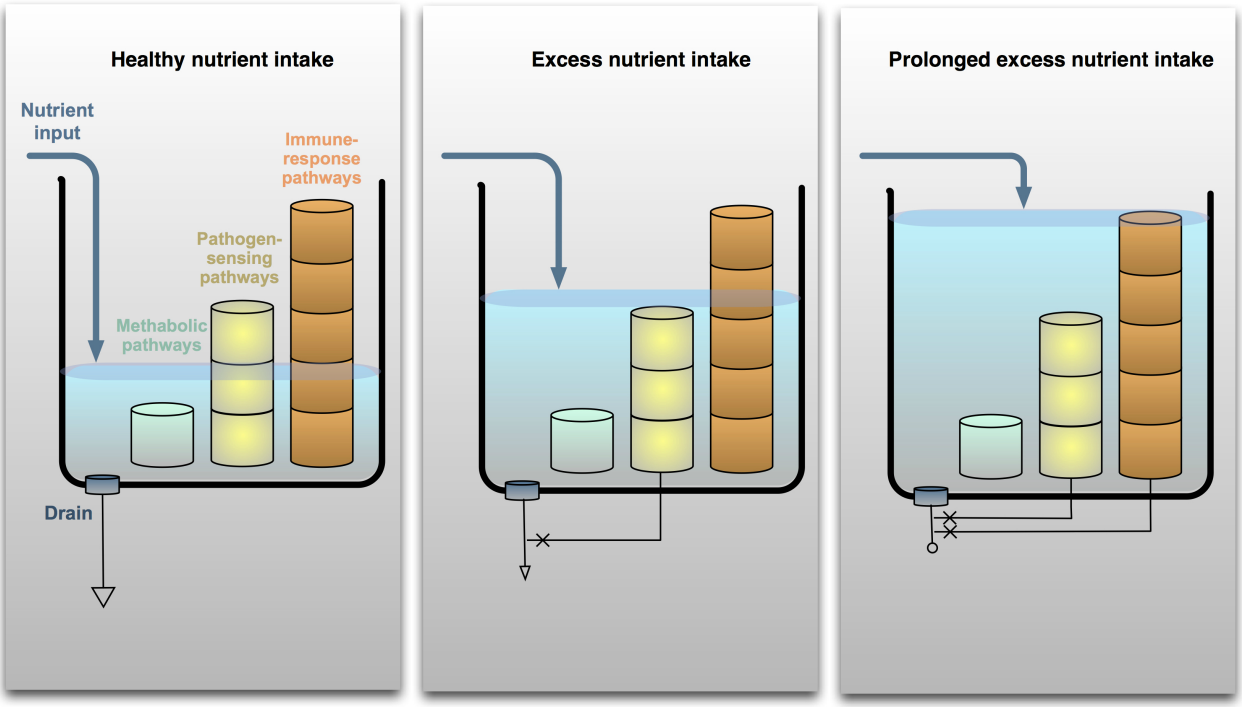



**Figure 2.** Nutrient overload signals spill from metabolic pathways to immune-response pathways. Nutrient input under normal or healthy conditions should engage metabolic pathways within the cells, leaving immune-response pathways inactive. With increased nutrient intake, the levels of nutrients flooding the system may rise enough that the overflow stimulates pathogen-sensing pathways. Because these pathways recognize biological molecules such as specific fatty acids, excessive amounts of nutrient moieties may also be able to activate such sensors. Once the immune sensors are activated, they may be antagonistic to the metabolic pathways, in effect blocking the drain of nutrient metabolism. If the nutrient excess persists to an extreme state, immune-response pathways of specialized immune cells may also be activated. The involvement of these pathways will intensify the inhibition of metabolic pathways and contribute to the backlog of nutrients in the system [14].



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## Methods

### A Multi-Scale Model for T2D (Concepts and Architecture of MISSION-T2D)

In this study, we intend to take a practical approach towards addressing the typical situation in which a person presents her/himself to the general practitioner with one or more signs of the onset of insulin resistance or diabetes, such as high waist circumference, elevated sugar blood levels (obtained through the fasting plasma glucose test), and/or elevated plasma triglycerides. The doctor will then need to ask what the best treatment schema for the particular person is (ie, which treatment will lead to the best results, with the fewest side effects, and in the shortest time). This might be a proposed lifestyle intervention, a drug treatment, or both. The optimum solution differs from patient to patient; therefore, in order to solve this problem the doctor will need to look at the patient's individual condition and perform a diagnosis from a systems perspective. Adopting the systems view acknowledges that any local change in a physiological system affected by an intervention will have repercussions on other parts of the system. For example, if a certain intervention merely blocks lipid accumulation in the liver, the lipid will start to accumulate and perhaps cause problems elsewhere, such as the heart muscle.

The picture is further complicated by patient-specific genetic, metabolic, and lifestyle traits that promote the stress-induced production of inflammatory mediators such as IL-1ß, TNF, chemokine (C-C motif) ligand 2 (CCL2), CCL3, and (C-X-C motif) ligand 8 (CXCL8). These inflammatory mediators will trigger the innate immune system, finally leading to a chronic low-grade inflammatory state (ie, tissue inflammation). This inflammation will lead to reduced insulin signaling (ie, insulin resistance in tissues and organs). The resulting need for increased insulin production will put pancreatic ß-cells under increasing chronic stress, which will induce a specific inflammation state impairing insulin production from pancreatic ß-cell islets. Finally, this will lead to more severe metabolic disturbances and to chronic hyperglycemia as a precursor of T2D.

In each case, the decision about which interventions to perform must take into account the effects that will arise due to interactions between different organs and processes in the body. To enable this, the diagnosis must take into account the actual level of flexibility of these same processes and organs, (ie, their capacity to cope with metabolic and inflammatory challenges). Thus, on the one hand, a diagnostic tool must be able to predict which processes are in fact at risk of reaching the limits of their capacity. On the other hand, it must predict which intervention(s) will be necessary to shift the metabolic/inflammatory demands in that individual to processes and organs that still have sufficient capacity, while at the same time reducing the overall metabolic/inflammatory load on the system.

The left panel of Figure 3 describes the relationships between different concepts that we will be considering in MISSION-T2D. The model inputs that take patient specificity into account are underlined in the diagram. These inputs include genetic traits (eg, variants of genes such as the immune cell receptor-coding gene CD44 and SPP1 (secreted phosphoprotein 1) [19], nutrition habits (eg, markers of glucose and free fatty acid intake), lifestyle habits (eg, physical activity), age, and genetic sampling of the gut microflora (measured by a human intestinal trait chip or HITchip).

At present, many types of data that are known or of potential relevance to this project are available in clinical or research settings. These include genomics, transcriptomics, metabolomics, proteomics, epigenetics data, and miRNAs, as well as variables derived from more classical physiology and clinical chemistry, and also from medical imaging. Relevant parameters that can be determined by imaging include the thickness of the inner layers of the arterial wall. The important question to answer is how these data can best be used to model different biological processes that relate to an individual's risk of developing type 2 diabetes, and then to select among the relevant variables the most suitable for implementation in cost-effective diagnostic or personalized digital coaching tools.

We understand that a wide variety of measured variables are involved in many different biological processes that are integrated on different scales of time and space (ie, from molecular to cells, tissues, organs, and the whole body). A practical solution to deal with the high number of factors involved and the complexity of interactions between the inflammatory and metabolic processes in several organs, and across many orders of magnitude of space and time scales, involves the integration of interconnected models at different aggregation levels of biological processes, roughly corresponding to these different spatial and temporal scales [20].

In this study we will therefore apply a novel multi-scale computational approach to model inflammation in type 2 diabetes. We will develop a composite simulation system embracing four levels of mathematical descriptions covering: (1) the intra-cellular metabolic and gene expression level, (2) the cellular level involving the dynamics of the immune system cells, (3) the organ level, and (4) the disease process within the whole body. Different mathematical and computational models will map aspects of physiology and pathology that are represented at each of these levels. The outputs of each model will directly feed the variables and/or the parameters of the next aggregated model so that it will be eventually possible to merge them all into a single workflow or multi-scale integrated simulation system (see Figure 5).

The models to be developed using MISSION-T2D will involve the following scales: First, the microscopic intracellular scale, or the molecular level, which links to cellular genome-scale networks (ie, the highest level of process detail). This type of modeling typically involves top-down statistical analyses of -omics responses to external stimuli which can be used to determine the subset of pathways and/or network modules that specifically respond to factors of interest and preselect them for bottom-up mechanistic modeling. Molecular scale models to be developed within MISSION-T2D will describe the cellular metabolism of ß-cells and macrophages and the transduction of nutrient components to stimulate the immune system and lead to the inflammatory state, focusing on gut-related processes



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and the onset of stress-induced inflammation. Second, the mesoscopic intercellular scale, or the tissue/plasma level, which links to the dynamics of tissue/organ-aggregated metabolic and inflammatory processes and plasma markers. These markers change on time scales that range roughly from minutes to days, and the data to calibrate models at this level are typically taken from challenge tests. Models to be developed at this level will involve the dynamic effects of nutrients on the immune system, and specifically the elicitation of a nonspecific inflammatory state leading to a full-blown activation of the adaptive (ie, specific) immune system response. Third, the macroscopic scale, or the organ level, which refers to the main organs affected by T2D, such as the gut and the adipose tissue. Processes to be modeled at this level will involve the triggering of the immune system, and specifically how different types of immune cells (eg, lymphocytes) and organs (eg, lymph nodes) communicate to start the immune-specific response. Data to calibrate models at this level are typically taken from diet/lifestyle/drug intervention studies. In this case the inter-organ process balance level will link the descriptors of integrated and aggregated effects of the nutrient-stimulated inflammation processes that have been defined at the mesoscopic scale roughly on a time scale of days to months. Finally, the whole body disease process level, which links to disease risk. Models developed on this scale will integrate and aggregate the disease-mediating effects of the variables measured or modeled at the macroscopic scale, typically on the multi-year time scale. Data to calibrate these models are typically taken from cohort studies. We will analyze the effect of model-predicted lifestyle interventions on parameters at the macroscopic scale, including physical activity, and will combine them with established clinical methods of T2D risk assessment. Therefore, we will be able to validate the predictions of our integrated model and propose new predictive reporter variables that can be applied to give feedback on T2D risk status, in both clinical and personal settings.

The novelty of our approach lies in the integration of various sources of biological data, and processing them by using mathematical and simulation tools, similar to the way nutrition and lifestyle habits are “processed” by the human body. The result of this processing is a physiological condition that can in certain cases become pathological. The approach is systemic, as we will include various levels of description. The final outcome of the integrated modeling platform will cover different space-time scales involved in the complex process of the T2D onset and progression (Figure 4), from the molecular event (milliseconds) up to organ deterioration (years), taking into account the contribution of genetics to nutritional habits.

This gene regulatory network model will be taken from literature [21] (see Figure 6 for comparison) and simulated as a Boolean (gene regulatory) network using the described techniques [22]. The macroscopic scale will then be represented by macroscopic observables such as the number of infiltrated macrophages in adipose tissue or the overall levels of insulin.

**Figure 3.** Left: Relationships between the concepts to be modeled in MISSION-T2D: Each aspect will be taken into account either through empirical data or via modeling, with submodels built up into a single integrated model. This will take as input information from genetics, nutrition, age, physical activity habits, and gut microbiota to elaborate a patient-specific risk assessment for the onset of T2D. Right: The pulsatile inflammatory response during feeding, showing differences between the responses of normal and obese individuals’ reactions over time: Fasting/feeding cycles induce low-level inflammatory responses in the metabolic cells of average-weight, healthy individuals that are easily resolved. During the high-fat diet or excess feeding that results in obesity, responses to food become more intense and frequent, and the resolution of the inflammatory response becomes less efficient, raising the baseline level of inflammation in metabolic tissues. Once the level of inflammatory response reaches a certain threshold in the metabolic cells, professional immune cells are recruited and activated. The participation of these cells in the inflammatory response alters the tissue environment toward a proinflammatory milieu and exacerbates the inflammation even further [14].

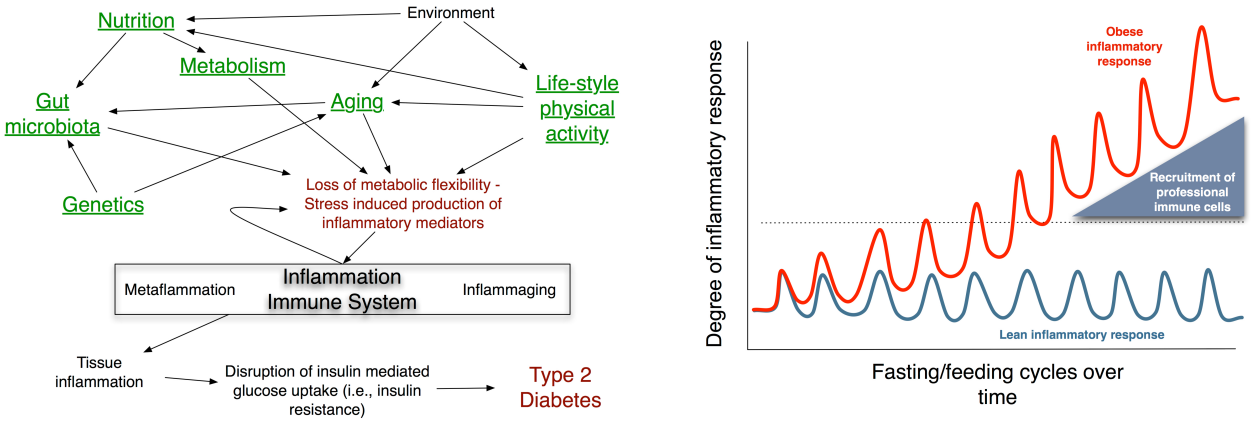




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**Figure 4.** T2D is a complex disease and its onset and progression cover different space-time scales, from molecular events (milliseconds) up to organ deterioration (years), taking into account the contribution of the individual genetic traits. MISSION-T2D project aims to cover and integrate models at all these levels, fully supporting the VPH initiative that aims to develop a computational framework to investigate the human body as a whole in health and disease [2].

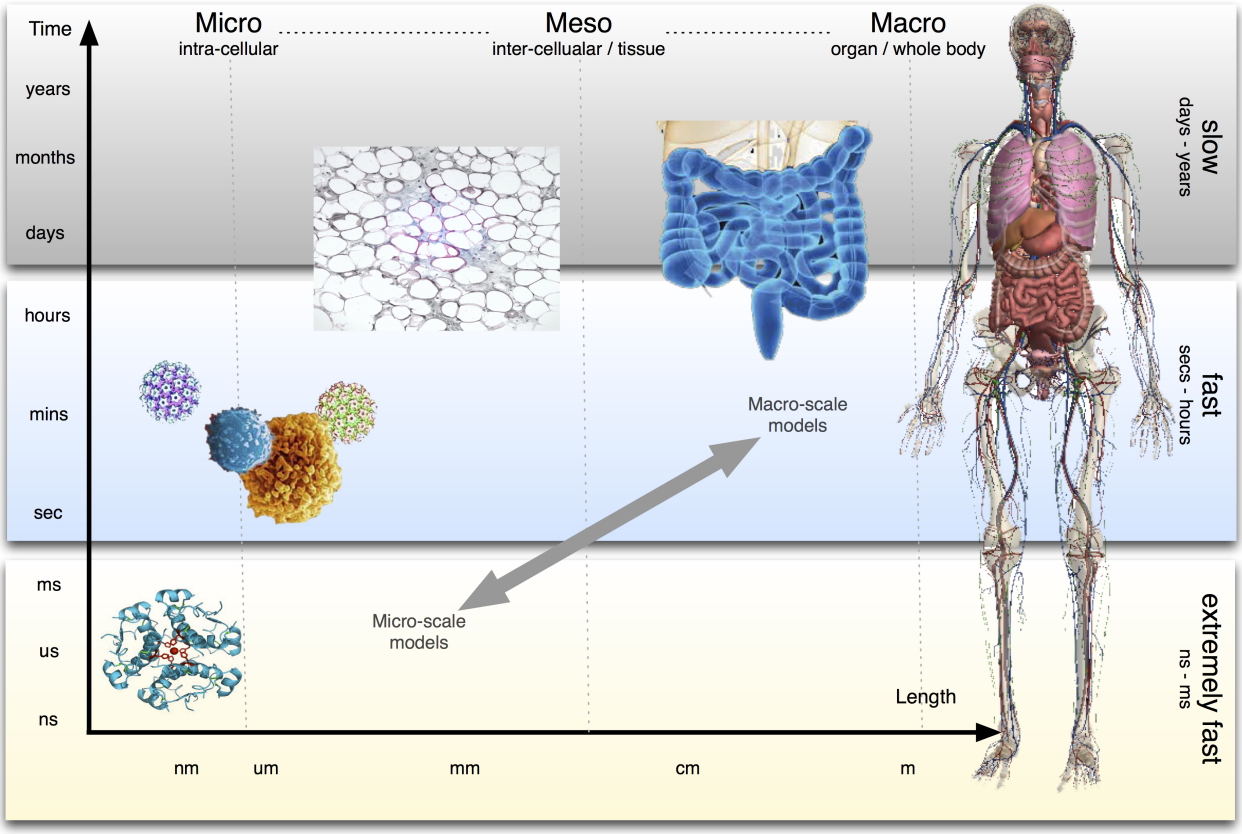




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**Figure 5.** A simplified systemic view of the models to be developed within MISSION-T2D and the interdependencies between them. Input-output relationships among modules of these models are depicted. Feedback (eg, IL-6 from the immune system to the stress-induced model) is not shown for simplicity.

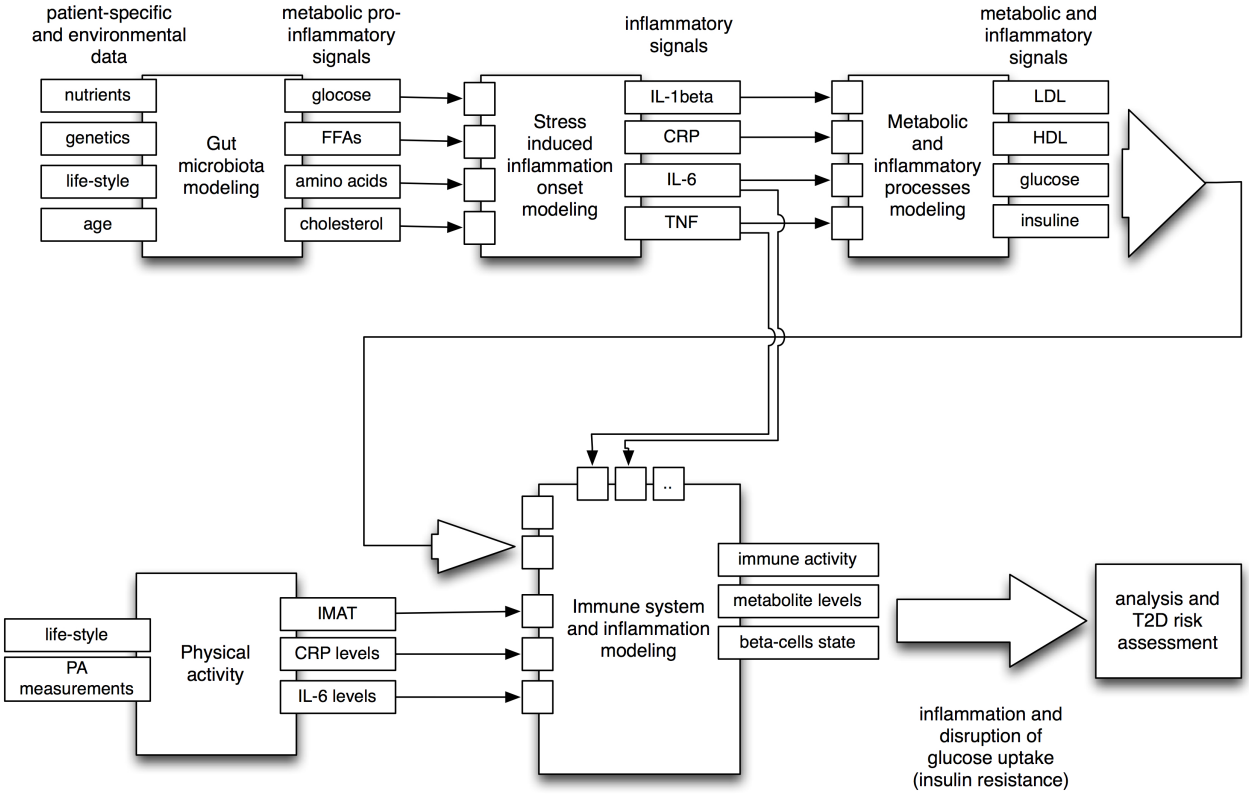
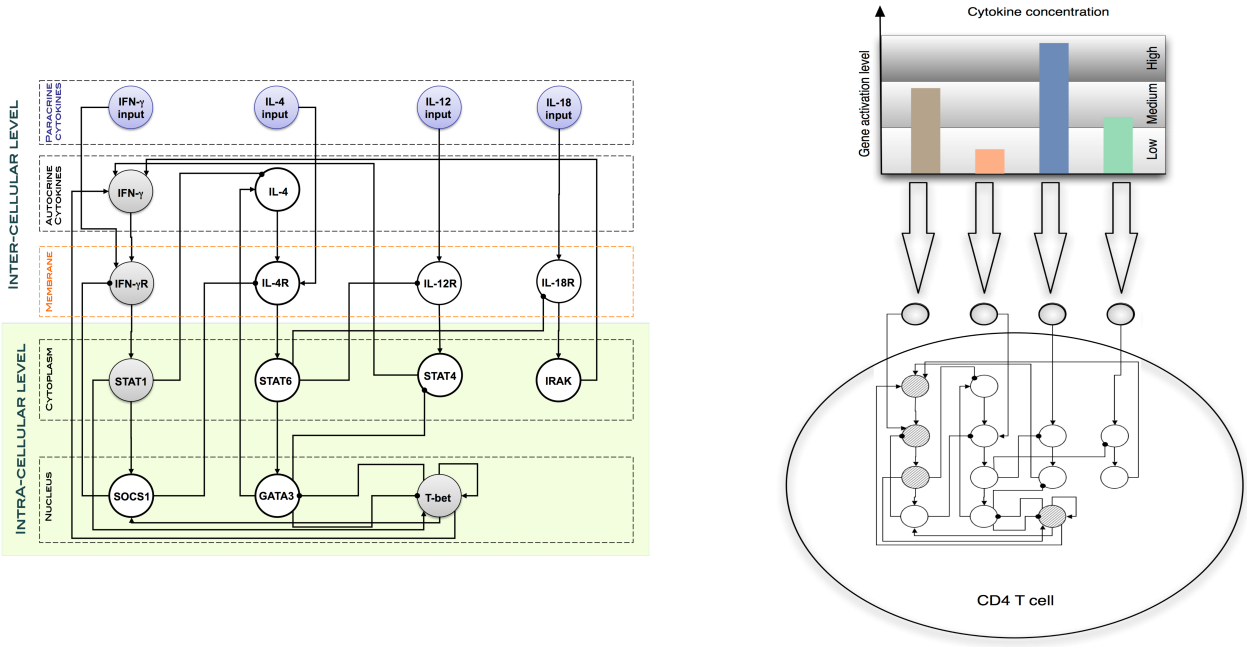



**Figure 6.** Left: Each helper T lymphocyte (Th cell) is equipped with an intra-cellular dynamics consisting of a gene regulatory network to describe the dynamical rule for the differentiation from Th0 to Th1/Th2 phenotype. Right: The regulatory network dynamics is a function of the cytokine environment [22].



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### The Integrated Scientific and Technological Platform of MISSION-T2D

The aim of MISSION-T2D is to be able to validate in silico the potential approach of targeting inflammatory mediators as a treatment for T2D, and to support a causative role for inflammation in the pathogenesis of the illness using quantitative data.

The integrated modeling platform to be developed using MISSION-T2D will offer an opportunity to qualitatively and quantitatively model the effect of different treatments and clinical approaches on various systemic features of the disease simultaneously. These will include defective insulin secretion by β-cells, insulin resistance in adipose tissue, metabolic parameters, and vascular complications among others. We will model the effects of using anti-inflammatory drugs, either alone or in combination, and will modify individuals' nutritional habits and other behavior such as physical activity, and will evaluate in silico the capability of each single factor to alter the course of the disease.

MISSION-T2D is an integrated model which will allow users to assess the efficacy of anti-inflammatory approaches for improving glycaemia and lessening the complications of T2D, and the durability of their effect. The integrated model platform that we plan to develop will also be able to give insight into the best therapeutic modalities, including whether life-long treatment or short-term interventions are better at breaking inflammatory flares. The model will provide quantitative data about anti-inflammatory strategies that target the underlying mechanisms of the disease, aiming to provide clinical guidance on how and when to start specific therapies in order to prevent the progression of early disease, or to impinge on the overt manifestation of the disease. These models will also provide indications for various immunomodulation strategies in T2D, including whether they will be well-tolerated, which side effects will occur and which drawbacks of immunosuppression will be present.

This approach, once validated, will provide a valuable tool for the physician in the diagnostics and treatment of this disease. Furthermore, our models will provide emotionally engaging, real-time, personalized, nutritional, and behavioral guidance as well as health tracking for individual patients (see Figure 7).

The definition of model structures at different levels will ensure that the models that are to be created or adapted from other published scenarios will be interpretable; and therefore, quantifiable at each individual level since the number of model variables at each level will remain limited. The coherence between models at different time scales (ie, strictly linking outputs at a given level with variables at the next higher level) will lead to a true systems model that is able to effectively span the different space and time scales involved. The overall architecture will translate input information (eg, derived from challenge tests, activity measurements, and baseline plasma analyses) onto the physical condition of a patient, lifestyle, and nutrition habits, and provide information that can be used for practical diagnostic and/or predictive purposes at a personalized level.

Therefore, the systems approach will effectively enable us to build disease risk prediction models by linking diabetes development (at the whole body level) to metaflammation-induced variation in insulin resistance on a time scale of weeks or months (at the macroscopic level), to dynamic processes in inflammation and metabolism at a time scale of hours or days (at the mesoscopic level), and to molecular details (at the microscopic level).

This integrated model will allow the simulation of lifestyle and nutrition habits of individual patients with specific genetic and metabolic characteristics for prolonged periods of time, thus effectively forecasting their risk of developing full-blown T2D. In other words, it will take as its input the cycles of fasting and feeding that induce the low-level inflammatory responses in metabolic cells that are easily resolved in average-weight and healthy individuals; however, it induces a less efficient resolution of the inflammatory response. in obese individuals with excessive or high-fat diets. This raises the baseline of inflammation in metabolic tissues and once the level of inflammatory response in the metabolic cells reaches a certain threshold, professional immune cells are recruited and activated, exacerbating the inflammation even further potentially leading to overt disease [14].



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**Figure 7.** Sensor technology and the use of portable communication devices offer the possibility of storing and accessing data from our daily life to improve self-knowledge. Insights gained by performing these measurements can be used, for example, to change life-threatening habits, adopt a healthier lifestyle, or take more informed treatment decisions.


## Results

This study was initiated in March 2013 and is expected to be completed by February 2016.

## Discussion

The aim of MISSION-T2D is to construct a predictive computer-based simulation tool for the development of type 2 diabetes. This tool will have three characteristics. First, it will be patient-specific. We will use clinical data (eg, blood sample parameters, age), genetic traits (eg, variants of immune specific genes such as CD44 and SPP1), nutrition habits (eg, glucose and free fatty acid intake), lifestyle habits (eg, physical activity) and a gut microbiota genetic sampling (measured through eg, HITchip) to build a patient-specific profile to be used as to set up the parameters and initial conditions of the integrated simulator. Second, it will be predictive. The integrated workflow will elaborate on the patient-specific parameters and perform a risk assessment for the onset of T2D in the individual concerned. Third, it will integrate medical, biological, and environmental data. The models will integrate environmental factors (nutrition and lifestyle habits) with medical (clinical tests results) and biological factors (pertinent genetic traits and gut microbiota), enabling the development of a predictive model for understanding the pathogenesis and the progression of type 2 diabetes. Moreover, the simulations will allow users to investigate the influence of other health factors such as age and physical exercise with the onset and evolution of the disease.

### Acknowledgments

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### Conflicts of Interest

None declared.



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## Abbreviations

**CCL2:** chemokine (C-C motif) ligand 2
**CXCL8:** chemokine (C-X-C motif) ligand 8
**EU:** European Union



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**FFA:** free fatty acid
**HITchip:** human intestinal trait chip
**IKKs:** inhibitor of kB kinases
**IL:** interleukin
**JNKs:** c-Jun N-terminal kinases
**MISSION-T2D:** The multi-scale immune system simulator for the onset of type 2 diabetes
**NF- κB:** nuclear factor kappa-light-chain-enhancer of activated B cells
**PKR:** protein kinase RNA-activated
**T2D:** Type 2 diabetes mellitus
**TLR:** toll-like receptors
**VPH:** Virtual Physiological Human

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Protocol

# A New Long-Term Care Facilities Model in Nova Scotia, Canada: Protocol for a Mixed Methods Study of Care by Design

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## Abstract

**Background:** Prior to the implementation of a new model of care in long-term care facilities in the Capital District Health Authority, Halifax, Nova Scotia, residents entering long-term care were responsible for finding their own family physician. As a result, care was provided by many family physicians responsible for a few residents leading to care coordination and continuity challenges. In 2009, Capital District Health Authority (CDHA) implemented a new model of long-term care called "Care by Design" which includes: a dedicated family physician per floor, 24/7 on-call physician coverage, implementation of a standardized geriatric assessment tool, and an interdisciplinary team approach to care. In addition, a new Emergency Health Services program was implemented shortly after, in which specially trained paramedics dedicated to long-term care responses are able to address urgent care needs. These changes were implemented to improve primary and emergency care for vulnerable residents. Here we describe a comprehensive mixed methods research study designed to assess the impact of these programs on care delivery and resident outcomes. The results of this research will be important to guide primary care policy for long-term care.

**Objective:** We aim to evaluate the impact of introducing a new model of a dedicated primary care physician and team approach to long-term care facilities in the CDHA using a mixed methods approach. As a mixed methods study, the quantitative and qualitative data findings will inform each other. Quantitatively we will measure a number of indicators of care in CDHA long-term care facilities pre and post-implementation of the new model. In the qualitative phase of the study we will explore the experience under the new model from the perspectives of stakeholders including family doctors, nurses, administration and staff as well as residents and family members. The proposed mixed method study seeks to evaluate and make policy recommendations related to primary care in long-term care facilities with a focus on end-of-life care and dementia.

**Methods:** This is a mixed methods study with concurrent quantitative and qualitative phases. In the quantitative phase, a retrospective time series study is being conducted. Planned analyses will measure indicators of clinical, system, and health outcomes across three time periods and assess the effect of Care by Design as a whole and its component parts. The qualitative



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methods explore the experiences of stakeholders (ie, physicians, nurses, paramedics, care assistants, administrators, residents, and family members) through focus groups and in depth individual interviews.

**Results:** Data collection will be completed in fall 2013.

**Conclusions:** This study will generate a considerable amount of outcome data with applications for care providers, health care systems, and applications for program evaluation and quality improvement. Using the mixed methods design, this study will provide important results for stakeholders, as well as other health systems considering similar programs. In addition, this study will advance methods used to research new multifaceted interdisciplinary health delivery models using multiple and varied data sources and contribute to the discussion on evidence based health policy and program development.

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**KEYWORDS**

mixed methods; framework analysis; primary care; long-term care

## Introduction

### Background

Until recently, people living in long term care facilities (LTCF) in the Capital District Health Authority (CDHA), Halifax, Nova Scotia, were responsible for finding their own family physician for primary care. Residents moving into LTCF could keep their existing family physician if the physician was willing and able to provide care in the LTCF. Otherwise, the resident had to find a local family physician who would agree to provide care prior to admission; often leading to admission delays. With many different family physicians providing care to a small number of residents in each facility, challenges arose with access to care, team communication, care planning, and coverage in emergency situations. Numerous studies have demonstrated that uncoordinated models of primary care in LTCF are less effective than those that are well-coordinated, which can result in limited access to proper primary care, and lead to suboptimal outcomes for elderly residents, particularly for end-of-life care [1-6].

In 2006, the Primary Care of the Elderly (PCOE) project was conducted to examine long-term care in CDHA. The PCOE project included a formal and grey literature review to identify potential models for providing primary care to the elderly, focus groups with nurse practitioners, family physicians, directors of care from continuing care facilities, staff of continuing care facilities, family members of frail elderly people, geriatricians, peer discussions, and a retrospective data review that were used to develop a new model of care called “Care by Design” [7]. Details of the PCOE project and findings can be found in their final report [7]. The project identified several concerns including: high rates of transfers from LTCF to emergency departments, even among those with “do not transfer” orders, lack of consultation with family physicians, and high rates of polypharmacy (the administration of multiple drugs at the same time for one or more health conditions) [7].

In January of 2009, the CDHA implemented a new model of care, known as Care by Design. This model included several important elements phased in over two years: (1) assigning all patients on one LTCF floor or wing the same physician and establishing a clear system of 24 hour on-call physician coverage; (2) designing measures to evaluate program performance; (3) implementing a program of standardized Comprehensive Geriatric Assessment for every resident using a tool designed specifically for the LTCF setting (the “LTC-CGA” – see Multimedia Appendix 1); and (4) an interdisciplinary team approach to the primary care (Multimedia Appendix 8). Specifically, interdisciplinary education has been an ongoing fluid part of Care by Design, directed by the co-leadership of the Long-Term Care Medical Advisory Committee and the District Council of Continuing Care on program specific elements such as clinical guidelines provided to each facility to be used along with education for staff on common conditions (eg, diabetes, hypertension, etc). In addition, an Extended Care Paramedic (ECP) program was introduced in collaboration with Emergency Health Services (EHS). The ECP program features a dedicated team of specially trained (or “extended care”) paramedics who respond to LTCF calls in order to address urgent care needs on-site to the greatest possible extent, and to aid in the coordination of planned transfers to hospital when necessary. Each of these elements was designed to address concerns identified in the original PCOE report (see Figure 1).

The quality improvement project, now called the Care by Design program, was initiated by front line family doctors with geriatric training. There was strong conviction that the change needed could be accomplished using some local models of care from the Veteran’s LTCF in Halifax, Nova Scotia, and an international model of care developed in the Netherlands nursing home medicine programs [8]. Funds were requested from CDHA for the PCOE project to define the problems and plan the intervention. The PCOE report was presented to the Nova Scotia Department of Health and Wellness, which provided funding for the first few years and since the program was successful, CDHA continued to support the program. The impetus for this quality work for both the Department of Health and Wellness and CDHA was mostly the high transfer rates of residents to emergency departments and associated high costs without clear clinical or system gains.

This paper outlines the protocol for a comprehensive inter-sectorial study of the Care by Design and ECP model, using a concurrent triangulation mixed methods approach. Care by Design is a coordinated model of primary and urgent care in LTCF that is unique in Canada. Its implementation provided an ideal opportunity to study this initiative by measuring patient and system outcomes with a quantitative time series design, along with a concurrent qualitative exploration of the



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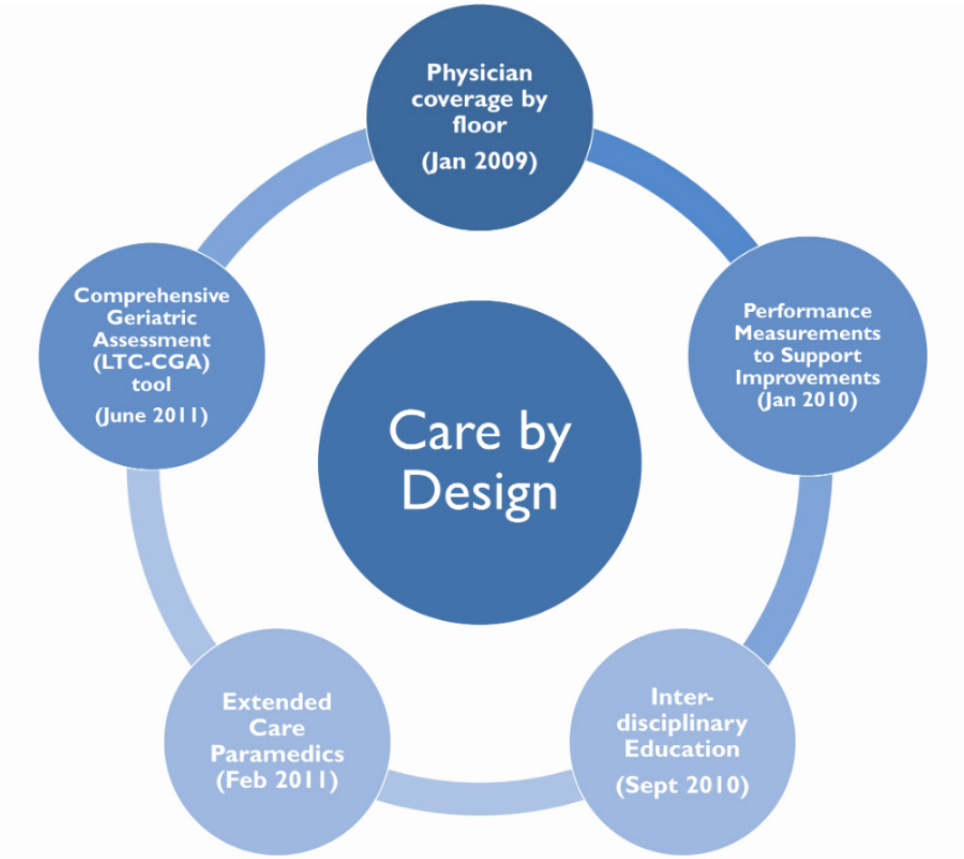
experiences of multiple stakeholder groups. Data collection is to be completed by early fall 2013.

### Objectives

This study has three main objectives: (1) to measure the effect of the new Care by Design model in LTCF and its major components; (2) to understand how key stakeholders experience the new Care by Design model components; and (3) to illuminate how the structure and process influence the outcomes for residents and care providers.

**Figure 1.** Care by Design elements and dates of implementation.




## Methods

### Mixed Methods Design

The mixed methods design employs a concurrent triangulation model [9] giving equal priority to our concurrently collected qualitative (QUAL) and quantitative (QUAN) data (see Figure 2).

As per the conventions of mixed method notation, QUAN refers to quantitative methods and QUAL refers to qualitative methods (Figure 2). The capitalization refers to each method being a significant contributor, rather than QUAN-qual where the quantitative methods would take precedence.

This study employed a mixed methods approach which included focus groups, in-depth semi-structured interviews, and an observational time series study. The mixed methods approach lends itself to a more comprehensive inquiry [10] to answer questions that one method alone cannot address. For example, while the quantitative data collection obtains the numbers of events that took place (ie, number of ambulance transports to emergency departments, number of visits with family physicians, number of medications prescribed, etc), it is the qualitative methods that delves into the complexity of health, health care, and the environment in which these events took place, helping to answer questions about why events occurred and what relationships exist between events. For the study to be truly mixed methods, the two approaches must be integrated [11-13].

Mixed methods is a valuable approach for this study, as the data gathered during the qualitative phase of the study informs the findings of the quantitative chart review. Similarly, the quantitative results demonstrate the outcomes related to perceptions and experiences shared by participants in the findings of the qualitative data.



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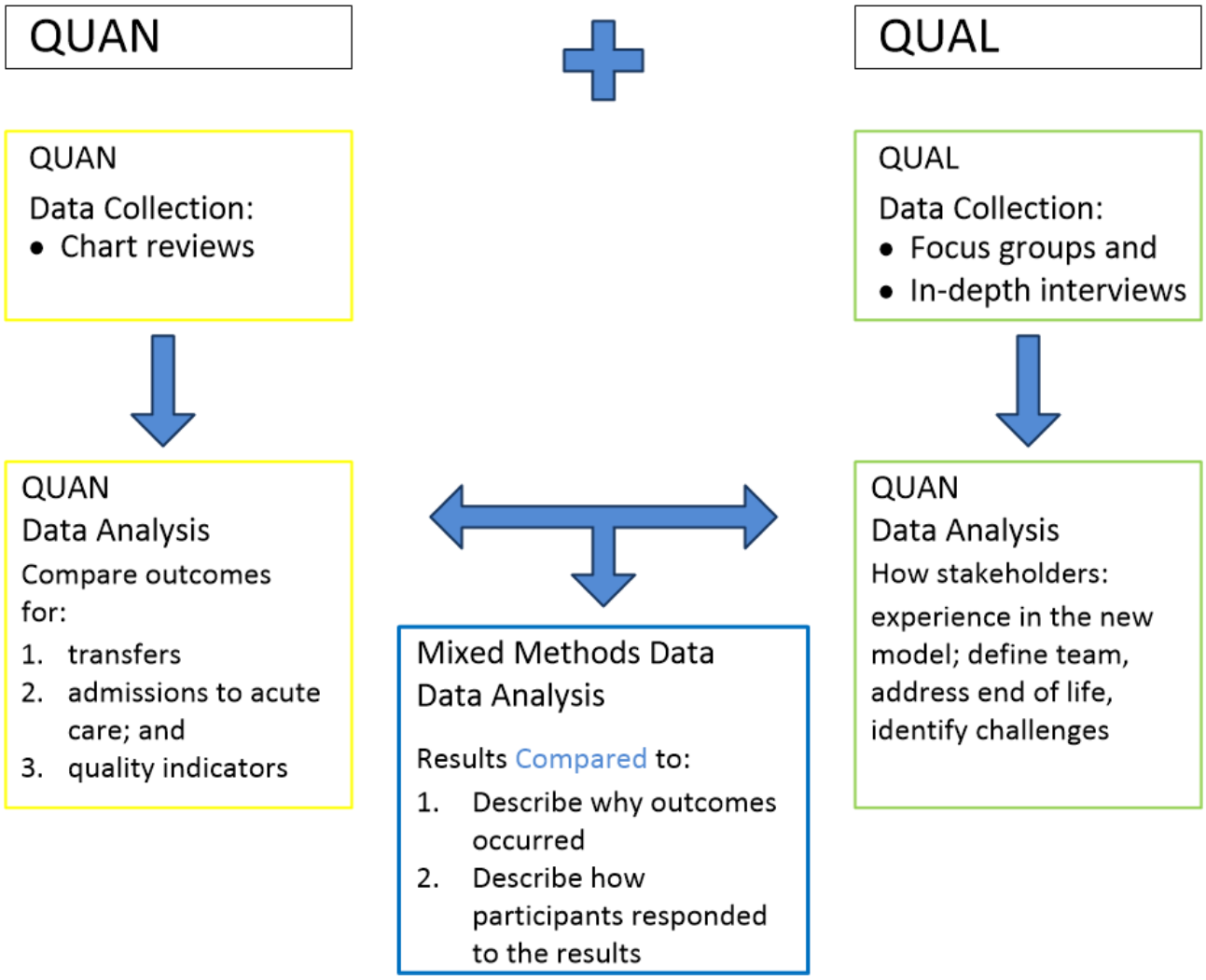
**Figure 2.** Concurrent Triangulation Design (adapted from Creswell and Clark 2011).




## Setting

In 2011, the Halifax, Nova Scotia census metropolitan area had a population of 390,328 people, with 13.1% aged 65 or older [14]. It is predicted that by 2036, 30% will be 65 and older, with 10% being over 80 years of age [15]. The CDHA is responsible for delivering core health services in the Halifax Regional Municipality. Ten of the twelve Care by Design participating LTCF located in the CDHA participated in the study. Two CDHA LTCF were excluded because their model of primary care differed from Care by Design in important ways which would make them difficult to compare: one is a teaching facility and one has a full-time "nursing home physician".

## Quantitative Approach

### *Overview*

The retrospective chart abstraction data are being collected from three time periods: time period 1: September 1, 2008-February 28, 2009 (before Care by Design or ECP programs in place); time period 2: September 1, 2010-January 31, 2011 (after Care by Design program implemented, before ECP program started. The original intent was to collect comparable six months of data from September 1, 2010 to February 28, 2011; however, due to early ECP training there was too much overlap in services for the month of February 2011); and time period 3: September 1, 2011-February 29, 2012 (after both Care by Design and ECP programs started; see Multimedia Appendix 2).

These time periods were chosen to reflect the implementation of different components of the new model of care, and to include the same months in each year in order to minimize confounding by seasonality (eg, transfer rates were expected to climb during influenza season each year). Data will be obtained using chart abstraction from three sources: LTCF charts, EHS records, and hospital emergency department and acute care charts.

### *Chart Abstraction Tool Development*

The starting point of our chart abstraction tool development is the PCOE project that examined the issue of LTCF to emergency department transfer in CDHA. As part of the PCOE project, a literature review was conducted and a paper chart abstraction tool with numerous indicators was developed and used. Our study team reviewed the PCOE tools, and revised them based on our newly developed objectives and research questions (see Table 1). The revised indicators were included in an Access database created for ease of data entry (Multimedia Appendix 9).



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**Table 1.** Research questions.

| Research questions |
|---|
| **Quantitative: What changes in health care outcomes are observed pre/post implementation of the new Care by Design model in LTCF?** |
| Is there a reduction in ambulance transfers to hospital with the new model of care? |
| Is there a reduction in the transfer of "comfort care" residents (for whom transfer to acute care is explicitly not part of the established goals of care) to hospital with the new model? |
| Is there a reduction in the rates of polypharmacy? |
| Is there a reduction in falls with the new model of care? |
| Is there improvement in wound care protocol adherence with new model of care? |
| Do we see increased care team communication recorded in charts? |
| Do we see a reduction in the number of attempts to contact family physicians to attend critical incidents with the new model? |
| **Qualitative: How do family doctors, nurse practitioners, registered nurses (RN), licensed practical nurses (LPN), continuing care assistants/personal care workers (CCA/PCW), administration and staff, ECP, and residents/families experience the new Care by Design model?** |
| What challenges exist under the new model? |
| How do the various stakeholders define the team? What would their ideal care team comprise and how would it function? |
| How does the model affect end-of-life care? (ie, Do families know who to talk to about end-of-life questions and planning? Are "comfort care" requests known and followed?) |
| **Knowledge Translation: How well-implemented and useful is the LTC-CGA as a knowledge translation tool?** |
| **Process goal. To study the implementation of the LTC-CGA tool as follows:** |
| What is the experience and perceived value of educating primary care physicians and nurses about the importance of the tool and how to use it? (eg, was training experienced as sufficient and well-implemented?) |
| What is the uptake of the LTC-CGA (ie, completion rates and completeness of all sections)? |
| Is the LTC-CGA acceptable to users? |
| Is the new billing code for LTC-CGA completion being used? |
| **Outcome goals:** |
| To test the efficacy of the LTC-CGA (ie, does its use improve care for older adults who live in LTCF)? Specific elements to be studied include usefulness in defining goals of care and impact on clinical care (eg, whether it accompanies residents transferred to emergency department, hospital admissions and inter-facility transfers). |
| Is the LTC-CGA useful for end-of-life discussions and planning? |
| **Mixed Methods: How do structure and process influence outcomes for residents and care providers?** |
| Which aspects of the new model are perceived to be attributed to changes observed in the chart review data by different stakeholders? |
| Do providers, administrators, and residents feel a reduction in ambulance transfers to emergency department (if found)? Is it indicative of better care for residents? Under what parameters would a reduction in transfers been experienced as improved care? What issues remain associated with ambulance transfers to emergency department under the new model of care in LTCF? (ie, access to physicians, communication, meeting the wishes and needs of residents, services provided by paramedics). |
| How do the various stakeholders experience the projected increase of residents dying in place in the LTCF? |
| What do stakeholders say about the ease-of-use and helpfulness of the LTC-CGA tool for team communication, care planning, and communication between providers and residents/family members? How does the completeness of the LTC-CGA reflect and have an impact on the experiences of stakeholders? |
| How is care team communication found in the chart reviews experienced by stakeholders? Are the experiences of team care approach under the new model captured in the chart review data? |

### *Outcomes and Data Elements*

Outcomes addressing specific research questions are categorized into three key areas: (1) system outcomes; (2) quality of clinical care; and (3) safety outcomes (see Table 2). Primary outcomes include transports of LTCF residents to emergency departments, polypharmacy (prevalence will be defined as 6 or more medications, a widely accepted definition that is associated with increased risk of inappropriate medication use and medication-related harms) [16], fall rates, wound care protocols, team communication, and provider contact.



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**Table 2.** Key outcome measures and data source.

| Category | Outcome measure | Data source |
|---|---|---|
| System Outcomes | Reason for 911 call (ie, breathing, falls, other) | LTCF charts |
| | Percentage of patients transported who had no visit from a family physician in LTCF within 1 and 4 weeks prior to transport to emergency department | LTCF charts |
| | Number of times family physician attended a team meeting during study time period | LTCF charts |
| | Family physician visits to patient 3 months prior to most recent Emergency Health Service call | LTCF charts |
| | Number of notes in chart from family physician during time period | LTCF charts |
| | Health care profession who made on-site assessment | LTCF charts |
| | Any investigations (ie, diagnostic imaging, blood work, other) 7 days prior to Emergency Health Service call | LTCF charts |
| | LTC-CGA present | LTCF charts; Hospital charts |
| | Percentage of cases where facility was able to reach the family physician prior to Emergency Health Service call | LTCF charts |
| | Percentage of cases with an onsite assessment by a family physician prior to Emergency Health Service call | LTCF charts |
| | Number of times Emergency Health Service (ECP and/or emergency paramedics) involved during time period | LTCF charts |
| | Number of patients transported to emergency department by ambulance | LTCF charts; EHS database |
| | Proportion of patients who are transported to emergency department who have advance comfort care directive requesting no transfer to hospital/acute care | LTCF charts; EHS database |
| | Whether LTC-CGA sent with resident to emergency department | Hospital charts |
| | If ECP involved in call | EHS database |
| | If ECP involved, whether they consulted with EHS physician | EHS database |
| | If ECP involved, whether they consulted with family physician | EHS database |
| | Length of Emergency Health Service call | EHS database |
| | Ambulance offload time in emergency department | EHS database; Hospital charts |
| | Length of stay in emergency department | Hospital charts |
| | Percentage of residents who were transported to emergency department that were admitted to hospital | Hospital charts |
| | Length of stay in hospital | Hospital charts |
| | Percentage of transferred residents who returned to LTCF upon hospital discharge | LTCF charts; Hospital charts |
| Clinical and Quality of Care | Number of assessments and treatments provided by Emergency Health Service | EHS database |
| | Admitting diagnosis | Hospital charts |
| | Death rate in hospital | Hospital charts |
| | Influenza vaccination rates | LTCF charts |
| | Rates of falls | LTCF charts |
| | Pressure wound care | LTCF charts |
| | Polypharmacy rates | LTCF charts |
| Safety Outcomes | Relapse rate back to Emergency Health Service system (number of patients seen by ECP and/or paramedics and not transported who had unexpected repeat 911 call made for them within 48 hours for a related reason) | EHS database |



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### *Participants*

We will proportionally sample and review a minimum 200 of the possible 1482 charts from LTCF (approximately 13% of all charts) during time periods 1 and 3 for whom a call to 911 for ambulance service was not made. We will also review all charts from hospital/ED transfers for all three time periods (estimated to be approximately 250 per time period). In addition, records of all hospital transfers during the study period will be reviewed from both emergency department and acute care charts.

### *Quantitative Data Collection*

Retrospective chart reviews will be conducted by three trained nurse research assistants on all residents' charts that had a 911 call from participating LTCF during the three time periods. In addition, a comparison stratified sample of 100 control LTCF charts of residents who did not have a 911 call made for them will be abstracted from time periods 1 and 3. These control charts are included to determine if any observed changes in access and coordination of care are the same as those who had 911 calls and will be stratified to be proportional to the size of the facility.

Data are being abstracted from three sources: LTCF charts, acute care charts, and an EHS database. Deterministic data linkage is used to match records from the three sources [17]. The data query begins with those with an emergency department transfer from an EHS database, which included records for all residents at participating LTCF who had a 911 call. The following data elements are provided for the purpose of linking EHS data to acute care and LTCF data: Emergency Health Service call identifier (to link to complete EHS dataset), health card number, date of service, date of birth, and location of service. Capital District Health Authority medical records required health card number, date of service, and date of birth to identify patient charts. Location of service is being used to ensure that the call was indeed from a LTCF. The health card number is the unique identifier to link datasets. If this element is missing from any of the data sources, the research associate will judge records as matching if date of service, date of birth, and location of service matched. Control charts of resident for whom 911 was not called will be reviewed as follows: 100 charts for time period 1 and 100 charts for time period 3, stratified proportionally from the difference LTCF based on their proportional number of beds.

A random sample of 10% of charts will be re-abstracted to assess inter-rater reliability between chart abstractors. LTCF charts had both paper and electronic format, depending on the LTCF and time period. All acute care charts existed within an electronic charting system. All chart abstraction data will be entered into a Microsoft Access database on a password-protected laptop computer. Data will then be entered into SPSS 20, cleaned, and prepared for analysis.

### *Planned Quantitative Analysis*

Descriptive statistics for outcome measures by time period will be explored initially for each outcome. Comparison of proportions and rates between time periods will be conducted. For example, chi-square analysis will be used to see if there is a change in the proportion of LTCF transports to emergency departments between time 1 and time 2. In another analysis, "number of physician notes in chart" will be turned into a categorical variable, and rates will be compared between time periods using chi-square and associated tests of strength of association (eg, eta). Later, we will explore multivariate regression models to predict primary outcomes. Types of regression models, such as continuous, logistic, and hierarchical modeling will be determined by the covariates chosen, and in relation to the research question under examination. For example, to predict LTCF transports to emergency departments, a logistic regression model would be developed using appropriate independent variables such as number of physician visits, frailty scores and polypharmacy. Significance is set a priori at $P<.05$.

## Qualitative Approach

### *Overview*

Qualitative data are collected through focus groups and individual interviews. Focus group and interview schedules were developed in consultation with the full research team. Digital audio recordings are transcribed verbatim and entered into Atlas.ti software for analysis.

### *Participants-Qualitative*

Focus group and interview participants live, work, or have a loved one living in a LTCF. They include a variety of key stakeholders – family physicians, nurse practitioners, RNs, LPNs, CCA/PCWs, residents, family members, ECP, and LTCF administrators. In the first stage, 11 focus groups were held with a range of 3-10 participants in each focus group, for a total of 75 key stakeholder focus group participants. One focus group was held for each of Care by Design physicians, LTCF administrators, and ECP. A total of 3 focus groups were conducted with RNs and LPNs, 2 with CCA/PCWs, and 3 with residents and/or family members. With an interview schedule based on preliminary analysis of focus group data, a total of 40 key stakeholders are participating in in-depth interviews (10 residents and/or family members; 3 administrators; 18 nurses (RNs & LPNs); 8 CCA/PCWs; 1 nurse practitioner, and 1 physician decision maker).

### *Qualitative Data Collection*

In the qualitative phase of the study we explore the lived experience under the new model from the perspectives of key stakeholders including family physicians, RNs, LPNs, LTCF administrators, CCA/PCWs, and ECP, as well as residents and family members (see focus group guides Multimedia Appendices 3-7). The qualitative component sheds light on how the model is working to meet the needs of providers and residents and where challenges still remain. This includes: (1) an exploration of how care teams are defined and experienced from the varied stakeholder perspectives; (2) whether the LTC-CGA facilitates better care for LTCF residents; and (3) how the new model functions in terms of end-of-life planning and communication between team members and with residents and families. The qualitative work considers recommendations for improvement and highlights significant benefits of the new model from the perspectives of key stakeholders.



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### *Qualitative Analysis*

Transcribed qualitative data is subject to rigorous data quality checks [18]. Transcriptions are entered into Atlas.ti qualitative data analysis software [19]. Data will be coded using an agreed-upon coding scheme developed by the research team. Thematic analysis, which allows for thematic coding within a structured framework approach, using open and axial coding to identify themes and categories as they emerge from the data will be used. Framework analysis [11, 20] will be conducted of narrative responses to open-ended questions about primary care and outcomes in LTCF, the acceptability of the Care by Design and ECP model, and its impact on clinical care.

### *Interpretive Lens: Framework Analysis*

A framework analysis approach, as described by Ritchie and Spencer (1994), will be used to describe and detect the phenomenon of interest [21]. This is a qualitative method of data analysis that is well-suited to research that has specific research questions, limited time frame, specific sample, and predefined issues [22]. It is particularly useful for explanatory analysis and understanding individual outcomes within a systems perspective [23]. Continually revisiting the question "what are the participants trying to describe?" allows the researcher to code for themes and describe the phenomenon in participants' own words. Use of this method allows the researcher to organize data while maintaining the original context and observations in which the data occurs, and to facilitate a systematic analysis [23], making it possible to track the researchers' interpretations, thus maintaining transparency and enhancing validity of the findings [24].

Framework analysis involves a series of five connected but distinct stages [21,22,25]. Data are sorted, charted, and sifted in accordance with key issues and themes, relying on the intuition and creativity of the analyst to see linkages among them. There is sufficient flexibility that analysis can wait until all data collection is complete, or it can begin part way through the study. Familiarization (step 1) will begin with becoming very familiar and comfortable with the data. These will be in the form of transcripts, written observations, and field notes. This will allow the analyst to become aware of any recurrent themes in the data. Development of a thematic framework (step 2) would follow. Emerging themes from within the data set form the basis of the thematic framework and can be used to sort and manage the data. Early consideration of connections between responses and relevance of identified issues begins at this stage. Careful notes of the framework development will be taken to increase transparency. The framework will be applied systematically, incorporating new data as it emerges (step 3). Step 3 is part of indexing, a process by which individual pieces of data are applied to the framework developed in step 2, allowing for easy access to the original context in which it was discovered. Charting (step 4) allows the researcher to build an understanding of the data as a whole. Data segments or quotes are arranged systematically in a chart or matrix according to the appropriate theme. Charts will include headings and subheadings developed in the thematic framework. The final stage (step 5), mapping and interpretation, involves analysis of key characteristics of the data, including associations between themes and creation of typologies.

The theoretical approach will incorporate Donabedian's classic structure, process, outcome framework for assessment of quality of care as it is widely applied in health services research field [26-28]. This framework, informed by Donabedian's framework, will assist with analysis and interpretation to ensure aspects of structure, process, and outcomes are assessed and linked [26-28].

## Planned and Potential Applications of Study Data

This work will have a wide range of applications for care providers, health care policy decision-makers, and research. It will provide analysis of the changes in LTCF health services and the impact on the healthcare, experience of stakeholders, quality of care, and possibly LTCF residents' quality of life. In addition, it will provide baseline data for improved health care planning in LTCF in Nova Scotia.

*Applications for care providers*: this study examines the health care and health outcomes of interdisciplinary care professionals from RNs, LPNs, CCA/PCWs, family physicians, and paramedics in LTCF. The results will inform aspects of the best practice related to primary care and team role integration. Results from this study not only provide insight into the impact of the changes resulting from Care by Design, but also identify areas for expansion and refinement of the model.

*Application for health care system*: this study examines the utilization of health care services and health professionals by residents in LTCF. Findings from this study will enable informed health care planning decisions and stimulate reform of legislation and regulation governing long-term health care delivery within the province.

*Applications for program evaluation of quality improvement*: as we plan for the health care and residential needs of our aging population, studies of this nature will be integral in developing methodology and findings related to program evaluation and quality improvement. This will be illustrated by analysis of the quantitative data at set intervals when new components to CBD were added. The data will provide information on the impact of each change on health services delivery in LTCF. The qualitative data will provide insight as to the nature of that impact and may identify areas for further quality improvement.

*Applications for research*: this work is an example of successful mixed methods evaluation research incorporating qualitative, quantitative, and mixed methods research questions and analytic techniques which may be useful to future research examining complex models of care. It provides a method of evaluation to compare other models of care for LTCF to further develop best practices. This method of evaluation will allow ongoing evaluation of future changes in the CBD model to maximize resource utilization in a cost effective manner.

In today's health care settings, there is a need to provide high-level, efficient, and quality care at all levels of a rapidly changing health care sector. This project will provide an example of evaluation of complex systems. They can be evaluated as change is occurring, providing comprehensive



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information of both quantitative and qualitative aspects of the change.

## Discussion

### Summary

Using mixed methods design, this study of Care by Design will add to the literature using methods to evaluate new models of primary care, and will contribute to the discussion on evidence-based health policy development, and will provide direct feedback to Care by Design stakeholders. In the mixed methods design different sources of time series chart abstraction data (over three time periods) relating to the implementation of Care by Design, and qualitative data from focus groups and interviews are combined for a comprehensive analysis. Led by an interdisciplinary research team, this multifaceted study design allows for examination of long-term care at several levels including system and structural elements, process elements including team collaboration and coordination, role integration, and care plan development and implementation; as well as analysis of health care and health status outcomes across LTCF residents. This study provides insight and recommendations at all levels of long-term care delivery and assesses the success and challenges of the components of Care by Design and ECP.

### Research Team

The interdisciplinary research team consists of experienced primary care researchers, a geriatrician-researcher, health services researchers, and care providers (family physicians, paramedics, emergency physicians, nurse practitioners, and nurses), long-term care administrators and residents' advocate. There is a strong representation of methodological skills including mixed methods, qualitative methods (including both focus groups and interviews), statistical analysis, chart abstraction, and large database analysis experience.

### Acknowledgments

We acknowledge our team members, Andrew Travers and Gary MacLeod, for their contributions to the conceptualization of the research questions and methods described in this manuscript. In addition, we thank the focus group and interview participants for sharing their time and experiences with us. This project would not have been as successful without the support of the administrators from the 10 participating LTCF. They knew the value in evaluating the new model of care and supported the project from the grant application stage through to data collection. They backed the project by providing letters of support to the funding agency and ethics board along with granting us access to their residents' charts and physical space to conduct the chart abstraction work. They also provided support through offering space for focus groups and interviews along with promoting the project with staff, residents, and family members.

Funding for this study was provided by Capital Health Research Fund, Dalhousie Department of Family Medicine, the office of the Director of Continuing Care (CDHA), Canadian Dementia Knowledge Translation Network, and the Network for End of Life Studies Interdisciplinary Capacity Enhancement. The study was approved by the CDHA Research Ethics board and also by the individual Research Ethics boards of participating LTCF in facilities where these existed.

### Authors' Contributions

EM is the principal investigator of the grant funded research implementing the protocol of the study she designed, conceived the protocol paper, and led the writing of the protocol. In addition, EM conceptualized and led the writing of this manuscript. MB is the project manager for the study, is conducting the qualitative data collection and analysis, and assisted in drafting the manuscript under EM's supervision. JJ is a co-investigator who contributed to the development of the methods, coordinated the retrieval of the EHS data, and is involved in the data analysis, interpretation, and manuscript development. MA, BC, FB, GA, and AT are co-investigators who were a part of the research team from its inception and contributed to all phases of the research and manuscript preparation. NE is a co-investigator and is involved in the qualitative research component of the project. All authors contributed to the development of the protocol and provided feedback and edits for the final manuscript.

### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Long-term care comprehensive geriatric assessment Tool.

[PDF File (Adobe PDF File), 104KB - resprot_v2i2e56_app1.pdf ]

### Multimedia Appendix 2

Care by Design study periods.

[PDF File (Adobe PDF File), 63KB - resprot_v2i2e56_app2.pdf ]



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### Multimedia Appendix 3

Focus group guide – administration and administrative staff.

[PDF File (Adobe PDF File), 37KB - resprot_v2i2e56_app3.pdf ]

### Multimedia Appendix 4

Focus group guide – nurses.

[PDF File (Adobe PDF File), 33KB - resprot_v2i2e56_app4.pdf ]

### Multimedia Appendix 5

Focus group guide – extended care paramedics.

[PDF File (Adobe PDF File), 34KB - resprot_v2i2e56_app5.pdf ]

### Multimedia Appendix 6

Focus group guide – physicians.

[PDF File (Adobe PDF File), 35KB - resprot_v2i2e56_app6.pdf ]

### Multimedia Appendix 7

Focus group guide – residents and/or family members.

[PDF File (Adobe PDF File), 37KB - resprot_v2i2e56_app7.pdf ]

### Multimedia Appendix 8

Care by Design path.

[PDF File (Adobe PDF File), 288KB - resprot_v2i2e56_app8.pdf ]

### Multimedia Appendix 9

Key Indicators.

[PDF File (Adobe PDF File), 30KB - resprot_v2i2e56_app9.pdf ]

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## Abbreviations

**CCA:** continuing care assistant
**CDHA:** Capital District Health Authority
**ECP:** extended care paramedics
**LPN:** licensed practical nurse
**LTCF:** long-term care facility
**LTC-CGA:** Long-Term Care Comprehensive Geriatric Assessment
**PCOE:** Primary Care of the Elderly
**QUAL:** qualitative
**QUAN:** quantitative



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Original Paper

# An Internet-Based Intervention (Condom-Him) to Increase Condom Use Among HIV-Positive Men Who Have Sex With Men: Protocol for a Randomized Controlled Trial

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## Abstract

**Background:** In the recent years, the Internet has been used as a medium to find sexual partners and engage in risky sexual behavior. This has changed the way in which men having have sex with men (MSM) seek sexual partners and has increased the number of high-risk sexual encounters. Therefore, developers of human immunodeficiency virus (HIV)-prevention interventions have also started using the Internet as a viable medium to promote safe sexual behaviors. However, much of the efforts thus far have been aimed at HIV-negative rather than HIV-positive MSM. HIV-positive individuals continue to engage in risky sexual behaviors and thus constitute an important group in which HIV prevention strategies need to be addressed. Therefore, HIV prevention in HIV-positive MSM is a critical issue.

**Objective:** Condom-Him, an Internet-based intervention tailored to increase condom use among HIV-positive MSM, was developed with the aim of improving condom use, self-efficacy, and intentions to use condoms among these individuals. The acceptability and feasibility of this Internet-based intervention will be examined in a pilot study.

**Methods:** We will perform a randomized controlled parallel-group superiority trial. HIV-positive MSM who currently engage in unprotected anal sex will be recruited for the study. Participants will be randomly assigned using a one-to-one allocation ratio generated by the computer program. The researchers will be blinded to participant's group assignment. Participants will be assigned either to use the Condom-Him intervention (experimental arm) or to view a list of websites containing HIV/AIDS related information (control arm). Self-administered questionnaires will be provided online before randomization (baseline) and two weeks after intervention (post-test).

**Results:** The study will include a total of 60 participants with 30 in each group. The results from this pilot study will provide further evidence for a larger study to examine the effectiveness of this intervention and will provide a cost-effective and widely accessible approach to HIV prevention for HIV-positive MSM.



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**Conclusions:** Internet-based interventions for HIV-positive MSM, a population that has been under-represented in the efforts for positive prevention of HIV within Canada, have the potential to provide a cost-effective strategy, which influences the way in which information is accessed and provided to high-risk individuals. The advantages of an Internet-based intervention include the potential to provide consistency in the delivery of an intervention and the ability to disseminate the intervention to a wider population. Internet-based interventions are perceived as vital tools in combating HIV infection within the realm of social media. Therefore, it is important to determine the feasibility and acceptability of these interventions before implementing them.

**Trial Registration:** Clinicaltrials.gov: NCT01726153; http://clinicaltrials.gov/ct2/show/NCT01726153 (Archived by WebCite at http://www.webcitation.org/6Jljzip8B).

***(JMIR Res Protoc 2013;2(2):e39)*** doi:10.2196/resprot.2723

**KEYWORDS**

HIV-positive; men having sex with men; condom use; self-efficacy; intention; HIV prevention; pilot study; intervention

## Introduction

### Overview

The number of human immunodeficiency virus (HIV)-positive individuals continues to increase in Canada. Among the high-risk groups, the group of men having sex with men (MSM) accounted for the greatest proportion (44%) of new infections in 2008 [1]. Various studies, which target the sexual risk behaviors of HIV-positive MSM, have found that 10% to 60% of these individuals do not routinely practice safe sex [2]. In addition, MSM recently infected with HIV had a median of 20 sexual partners within the previous year, and they continued to repeatedly engage in high-risk sexual behavior, particularly unprotected anal intercourse [3]. Moreover, 34% of MSM recently diagnosed with an HIV infection did not change their risk behaviors after the diagnosis of their condition, and 20% actually increased their risk behaviors after the diagnosis [3]. The potential outcomes of engaging in unprotected sex with partners who are HIV-negative or whose status is unknown are the possibility of infecting others with HIV and putting oneself at risk for contracting sexually transmitted infections (eg, syphilis, gonorrhea, and herpes virus infection) [4]. Many individuals who engage in risky sexual behaviors use the Internet to meet their sexual partners, and the Internet itself may facilitate such risk-taking behaviors [5,6]. In keeping with the current trends, the individuals working in the field of prevention of HIV infection need to incorporate the same medium as that used by high-risk individuals to reduce risky sexual behaviors. Thus, developing technological innovations such as Internet-based interventions is critical.

### Computer-Based Online Interventions

Computer-technology-based interventions (CBIs) [7] provide an alternative to human-delivered interventions for prevention of HIV infection. Noar, Black, and Pierce [8] defined CBIs as those that use computer technology as the primary or sole medium for intervention delivery. To date, few trials of health interventions that use computer technology and are conducted entirely online have been performed [9]. In the case of such interventions, all aspects of the study must be implemented online, that is, participant recruitment, randomization process, data collection, and delivery of the actual intervention. Many of the current CBIs recruit participants using methods other than the Internet and collect data in a face-to-face format, and only provide the actual intervention online.

### Advantages of Internet-Based Studies

Previously, HIV prevention interventions were mainly delivered on individual or group levels. However, many clinical and community settings do not have adequate human resources required for implementation of such methods [8]. Therefore, the ability to disseminate efficacious interventions into many practice settings remains limited. In addition, the barriers and challenges of intervention fidelity have limited the public health impact of behavioral HIV prevention interventions [8]. CBIs have the advantage of providing consistency in the delivery of an intervention and enable participants to initialize their participation in the study at any time of the day and at a location convenient to them. Online participation removes barriers such as scheduling times and human resources that may restrict participants' participation or the ability to provide the intervention to a number of individuals. For example, individuals in rural settings, for whom it may be difficult to access the resources, would able to participate in the CBIs without the costs associated with travel and/or taking time off from work. Further, the anonymity provided by Internet-based interventions is an advantage, specifically to those who may feel stigmatized. For instance, individuals who have not yet disclosed their HIV infection status and who may feel hesitant about participating in an intervention geared towards those who are HIV-positive could participate in such CBIs because the disclosure factor would not be relevant with an Internet-based intervention. In addition, a previous study has shown that typically, participants answering questionnaires online report higher rates of sexual behavior than in pen-and-paper or interview formats [7]. Moreover, the cost associated with Internet-based interventions is low, and human facilitators are not required for implementation of the intervention; therefore, the intervention can be run on numerous occasions. In addition, the data collection methods are less costly because questionnaires do not have to be mailed to the participants, and in-person are not required for collecting data [9]. Finally, online data collection is quicker, because the need for booking appointments or mailing questionnaires is eliminated. Online questionnaires are immediately available to participants for completion, and thus provide immediate accessibility to the data.



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### Interventions to Foster Condom Use Among HIV-Positive MSM

Previously, HIV prevention programs were primarily focused on HIV-negative subjects or subjects whose HIV status was unknown. Safe sex behaviors such as condom use should also be practiced by HIV-positive individuals. However, little attention has been focused on interventions targeting this population. The National Institute of Health and the Centers for Disease Control and Prevention have identified a need for behavioral interventions in HIV-positive individuals [10]. To fill this scientific gap, we plan to conduct an online pilot randomized controlled trial (RCT) to evaluate the acceptability and feasibility of Condom-Him, an Internet-based intervention developed to promote condom use among HIV-positive MSM with partners who are HIV-negative or whose status is unknown.

The primary outcome of the tailored Internet-based intervention is to increase condom use among HIV-positive MSM. The primary objective of this study is to examine the overall acceptability and feasibility of the tailored Internet-based intervention. The secondary objective of this study is to examine the preliminary efficacy of the tailored Internet-based intervention in increasing self-efficacy and intention to use condoms.

## Methods

### Study Design

The design of the proposed pilot study to evaluate the acceptability and feasibility and acceptability of the tailored Internet-based intervention in increasing condom use among HIV-positive MSM is a randomized controlled parallel-group superiority trial (NCT01726153). The flow of participants within the randomized control trial is shown in Figure 1. Participants will be randomly assigned using a one-to-one allocation ratio. Random assignment will occur only after participants have completed baseline questionnaires. The random assignment will be performed by the computer system that has been programmed by the computer/Web-intervention programmer. Participants cannot be blinded to their assigned arm. Individuals within the control arm receiving a list of various websites will be aware they have not been allocated to use the tailored Internet-based intervention. Participants in the experimental arm (Condom-Him) will be aware that they have been allocated to use the tailored Internet-based intervention. The researcher will be blinded to the participant's treatment assignment. The research assistant, who will be downloading the data, will be the only individual aware of the participant's assignment. The research assistant will not have any participation in the random assignment of participants because this process does not involve any individuals and is entirely performed using the computer program. The outcomes of the study will be collected at two time points: pre-intervention (T0) and two weeks after intervention (T1). The participants will be sent an email two weeks after the intervention to remind them to revisit the study website to complete the post-test questionnaires. The study has been approved by the research ethics board of both the academic and research institutions.

### Experimental Arm: Condom-Him

The tailored Internet-based intervention Condom-Him was designed to increase condom use, self-efficacy in condom use, and intention to use condoms among HIV-positive MSM and their partners who are HIV-negative or whose HIV infection status is unknown. The welcome page of the Condom-Him intervention study is shown in Figure 2. Condom-Him is a tailored interactive single session lasting approximately one hour. The single session is tailored to the specific needs of the participants determined from their responses to the baseline questionnaire about self-efficacy and intention to use condoms. The intervention was tailored on the basis of cutoff scores for self-efficacy and intention measures. On the basis of their responses, the participants are classified into the high or low self-efficacy in condom use groups. A cutoff score of 0-23 indicates high self-efficacy, and a cutoff score of 24-48 indicates low self-efficacy. In addition, the intention to use condoms was also tailored using a cutoff score of 0-2, which indicated a low intention, and a score of 3, which indicated a high intention to use condoms. Subsequently, the participants were profiled into one of the four possible profiles: (1) high self-efficacy and intention, (2) low self-efficacy and intention, (3) low self-efficacy and high intention, and (4) high self-efficacy and low intention. The participants were then guided through the online session by a virtual "peer", who provides tailored intervention messages particular to their profile in addition to providing stories and videos and interactive activities to increase self-efficacy and intention to use condoms. The single session is divided into three segments to increase condom use, self-efficacy in condom use, and intention to use condoms as follows: (1) planning condom use when having anal intercourse, (2) negotiating the use of a condom with a partner, and (3) choosing not to have sexual intercourse without a condom.

Within each of the three segments of the intervention, participants are given tailored messages pertaining to the focus of the segment. The Intervention Mapping method was used to develop the intervention. This process consists of six consecutive steps to systematically develop health promotion programs using theory, empirical evidence from the literature, and additional evidence from research [11]. The theory-informed methods and practical strategies selected to increase condom use practices of the target population were consistent with the social cognitive theory and the theory of planned behavior.



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**Figure 1.** Flow of participants through randomized control trial. As the study is in progress, some n='s are left blank.

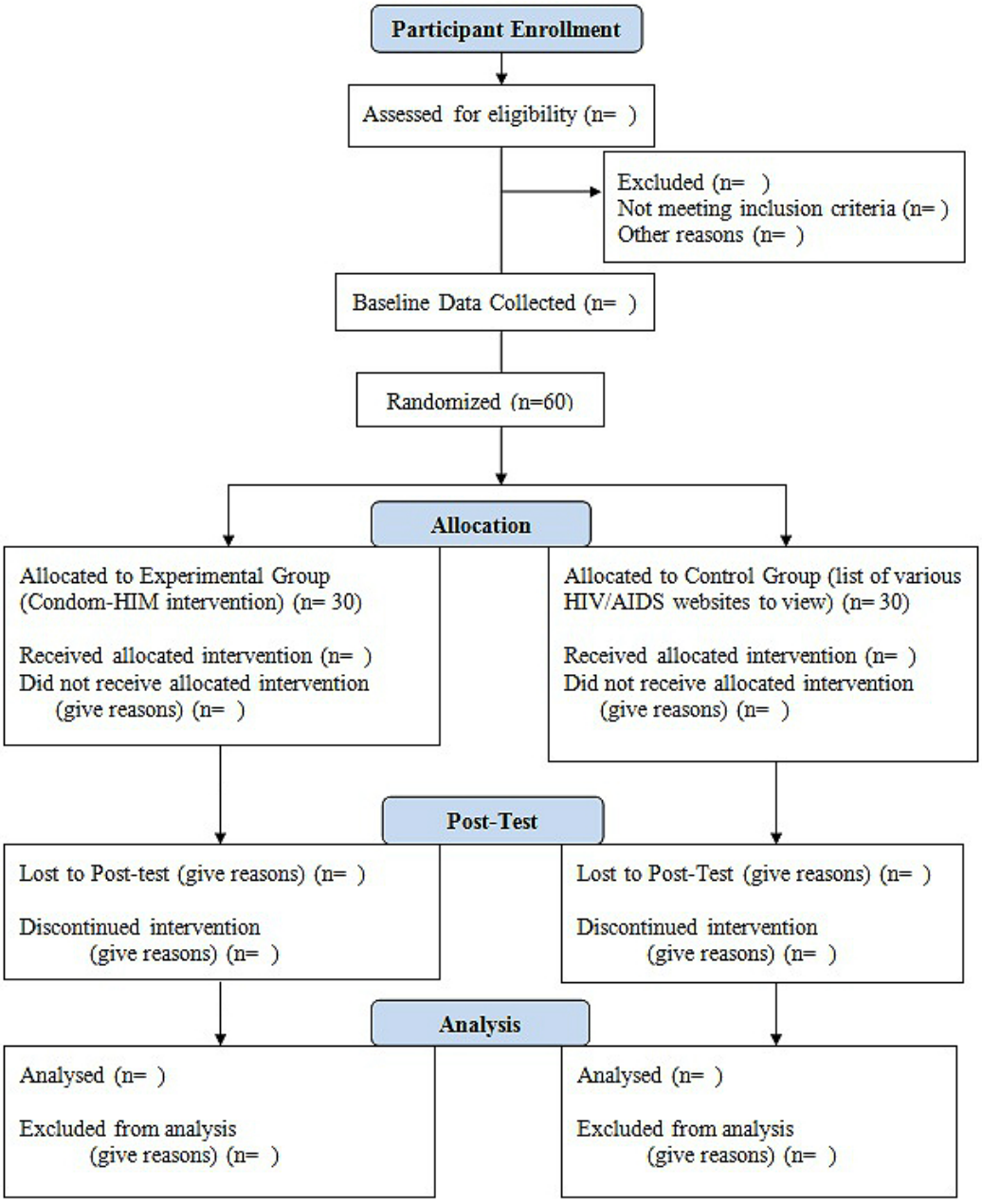




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**Figure 2.** A screenshot of the Condom-Him intervention study.


## Control Arm

The control arm involves links to various websites that address standard information HIV/acquired immunodeficiency syndrome (AIDS). Participants in the control group are invited to view this list of predetermined websites at their convenience.

## Sample Size

Because of the pre-experimental nature of the proposed pilot RCT study, we aim to achieve a sample size of 60 with 30 participants per group. The sample size calculation is based on the rule of 10 cases per independent variable included in the analysis [12]. A convenience sample of participants will be randomly assigned either to the experimental arm (Condom-Him) or to the control arm, which includes a list of various websites providing information relating to HIV/AIDS.

## Planned Inclusion Criteria

Individuals will be selected to participate in the study if they meet the following preset inclusion criteria: (1) 18 years of age or older, (2) HIV-positive, (3) MSM, (4) engage in unprotected anal intercourse with a partner who is HIV-negative or whose HIV infection status is unknown, (5) read English, and (6) have access to a computer and the Internet.

## Participant Recruitment

A two-pronged approach will be used to recruit participants. The first method of recruitment will use Internet-based methods (ie, advertisement in chat rooms, online classified advertisements, social media such as Facebook and Twitter, and links to the intervention website posted within various HIV/AIDS community center websites). The second method of recruitment will use offline strategies (ie, flyers and brochures will be posted in various community sexual health clinics). In addition, advertisements in local newspapers will be used to aid in participant recruitment. Participants interested in the study will be directed to the study website where further information about the study will be provided via a video. The interested participants will be asked to complete a Web-based consent form. The consent form will provide information relating to the study in addition to telephone numbers and email addresses of the research staff for further questions before consenting to participate.

## Random Assignment

Eligible consenting participants will be randomly assigned either to an experimental group (Condom-Him) or to a control group (list of websites with various HIV/AIDS information). The participant assignment protocol will be based on a ratio of 1:1, which will be performed using a computer program. The computer program will automatically allocate participants randomly to the experimental or control groups. Because of the automatic nature of the allocation process, direct exposure to the treatment allocation process by any members of the research team is eliminated.

## Measurements

All measurements are self-administered online. The data that is collected online will be stored on a secure server located at the Research Chair, Centre Hospitalier de l'Université de Montreal.



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### Sociodemographic Characteristics

Standard questions will be used to record age, level of education, and sexual history such as date of HIV-positive result, current involvement in treatment, current viral load count, type of partner (casual/primary partner), perceived status of the partner (positive, negative, or unknown), and previous exposure to any sexually transmitted diseases.

### Self-Efficacy

The self-efficacy for condom use measure contains a set of items to rate the belief of participants that within the next 6 months, they will be able to use condoms every time they have anal sex in different situations with a partner who is HIV-negative or whose HIV infection status is unknown. A 4-point response scale, which ranges from "strongly agree" (0) to "strongly disagree" (4) is used. The psychometric properties of the measure show good internal consistency; Cronbach alpha=.96 [13].

### Intention to Use Condoms

To measure the intention of the participants to use condoms, participants are asked three questions about their intentions over the next 6 months to use a condom. The scale is a 2-point response ("certainly not"/"yes certainly"). The psychometric properties of the measure show good internal consistency; Cronbach alpha=.89 [13].

### Condom Use

To determine condom use, the participants are asked the following question "In the past 2 weeks, thinking about the times you had anal sex with a regular or casual male partner, what percentage of times did you use a condom with someone who was HIV-negative or of unknown status"? This measure showed acceptable psychometric properties [13].

### Acceptability of Condom-Him

The Treatment Acceptability Measure Used for Hiv Prevention Interventions [14] Contains a Set of Items for the Participants to Rate the (1) Appropriateness and Suitability of the Intervention to Assist With Increasing Condom Use, (2) Effectiveness of the Intervention in Helping Them Increase Their Condom Use, and (3) Convenience (ie, Ease of Implementation) and Willingness to Comply With the Intervention Strategies/activities. We Used a 4-Point Response Scale, Which Ranged From "not At All" (0) to "very Much" (4). High Scores Reflect a Positive or Favorable Appraisal of the Intervention. the Psychometric Properties of the Measure Show a Good Internal Consistency; Cronbach Alpha=.86 [15]. in Addition, the Measure Contains Two Qualitative Questions Asking Participants to Indicate "what Makes This Intervention Most and Least Appealing".

### Feasibility of Condom-Him

The feasibility of the Internet-based intervention will be measured through the recruitment and retention rates, duration of intervention participation, and need for prompts or reminders to complete the post-test questionnaire.

### Utilization of Condom-Him

The utilization of the Internet-based intervention will be measured on the basis of the length of time the participant spent in completing the single session.

### Analysis

#### *Preliminary Analysis*

Descriptive statistics will be used to characterize the participants in terms of a sociodemographic profile. We will examine the distribution of these variables for normality, which is required for subsequent statistical analyses.

#### *Analysis to Address Study Objectives*

Independent *t* tests will be used to examine the differences between the control and experimental groups in terms of the participants' self-efficacy, intention to use condoms, and actual condom use before the intervention and 2 weeks after the intervention.

Descriptive statistics will be used to examine the acceptability rating of the intervention. In addition, qualitative responses of the participants to open-ended questions about what they find most and least appealing about the Condom-Him will be analyzed to identify the strengths and weaknesses of the intervention as perceived by the participants. Recruitment and retention rates for the control and experimental groups will be used to determine the feasibility of the intervention and online data collection methods. Lastly, descriptive statistics will be used to examine the utilization of the intervention.

## Results

The results of this pilot study will enable researchers to understand the feasibility, acceptability, utilization, and preliminary efficacy of the Condom-Him Internet-based intervention in increasing condom use for HIV-positive MSM. In addition, the results of this study will highlight the possibilities and potential challenges inherent in Internet-based intervention research. Further, our results will enable designing of a larger RCT to determine the effectiveness of the Condom-Him Internet-based intervention. Rosser et al [6] showed that in countries with high Internet penetration, Internet-based interventions appear to be the most promising approaches for prevention of HIV infection. The Internet-based intervention could provide a cost-effective and widely accessible strategy for prevention of HIV infection, particularly in HIV-positive MSM, a population that has been under served and yet represents a high-risk group for transmitting HIV through unprotected anal intercourse. Our RCT has been funded, and we have started the recruitment and intervention phase. Results of the pilot RCT are expected in September 2013.

## Discussion

Our proposed study protocol has some limitations. The accuracy of self-reporting may be a cause of concern when dealing with reports of sexual practices. However, previous studies indicate that participants report higher rates of sexual practices when completing Internet-based questionnaires than those of a



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paper-pencil format. This may be because of the nature of anonymity provided by the Internet-based questionnaires. Further, an Internet-based intervention may perpetuate a divide between those who regularly use a computer and have access to the Internet and those who do not. The recruitment methods proposed in the protocol outline methods that use both online and offline strategies. These strategies aim to minimize the divide in recruiting only those participants that regularly use a computer and the Internet. Participants interested in participating in the study may do complete the Internet-based questionnaire at their convenience. Retention of participants is often a concern with Internet-based interventions. To minimize the loss of participants to follow-up, a friendly email is automatically sent to the participant 2 weeks after the intervention as a reminder to visit the Internet-based intervention to complete the post-test questionnaire. In addition, the participants are notified that if a problem occurs, they are able to contact the research team via email or telephone for help with accessing the Internet-based intervention. Data security is often a concern with Internet-based interventions. Within this study, the data collected are stored on a server, which is located within one of research centers of the affiliated universities. The server is managed by an extensive information technology team with firewalls built into the system. The data are only accessible to the researcher and one information technology expert on the research team. The data collected are coded and downloaded into SPSS for further analysis. Subsequently, the data on the server are removed and destroyed.

## Acknowledgments

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [16].

[PDF File (Adobe PDF File), 981KB - resprot_v2i2e39_app1.pdf ]

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## Abbreviations

**AIDS:** acquired immunodeficiency syndrome
**CBIs:** computer-technology-based interventions
**HIV:** human immunodeficiency virus
**MSM:** men having sex with men
**RCT:** randomized controlled trial

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Protocol

# Share2Quit: Web-Based Peer-Driven Referrals for Smoking Cessation

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## Abstract

**Background:** Smoking is the number one preventable cause of death in the United States. Effective Web-assisted tobacco interventions are often underutilized and require new and innovative engagement approaches. Web-based peer-driven chain referrals successfully used outside health care have the potential for increasing the reach of Internet interventions.

**Objective:** The objective of our study was to describe the protocol for the development and testing of proactive Web-based chain-referral tools for increasing the access to Decide2Quit.org, a Web-assisted tobacco intervention system.

**Methods:** We will build and refine proactive chain-referral tools, including email and Facebook referrals. In addition, we will implement respondent-driven sampling (RDS), a controlled chain-referral sampling technique designed to remove inherent biases in chain referrals and obtain a representative sample. We will begin our chain referrals with an initial recruitment of former and current smokers as seeds (initial participants) who will be trained to refer current smokers from their social network using the developed tools. In turn, these newly referred smokers will also be provided the tools to refer other smokers from their social networks. We will model predictors of referral success using sample weights from the RDS to estimate the success of the system in the targeted population.

**Results:** This protocol describes the evaluation of proactive Web-based chain-referral tools, which can be used in tobacco interventions to increase the access to hard-to-reach populations, for promoting smoking cessation.

**Conclusions:** Share2Quit represents an innovative advancement by capitalizing on naturally occurring technology trends to recruit smokers to Web-assisted tobacco interventions.

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**KEYWORDS**

Web-assisted tobacco interventions; recruitment; peer-driven chain referrals; respondent-driven sampling



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## Introduction

Smoking is the number one preventable cause of premature death in the United States [1-5]. Although cessation programs have been successfully implemented, the rates of cessation are lower than desired [6]. Effective and easily disseminated interventions such as Web-based smoking cessation websites [7-12,4,13-14] can reach a greater number of smokers [15]. However, these interventions are underutilized [16-18].

Chain-referral methods have rapidly become the methods of choice for recruiting hard-to-reach subjects from their social networks [19-20] and have been used as channels for delivery of a peer-driven intervention [21]. Natural helpers or "Peer Navigators (PNs)" from the community can be trained to effectively deliver health information while increasing access to interventions [22-23]. These "grassroots" and participatory chain referrals unfold in line with the social network dynamics. Hence, PNs facilitate access to high-risk groups, in which individuals are often "like themselves", within relatively short periods of time. Person-to-person spread of cessation has been a vital factor in the population-level decline in smoking in the recent decades [24]. Furthermore, the decision to stop smoking is not solely an individual one but a reflection of the choices made by groups of people connected to each other [24].

Outside health care, Web-based chain referrals have become quite common to recruit users. Consider the example of the Obama campaign's use of Facebook to reach unlisted young voters through their friend networks [25] or the example of using peer referrals to recruit more than 75 million users to play a Facebook game called Farmville. However, Web-based chain referrals as a means to recruit patients to online health interventions has not been extensively studied thus far.

Because proactive referrals are more successful than passive referrals [26-29], in our trial, Share2Quit: Web-Based Peer-Driven Referrals for Smoking Cessation, we will build and test a suite of proactive Web-based tools such as email and Facebook referral functions to recruit smokers to a Web-based tobacco intervention system (Decide2Quit.org). We will use respondent-driven sampling (RDS), a controlled chain-referral sampling technique designed to remove inherent biases in chain referrals and obtain a representative sample [30,20]. We hypothesized that smokers with a high social connectivity will have higher numbers of successful recruits. In addition, we hypothesized that the referral success will be higher for women than men. In this paper, we describe our development and research protocol.

## Methods

### Overview

Our goal in the Share2Quit trial is to use chain referrals to recruit smokers to Decide2Quit.org, an evidence-based Web-assisted tobacco intervention system. Decide2Quit.org includes multiple tobacco cessation functions, including tailored patient messaging, secure messaging with tobacco treatment specialists, interactive patient education, and smoking cessation planning [31-33]. On the basis of the projected costs for each sample unit, which depend on the number of seeds we recruit and the number who might complete the follow-up questionnaire, we project a sample size of up to 1200 under the constraint of our budget. The protocol below describes our approach of tool development, and our plan to implement the RDS chain referrals. The Share2Quit study has been approved by the University of Massachusetts Medical School Institutional Review Board.

### Respondent-Driven Sampling

#### *Rationale*

Chain-referral methods yield a convenience sample that is not necessarily a representative sample of the population of interest. RDS provides a method of quantifying and adjusting for biased samples [30,20]. Using RDS sample weights we may be able to say, for example, whether a certain demographic or risk group is underrepresented in our sample. In addition, RDS methods provide a means of ensuring that our sample is not overly correlated with the initial sample "seeds", which are non-randomly selected and are likely not representative of the overall population.

Similar to other chain referrals, RDS begins with identifying the initial participants (initial PNs), known as "seeds", who have a particular characteristic of interest. The initial seeds then recruit individuals from their current social or risk-behavior network for participation in the study. Successive sets of respondents then recruit individuals from their social network for participation. RDS implements behavioral compliance through a group-mediated control triggered by secondary incentives [20]. Incentives are of two types: primary incentives that are given directly to an individual for completing a task, and secondary incentives that are given to a peer to elicit participation from another peer. Secondary incentives are more powerful because peers have better access to participants and can overcome barriers, influence participation, and more effectively monitor participants [20].

RDS has several key requirements, including [30] (1) the population being recruited must be socially networked and (2) starting with the PN seeds, each participant is allowed to recruit no more than a pre-specified number of recruits (a recruitment quota). Quotas are an important control for PNs with larger networks to prevent over-recruiting from among their peers, and thereby creating biased samples with shorter chains [34-35,20]. Online, the quotas will also reduce the potential of recruiting solely for incentives because the total incentive is limited.

We will implement multiple strategies as described below to keep the number of seeds and the number of recruitments per sample unit low, and thus reduce the correlation between sample units. A recent critique [36] of RDS showed that high levels of assortativity (like-with-like preferential attachment) within the social network can drastically increase the variance of RDS estimators. Assortativity is the propensity with which the nodes of similar connectivity are connected to each other [36-37]. However, the efficiency of the sampling method can be considerably improved using few simple modifications. We propose the following two innovations to RDS.



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### *Innovation 1: Adaptive Sampling Strategy to Decrease Intra-Sample Correlation*

Intra-sample correlation describes how strongly units in the same group describe each other that is, it measures the relatedness of two individuals in the chain [38]. A previous study showed that the covariance between sample units in a chain-referral design is a decreasing function of distance between the sample units in the recruitment chain, where n is the sample size, $n_S$ is the sample size for units with state *S* (eg, a given race or age profile), $d_{uv}$ is the distance between units u and v in the recruitment chain, and σ is a matrix of Markovian transition probabilities and the estimated proportion of the population with state *S* [39].

A straightforward way to decrease the intra-sample correlations and thereby increase the precision of samples obtained using RDS is to modify the sampling process in such a way that this average distance is increased. We have devised an adaptive sampling algorithm to address this issue. The algorithm operates by finding an optimal recruitment quota, which changes as the sample is collected. The quota is selected in a way that maximizes the probability that the sample will be collected at the desired rate (recruitments per unit time) while minimizing the probability of the recruitment chain from dying out.

RDS samples have significant uncertainty in the timing and logistics of sample collection because the referral process depends on the behavior of the study population that is not known ahead of time. For example, the speed of sample collection depends on the number of recruitments made per respondent (Share2Quit PN) and the average time between initial recruitment of the PN and subsequent referral. This problem also affects the decision of the number of seeds to be use to initialize the sample.

To address the problems of sample design with respect to seed selection and choosing an appropriate recruitment quota, Dr Volz developed the respondent-driven sampling simulator (RDSS) [40], which will allow us to simulate thousands of recruitment trees given the underlying parameters such as the recruitment quota and number of seeds. The main output of these simulations is the length of time required to achieve the desired sample size, as well as the probability of sample failure (the probability that the recruitment tree does not achieve the required sample size because of non-response). This information will allow us to determine the optimal number of seeds and recruitment quota.

Additional sample design considerations must be made because both referrals and the study surveys are expected to take place online. We have recently gained valuable insights into Internet-based RDS by conducting a study [41] of 3448 young adults (ages 18-24) across the United States designed to assess Internet use, drug use, and sexual risk behaviors. Several findings from this study can be applied to Share2Quit. To prevent fraudulent recruitment, such as when an individual adopts multiple personas with the objective of interviewing multiple times, it is important to actively observe the chain-referral process for warning signs, such as multiple recruitments from related IP blocks and email addresses. Online recruitment is generally much faster than standard coupon-based recruitment. Certain demographics, especially the highly educated white males and Asians, have been observed to recruit at a much higher rate than the other sociodemographic groups. To prevent this trend from skewing the composition of the sample toward these demographics, it is essential to control the interval between interviews of the recruiter and those that are nominated by the recruiter. This is accomplished by tuning the time between the interview and when our system sends out the invitation to the nominated individuals.

### *Innovation 2: Improved Estimation of Sample Weight*

Methods for estimation of sample weight may utilize sociometric degree as well as the assortative mixing patterns of respondents. Several competing estimates were compared in a recent study, which showed that one of the most simple estimators is also relatively stable and accurate. Therefore, in this study, we intend to use variations of the RDS2 estimator [42]. We propose to use additional sociometric information not ordinarily collected during RDS studies. We used the counting procedure of McCarty et al [43] and assessed the sociometric degree in categories such as age, race, gender, and the type of relationship. This approach not only yields accurate estimates of the total degree but also provides information about assortative mixing patterns in the underlying social network. Information of the assortativity patterns enables us to devise accurate estimates of sample inclusion probabilities; for example, if most recruitments are made by men, we would adjust upwards the estimated inclusion probability for someone who reports knowing many men. We call the estimator that uses this auxiliary estimator RDS2+[39]. These new methods have not been implemented in an empirical setting thus far, and Share2Quit provides an appropriate test-bed.

## Preliminary Concept of the Intervention

Initially, we will describe our preliminary concept of the intervention and then describe how we will refine it by using user input. The tools that we plan to develop for Share2Quit are as follows:

- Automated recruitment messages: PNs can use a secure email or Facebook form to market the intervention. Once the smoker completes an online consent form, the PNs can refer this individual to the intervention simply by entering his/her email or Facebook ID into a secure form. The referred smoker will then receive a series of 10 automated emails or Facebook messages encouraging him/her to register on the intervention website.
- Feedback reports and persuasive message templates: After making initial referrals, the PNs will be provided feedback reports on the registration status of their recruits. The system will allow the PNs to prompt referred smokers to register by using specific messaging templates (a menu of motivational and informational messages that the PNs may choose to modify). Templates will be created as communication facilitators, so PNs navigators do not have to create messages but can just “pick and send”
- Social networking widgets: Share2Quit will have a menu of social networking widgets (eg, quit smoking progress counter and link to a “chemicals in smoking game”). These



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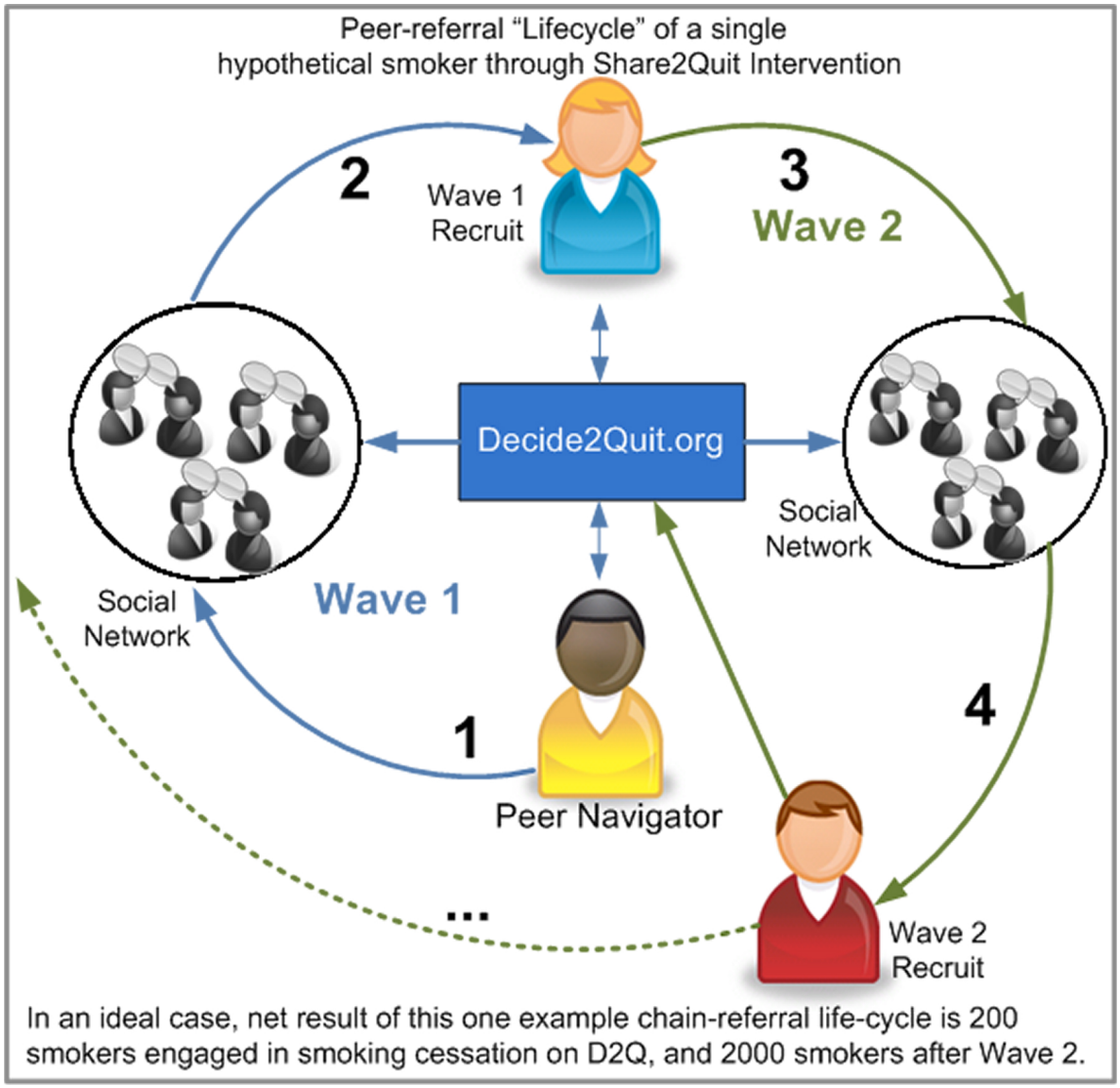
widgets allow PNs to share information on Decide2Quit.org with their social network.

The goal of these components is to recruit and engage new smokers to the intervention site and, subsequently, recruit the same group of smokers to chain-refer within their social networks. Share2Quit will begin with the recruitment of an initial set of seed PNs. The flow of the referral "lifecycle" of a single PN through the Share2Quit intervention is shown in Figure 1. To initiate the intervention, a PN (P1) will use the Share2Quit tools to engage and recruit a current smoker from their social network to register on the intervention website. The current smokers (Wave1-1, Wave1-2, etc) will then register on intervention site and will begin to use the Decide2Quit.org system. As part of the system, after their first visit to the website, these new smokers will be recruited to engage as PNs, so that they may also refer current smokers in their social network (W2-1, etc). We will adhere to the best practices of RDS and maintain a low quota, but the actual number will be based on our formative work and the adaptive sampling strategy described above.

**Figure 1.** Equation for covariance between sample units in a chain-referral design.

$$\hat{Cov}\left(S(u),S(v)\right) = \hat{P}_S^2\left(\frac{n}{n_s}\left(\sigma^{d_{uv}}\right)_{SS} - 1\right)$$

**Figure 2.** Peer-referral "Lifecycle" of a single hypothetical smoker through Share2Quit Intervention: 1: Seeds or peer navigator consents to be in the study and refers smokers from his network using S2Q tools. The system contacts the referred smokers and prompts them to register. 2: The referred smokers register on the system and consents to become a peer navigator (Wave 1 recruit). 3: The Wave 1 recruit then refers smokers from their social network and similarly the system prompts these smokers to register. 4: The referred smokers then registers on the system (Wave 2 recruit). 5: The chains progress until the target sample size is reached.



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### Designing the RDS Chains Using RDS Simulations

We will perform RDS simulations to provide information about the design of our chains. RDSS requires the following data to simulate the RDS chains: (1) time required for recruitment and (2) number of expected recruits per seed (ie, how many social contacts the respondent thought would be open to chain-referral recruitment). Thus, our first step will include an online survey of smokers (n=50). We will recruit these smokers through Google advertisements. We will assess the number of smokers an online smoker is connected with, the strength of these social ties, and the time to recruit. In addition, we will assess prior referral behavior and willingness to refer to a Web-assisted tobacco intervention system (see Multimedia Appendix 1 for our draft survey instrument).

### Integrating Share2Quit Tools With Our Previous Work (Decide2Quit.org) Using an Agile Methodology

The Web-based Decide2Quit.org was programmed using Microsoft's ASP.NET version 3.5 (Microsoft Corporation, Redmond, WA, USA) and C# technology. We used Microsoft SQL Server version 2000 as the database. Decide2Quit.org was programmed using a modular architecture, which makes it easier to add Share2Quit functionalities. We will develop Share2Quit functions using an Agile methodology that is characterized by its phased and collaborative nature [44]. Unlike traditional approaches, the Agile methodology recommends forming an overall strategy and then collaboratively developing a system in phases. This approach is especially advantageous in a research setting because developers can easily adapt to changing requirements. Share2Quit functions will be developed in compliance with Health Insurance Portability and Accountability Act (HIPAA) standards using Secure Socket Layer technology.

### Usability Testing of Chain-Referral Tools

#### *Overview*

Current and ex-smokers (5-10) will be recruited from central Massachusetts to perform individual in-depth interviews alpha testing the potential human-computer interface. We will use the "Think Aloud" protocols described by Kushniruk [45,46] as follows: while the participants are reviewing the content and interacting with the program, they will be asked to vocalize their thoughts, feelings, and opinions. Think Aloud allows you to understand how the user approaches the interface and what considerations they have in mind when utilizing the interface. Usability sessions will be conducted by the UMass Division of Health Informatics mobile usability lab and Morae usability software. Morae [47] has successfully been utilized in testing Web-based software [48,49] and enables live remote observation of the subject being tested (eg, recording of clicks, keystrokes, and other events). In addition, Morae allows for annotation of the usability sessions by the observer. Prompts will be used to elicit the response on any item for which the user has not provided feedback (see Multimedia Appendix 2 for sample usability prompts). We will exclude these pilot test participants from the main study.

#### *Interview Analysis*

Interviews will be transcribed and anonymized. There are several approaches to evaluating qualitative data, including thematic analysis, narrative summary, and grounded theory [50]. Because our primary goal is to understand the process of using Share2Quit, we will use a combination of thematic and narrative analyses. The transcribed interviews will be reviewed by two independent reviewers to develop preliminary themes. To develop themes, we will use an open-coding approach to be maximally inclusive. Each open-ended question in the interview guide will be assessed separately, and then the reviewer will generate larger summary themes for the overall interview. The themes will then be reviewed with the larger investigator group to resolve disagreements. From the themes, we will create summary tables of key points. We will complete this method twice while collecting interviews. Thus, we will assess for theme saturation and further revise our data collection methods to focus on details of interest for the second wave of interviews. Narrative summary is best used when qualitative data follow a logical order [51]. On the basis of the interview transcriptions and example Share2Quit tools provided to smokers, we will develop Share2Quit workflow process diagrams to be used in system development and education of PNs.

### Intervention

#### *Overview*

The intervention will begin with the recruitment of seeds. Current and former smokers above the age of 21 will be eligible to participate as seeds. We will recruit seeds using multiple approaches. Initially, we will recruit from the current cohort of smokers already registered in Decide2Quit.org. Between 2010 and 2012, we recruited 1777 smokers in our current R01 (NIH 5R01CA129091-04). We will email these smokers offering them the opportunity to participate in Share2Quit and refer smokers. In addition, we will recruit seeds through Google and Facebook advertisements. Once the seed consents using an online form, he or she will be provided access for 30 days to refer the smokers. We will begin with a recruitment quota of 3 as recommended in the RDS best practices, but we may increase the quota on the basis of RDSS simulations as described above on the actual referral data. Once these seeds refer smokers, newly registered smokers will also be offered the opportunity to recruit additional smokers. Seeds and PNs will have to complete an informed consent form before being provided with the referral tools. Each smoker will be provided a monetary incentive for recruiting smokers.

#### *Data Collection and Analyses*

We will collect data at multiple points in time, including at registration with our system, at agreement to be a PN, at referral, and at follow-up. We will use our existing Web analytics tracking program to monitor use of the system. We will use this tracking data and determine our primary outcome variables of referral success. These include the number of successful new recruits per recruiter and the length of subsequent referral chains. All PNs and recruits will be connected through a unique identifier. Follow-up will be conducted after seeds and PNs have 30 days of access to the tools. We plan to perform 3



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analyses: an evaluation of the impact of each component tool of Share2Quit, a comparison of the characteristics of chain-referred smokers to those recruited through physician practices, and identification of predictors of successful recruitment chains (adjusted using RDS sample weights). In addition to the new smoker registration, we have expanded data collection to include the pre-referral (PN survey), during referral, and follow-up time periods (Table 1 and Multimedia Appendix 3 [41,52-55]).

**Table 1.** Key data elements.[a]

| Data elements | Parameters tested |
|---|---|
| New smoker registration | Demographics (age, gender, ethnicity, education, marital status) |
| | Smoking-related comorbidities |
| | Allow smoking at home |
| | Number of cigarettes smoked per day |
| | Quit in last 12 months |
| | Want to stop smoking |
| Peer-navigator survey | Number of estimated smokers in network (family, friends, and acquaintances) |
| | Previous website referrals |
| | Number of subjects willing to be referred |
| | Syme/Berkman Social Network Index [52,53] |
| Share2Quit referral form | Demographics of referred smoker (age, sex, race) |
| | Nature of relationship with referrer |
| | Length of relationship |
| | Number of interactions |
| | Tools used for interactions |
| PN follow-up survey | Number of subjects attempted to refer |
| | Sociometrics of refused (friend, family, or acquaintance) |
| | Influence on PN smoking |
| | Satisfaction with Share2Quit tools |
| Decide2Quit.org Web tracking (all users) | Number of logons, pages visited, time on page, etc |
| | Number of referrals |
| | Number of new registrations |

[a]All instruments linked through unique RDS ID codes to connect recruitment waves

### *Comparing Samples*

Our new smoker registration survey includes demographic questions, tobacco use behaviors, and previous participation in Web-based smoking cessation sites. We will compare the RDS sample characteristics with those of our current samples obtained from physicians and dentists by conducting a bivariate analysis.

### *Tool Success*

In this study, we will allow PNs to select the tools they use. We will track the use of these tools online. Then, we will compare the impact of each tool and tool combination on measures of referral success

### *Primary Analyses*

RDS-sample weighted network analysis (predictors of successful referrals): As discussed, we will use RDS to generate a sample of chain-referred smokers. In previous Web-based RDS analyses, the investigators noted that some sociometric “stars” who become hubs are highly successful at referring. We propose analyses to understand which characteristics of those referred can be used to predict registration, and which characteristics of the PNs can be used to predict successful chain referrals.

We propose to evaluate age, sex, ethnicity, and measures of social connectedness. We hypothesize that PNs who report high social connectivity will have higher numbers of successful recruits. In addition, we hypothesize that referral success will be higher for women than men. Inferences about the social network will be drawn from data collected during recruitment, and this data will be used to create sample weights. All analyses will use these sample weights generated from the RDS to make inferences for the population of interest. Our primary analysis will assess the association of social connectedness and a measure of referral success. Our outcome variable will be the number of referrals by a PN. The independent variable will be the Social Network Index from the adapted Syme/Berkman social network scale (I=lowest score, IV=highest score) [53]. This scale comprises 4 components (marital status, contacts with friends



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and family, membership in groups, and group associations), and we will use them for our study. We will first compare bivariate associations, and then perform multivariable modeling using ordinal logistics adjusted for variation in tool use and other predictors significant in bivariate association or those that need to be included because of our conceptual rationale.

### Power Calculations for Comparing the Association of Referral Success and Social Connectedness

Our main hypothesis is that people who are highly socially connected (as measured by the social network scale [52,53]) will have a higher proportion of referrals than those not very socially connected. Although we expect a sample up to 1200, power calculations for RDS samples must acknowledge the association between recruits and are adjusted for a design factor (up to 2) [36]. Thus, for power calculations, we have reduced the real sample size of 1200 to an adjusted, effective sample size of 600 to be conservative (Table 2). While the recent work by Goel et al [36] suggests that a more appropriate design effect for power calculations would be 5-10, we believe on the basis of stochastic simulation that the modifications to the sample design (such as the adaptive recruitment quota) will shrink the design effect to 2-3. As discussed, we will use an adaptive sampling strategy, varying timing and quotas dynamically under the guidance of Dr Volz. To simplify power calculation, we assume that each PN will be able to recruit up to 2-3 new smokers because of our quota. Although each PN has a truncated range of recruitment (eg, 0-3 recruits out of 3 possible), when averaged over groups of PNs, we can approximate a proportion. We based the power calculation to detect a significant difference in the proportions of successful referrals in two groups on the basis of dichotomization of the social network scale. We assume that a certain number of the 600 referees will be highly socially connected and will have a certain proportion of successful referrals. We show detectable differences in Table 2. Sample size of 300 in each group achieves 80% power to detect a difference between the group proportions of -0.06 if group one has 10% of successful referrals (successful referrals in group two will be 4% or 0.04) and can still detect a 11% difference if group one has 50% successful referrals (successful referrals in second group will be 39% or 0.39). The test statistic used is the two-sided Z test with pooled variance and a targeted alpha level of 0.05. Calculations were made using PASS [56]. Because of the small number of seeds and a restricted range, the proportion (or count) may not represent a continuous variable. In addition to standard approaches, we will use quantile regression if required depending on the distribution of the outcome. Quantile regression is a different method of approaching central tendencies and dispersion that can be used for categorical outcomes.

**Table 2.** Power calculations for comparing the association of referral success and social connectedness.

| Number of highly socially connected peer navigators ($N_1$) | Number of peer navigators not highly socially connected ($N_2$) | Proportion of successful referrals among $N_1$ | Absolute detectable difference |
|---|---|---|---|
| 300 | 300 | 0.1 | 0.06 |
| 300 | 300 | 0.5 | 0.11 |
| 200 | 400 | 0.1 | 0.06 |
| 200 | 400 | 0.5 | 0.12 |
| 100 | 500 | 0.1 | 0.07 |
| 100 | 500 | 0.5 | 0.15 |

## Results

This protocol describes the evaluation of proactive Web-based chain-referral tools, which can be used in tobacco interventions to increase the access to hard-to-reach populations, for promoting smoking cessation.

## Discussion

Our overall goal is to increase access to a smoking cessation intervention by recruiting PNs (former and current smokers) who will be trained to refer current smokers from their social network. Previous studies and our preliminary data suggest multiple barriers in the reach of smoking cessation interventions, including those delivered online. Thus, new approaches are required to increase the reach of these interventions [57].

Peer navigation leverages current online trends because social network tools are increasingly popular. For example, Facebook has over 99 million users [58]. On an average, users spend 55 minutes daily on Facebook, maintaining 130 “friends”, writing 25 content-related critiques, and rating via the “like” button 9 times per month [59]. Facebook users are more likely to trust peer referrals to products [60-62]. Moreover, social network referral tools such as the “like” and “become a fan” mechanisms, are pivotal in attracting new users. A recent survey showed that 41% of respondents claim that they joined a Facebook fan page to communicate to their friends what products they support [60-62]. These findings are not limited to one demographic group. In addition to Whites (31%), Hispanics (50%), Asians (46%), and African Americans (44%) consider social networks a useful tool for researching new products [61].

To our knowledge, Share2Quit will be the first study to test online social networks and chain referrals to proactively recruit smokers to a Web-based smoking cessation intervention. Thus, Share2Quit represents an innovative advancement by capitalizing on a combination of naturally occurring technology trends to recruit smokers to our Decide2Quit.org Internet-based cessation intervention. Drawing from our previous Web-based



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smoking intervention work, Share2Quit will test a suite of tools designed to allow PNs to market and prompt current smokers within their social network to participate in a cessation site. Share2Quit PNs will be selected from a pool of smokers currently participating in Decide2Quit.org. Given that the PNs will be connected to the smoker(s), recruitment messages are more likely to be personally relevant and more effective than conventional advertisements. Share2Quit will implement best practices of RDS and the recent innovations of WebRDS, including the use of multiple strategies to keep the recruitment quotas low, adaptive sampling to decrease intra-sample correlation, and collection of additional sociometric information to enhance sample weights. Thus, our approach is uniquely suited to recruit smokers that may otherwise be considered hard-to-reach [19]. We will track the referrals through unique identifiers to better facilitate an analysis of the social networks.

Our study has some limitations. Like most online light-touch interventions, the data we are collecting on the PNs is mostly through self-report, and we cannot confirm the veracity of these data. Because our study is a highly innovative, high-risk study, considerable uncertainty is present in our sample size calculation, and we may have overestimated this number.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Share2Quit interview.

[PDF File (Adobe PDF File), 159KB - resprot_v2i2e37_app1.pdf ]

## Multimedia Appendix 2

Share2Quit interview with usability prompts.

[PDF File (Adobe PDF File), 142KB - resprot_v2i2e37_app2.pdf ]

## Multimedia Appendix 3

Key data elements.

[PDF File (Adobe PDF File), 413KB - resprot_v2i2e37_app3.pdf ]

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## Abbreviations

**HIPAA:** Health Insurance Portability and Accountability Act
**PN:** peer navigator
**RDS:** respondent-driven sampling

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Protocol

# A Prospective Natural History Study of Quitting or Reducing Gambling With or Without Treatment: Protocol

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## Abstract

**Background:** Only a small percentage of gamblers ever seek treatment, often due to stigma, embarrassment, or a desire to handle their problems on their own. While the majority of pathological gamblers who achieve remittance do so without accessing formal treatment, factors related to successful resolution have not been thoroughly explored.

**Objective:** Employing a prospective natural history design, the study will therefore undertake an investigation to explore life events, motivating factors, and strategies used by problem gamblers to quit or reduce their gambling without formal treatment.

**Methods:** Prospective participants (19 years or older) currently gambling at problematic levels with strong intentions toward quitting gambling will be directed to fill out a Web-based survey. Eligible participants will subsequently complete a survey that will assess: (1) types, frequency, and amount of money spent on gambling, (2) life events experienced in the past 12 months, (3) level of autonomous motivation for change, and (4) use of treatment services. Every 3 months for the duration of one year following the completion of their baseline survey, participants will be sent an email notification requesting them to complete a follow-up survey similar in content to the baseline survey. The four surveys will assess whether participants have experienced changes in their gambling behaviors along with positive or negative life events and motivations for change since the last survey. Individuals who are in the action and maintenance stages of quitting gambling at follow-up will be also asked about their techniques and strategies used to quit or reduce gambling. At 18 months post baseline, participants will be asked to complete a fifth and final follow-up survey that will also assess whether participants have experienced any barriers to change and whether they resolved their gambling to low risk levels.

**Results:** The study has commenced in May 2013 and is currently in the recruitment stage. The study is scheduled to conclude in 2016.

**Conclusions:** As this study will examine the active ingredients in natural recovery from gambling problems, the results will inform ways of promoting change among the large number of problem gamblers who do not seek treatment as well as improve treatment for those who do seek help. The information gained will also be useful in identifying effective self-help strategies for those who face challenges in accessing treatment, may be incorporated in standard treatment, provide brief intervention techniques, as well as inform relapse prevention strategies.

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**KEYWORDS**

gambling; treatment; life events; motivational factors; natural recovery; prospective natural history study; longitudinal study



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## Introduction

### Natural Recovery From Addictions

Natural recovery from addictions is not a recently recognized phenomenon. A variety of terms have been used to describe it including self-change, spontaneous remission, maturing out, and natural remission [1]. Recognition of natural recovery has been met with resistance because the majority of the research on addictive disorders has used clinical treatment samples and because the traditional disease model of addiction has typically regarded addiction as progressive and irreversible. However, over the past couple of decades, a significant amount of research has focused on exploring the natural course of various types of addictions. This research has revealed that recovery from addictions without formal treatment is common [2].

### Natural History Research of Problem Gambling

There are three main types of natural history research: (1) epidemiological studies that examine the prevalence of untreated change from an addictive behavior, (2) retrospective natural history research that recruits samples of former problem gamblers who quit or reduced their gambling at some point in the past and explores how they succeeded with this change, and (3) prospective natural history studies that recruit gamblers who intend to quit or reduce their gambling and follows them over time to explore factors associated with successful change. Each of these types of research has its strengths and weaknesses. Epidemiological survey research has the advantage of employing representative samples, but often lacks a "depth" of information that allows the researcher to explore factors associated with change. Slutske [3] used two epidemiological surveys from the United States and found that the majority of people who remitted from pathological gambling did so without accessing treatment or Gamblers Anonymous (only 7-12% sought treatment). Similar results have been noted in Ontario, Canada [4]. Retrospective research studies can recruit samples of people who had serious gambling problems that they dealt with in the past without treatment. Further, retrospective studies can go in depth into the factors that lead to the person's recovery. In the gambling research area, this method has been employed in two studies [5,6]. The studies found that participants emphasized reasons for change such as emotional and financial consequences, hitting "rock bottom," and issues related to self-image. In addition, both studies found that resolved problem gamblers with more severe gambling problems prior to resolution were more likely to have accessed treatment as compared to those with less severe problems prior to resolution. Finally, a study by Hodgins and el-Guebaly [5] found evidence for a life-events driven process of recovery without treatment such that resolved participants endorsed an increase in positive life events and a decrease in negative life events when comparing the time before to the time after resolving their gambling problems. The importance of this life-events driven process in recoveries without treatment has also been noted in retrospective research involving other addictive behaviors [7]. Specifically, in the context of alcohol-related problems, particular life events have been shown to contribute to recovery and sustained remissions to a much greater degree than maturing-out reasons or interventions from medical personnel or family members [8,9]. In this larger research area, motivation has been identified as the other main theme responsible for driving and maintaining change and recovery from ones' addiction, particularly, internally driven recognition of the need to change [7,10]. Hodgins and el-Guebaly [5], in particular, have noted that in addition to life events, recovered gamblers attributed intrinsic/autonomous motivational factors such as using "will power," establishing self-respect/goal commitment, and a sense of accomplishment/pride as those responsible for maintaining their state of change. While these cognitive/motivationally laden intrinsic factors may indeed contribute to maintaining a recovered state, past research was unable to address how intrinsic motivations help individuals recover naturally in the first place.

Retrospective natural history research, while being a powerful tool to investigate processes of change, suffers from the weakness of the potential of a recall bias (ie, the event under study often occurred many years in the past and participants' recall may be faulty). While prospective natural history research cannot often explore resolutions in as much depth as retrospective studies, prospective research has the distinct advantage of circumventing difficulties with faulty recall of events because change from problem gambling occurs after the initial measure of the predictor variables. Further, the hypothesized factors believed to be important in predicting successful change (collected before the actual change was made) can be related prospectively to successful change in order to differentiate those people who actually succeed from those who relapse back to problem gambling.

Despite the strengths of a prospective research design for natural history research, very little research of this type has been conducted. In the area of alcohol research, prospective studies have been conducted by Tucker [11] and Cunningham [12] with Tucker examining the role of discretionary spending on alcohol as a predictor of success at resolution from alcohol problems, and Cunningham exploring the relative contributions of life events and motivation for change as predictors of successful long-term resolutions. For gambling, Hodgins and el-Guebaly [13] conducted the only relevant study in which relapse to pathological gambling was prospectively related to hypothesized precipitants. While the subjects employed in this study had primarily attended or were currently attending treatment (making the study less relevant to research on untreated recovery), the results are interesting in that the most frequently reported attributions prior to relapse had to do with cognitions about winning and feeling the need to make money. The present prospective natural history study will differ from that conducted by Hodgins and el-Guebaly, in that we will explore the factors related to successful resolution from gambling problems rather than those factors related to relapse to pathological gambling. In addition, we will recruit samples of treated and untreated participants in order to allow comparisons of these two pathways to change.

### Specific Aims

The prospective natural history study will attempt to explore factors that relate to successful recovery from gambling problems. By examining prospectively both treatment assisted



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and natural recovery participants in a community sample, this study will investigate and address the factors related to successful resolution and reduction of gambling behaviors. In addition, the study will also examine and identify techniques related to maintenance and successful recovery from gambling problems.

### Hypotheses

Following the present natural history literature on the topic of recovery from gambling problems, three primary hypotheses are made.

The first hypothesis, life events, states that participants who experience an increase in positive life events and a decrease in negative life events will be more likely to display reductions in their problem gambling severity.

The second hypothesis, motivational, states that participants who display autonomous motivation for change will be more likely to reduce their problem gambling severity as compared to those who display nonautonomous motivation for change.

The third hypothesis, severity, states that participants with more severe gambling problems will be less likely to succeed at their change without treatment as compared to those with less severe gambling problems.

## Methods

### Participants

Participants will be recruited using a comprehensive strategy employing newspaper, Web-based, and television advertisements. Prospective individuals, 19 years or older, will be directed to fill out a brief Web-based screener that assesses age, problem gambling severity, and attitudes and intentions toward quitting gambling according to the transtheoretical model (TTM) of behavioral change [14]. Eligibility of individuals will be determined by agreement to be followed-up, a current score of 5 or more on the Problem Gambling Severity Index (PGSI) [15], and seriously thinking of quitting or cutting back gambling within the next 6 months (contemplation stage) or 30 days (preparation stage). Participants who have ever used, are currently using, or are planning on using treatment for their gambling concerns will not be excluded from the study. These participants will instead be treated as a comparison group since the same natural history hypotheses are relevant to both treated and untreated problem gamblers.

### Study Design and Procedures

The prospective natural history study will recruit problem gamblers who are seriously thinking of quitting or cutting back gambling within the next 6 months or 30 days, and follow them over an 18-month period to examine factors and techniques related to quitting or reducing gambling with or without treatment. Potential participants, self-identified as seriously thinking of quitting gambling will be directed to log on to a website listed on the advertisement. Subsequently, individuals, will be directed to a webpage containing a consent form, where they will be asked to enter their email address and confirm that they have read and understood the research and their rights before proceeding to a brief Web-based screener. The standing research ethics board of the Center for Addiction and Mental Health has approved this study. The brief screener will assess age, problem gambling severity, and attitudes and intentions toward quitting gambling according to the TTM of behavioral change [14]. Individuals identified as 19 years or older, seriously thinking of quitting or cutting down their gambling in the next 6 months or 30 days, currently gambling at problem gambling levels (PGSI score of 5 or more will be used to determine problem gambling), and willing to be followed-up for the duration of 18 months will be deemed eligible for study participation [15]. In an effort to engage participants in the study and reduce the likelihood of loss at follow-up, participants who are identified as eligible, based on their responses to the Web-based screener, will be immediately notified that they will receive a paper consent form in the mail in a few days. These individuals will be sent a paper consent form to sign and return in a postage-prepaid envelope in order to be invited to complete the baseline survey. Participants deemed ineligible, as per the screener, will be told that only if they are found eligible will they be contacted to fill out the baseline survey.

Following the return of a signed paper consent form, participants meeting eligibility criteria will be sent an email notification requesting them to fill out a baseline survey. The baseline survey will assess: (1) demographic characteristics and types, frequency, and amount of money spent on gambling, (2) life events experienced in the past 12 months (Life Events Questionnaire) [16], (3) level of autonomous motivation for change using the Treatment Self-Regulation Scale adapted for gambling to address intrinsic health change behavior [17-19]; guilt and shame proneness using the Test of Self-Conscious Affect, Version 3 (TOSCA-3) [20], (4) alcohol consumption using the Alcohol Use Disorder Identification Test-C (AUDIT-C) [21], (5) use of treatment services, and (6) past and current drug use and mental health diagnoses of Diagnostic and Statistical Manual of Mental Disorders-IV Axis-I disorders. Following the completion of the baseline survey, participants will be included as part of the study and will be sent an honorarium in the form of a $20 Amazon.ca gift certificate. At 3 months and every 3 months for the duration of one year following the completion of their baseline survey, participants will be sent an email notification requesting them to click on a hyperlinked Web address to complete a follow-up survey. Figure 1 shows the diagram of the study design. The four follow-up surveys will be similar in content to the baseline survey and will assess whether participants have experienced changes in their gambling behaviors along with positive or negative life events and motivations for change in the past three months. Individuals who are in the action and maintenance stages of quitting gambling at follow-up will be also asked of their techniques and strategies used to quit or reduce gambling using the Process of Change Questionnaire [22,23] modified for gambling. Following the completion of each follow-up survey, participants will be sent an additional $20 Amazon.ca gift certificate honrarium. In order to remain consistent and ensure that all participants are answering questions in the same manner, the point of reference for the four follow-up surveys will be life events, motivations, and gambling behavior in the last 3 months. At 6 months after completion of the fourth follow-up (18 months post baseline) survey, participants will be asked to complete a



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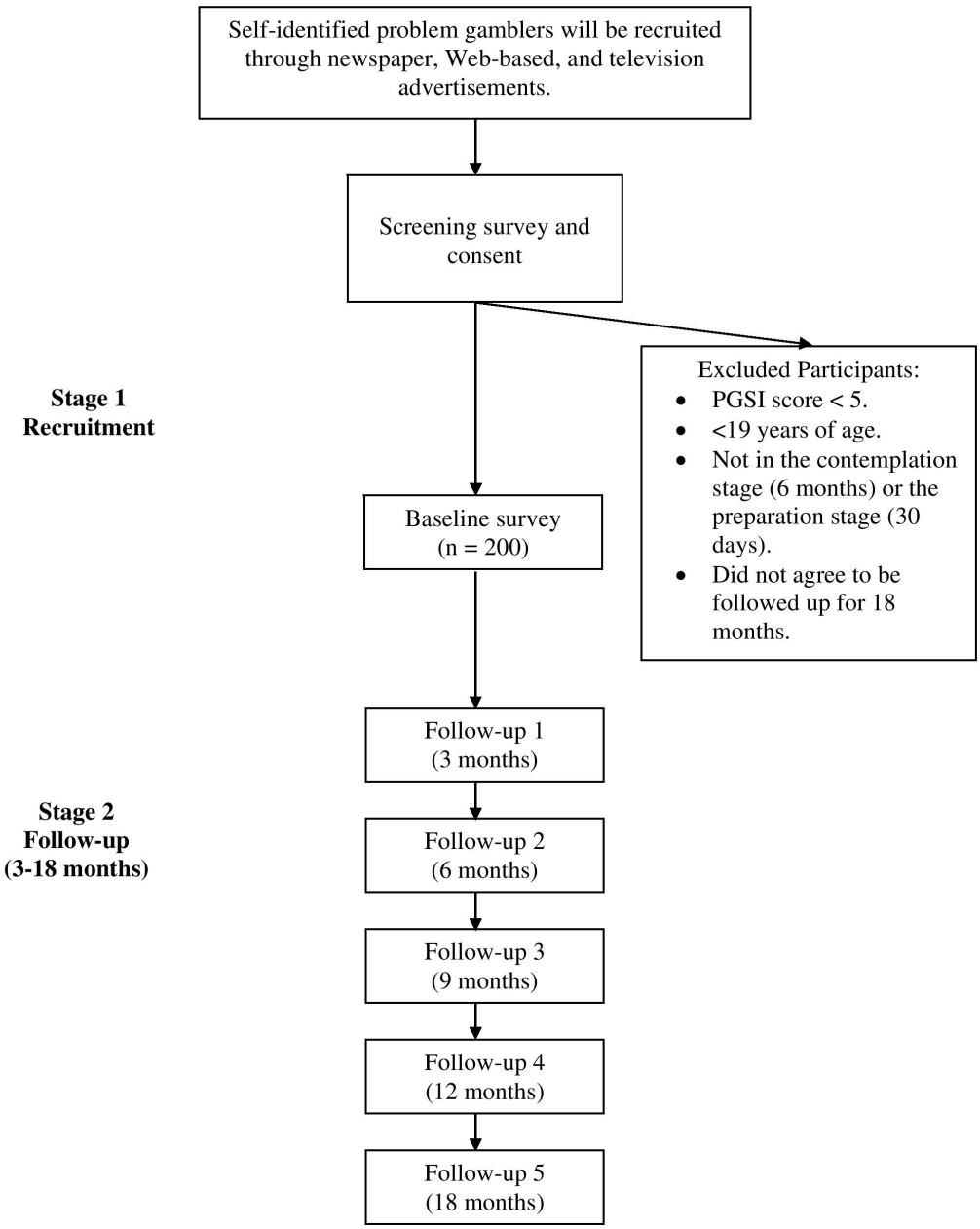
fifth follow-up survey. The fifth follow-up survey will be similar in content to other follow-up surveys, but it will also assess whether participants have experienced any barriers to change and whether they resolved their gambling to low risk levels. Following the completion of the fifth follow-up survey, participants will be sent an additional honorarium in the form of a $40 Amazon.ca gift certificate. In an effort to reduce loss to follow-up, at each follow-up period throughout the duration of the study, participants will be sent up to 3 automatic email reminders to complete their follow-up surveys.

**Figure 1.** Overview of the study.



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## Description of the Measurement Tools Used

### *Screening Tools*

The PGSI is a 9-item measure of problem gambling. Response choices for each of the PGSI questions are on a 4-point scale of "0 - never", "1 - sometimes", "2 - most of the time", and "3 - almost always". Totaled score cut-offs assign individuals to categories of "nonproblem gambler" (PGSI = 0), "low risk gambler" (PGSI = 1 to 2), "moderate-risk gambler" (PGSI = 3 to 7), or "problem-gambler" (PGSI >7). Most recently, Currie et al [24] have proposed a rescoring of the cut-offs for the low-risk (1-4) and moderate-risk (5-7) categories, showing better delineation between the two categories in a number of gambling-related dimensions. Our research will thus employ this revised PGSI scoring method, thereby decreasing chances of false positives and concurrently enabling us to test the reliability of the newly revised PGSI categories over the course of the study.

### *Content of the Baseline Survey*

#### Types of Questionnaires

The baseline survey will assess the following: (1) types, frequency, and amount of money spent on gambling, (2) the life events experienced in the past 3 months as measured using a simplified version of the Life Events Questionnaire (LEQ) [16], (3) level of autonomous motivation for change will be measured using the Treatment Self-Regulation Scale (TSRQ) adapted for gambling to address intrinsic health change behavior [17,19,25,26], (4) use of treatment services, (5) demographic characteristics such as gross household income, (6) alcohol use using the 3-item AUDIT-C questionnaire [21], and (7) past and current drug use and mental health diagnoses.

#### The LEQ

The LEQ [16] assesses a total of 78 life events in eight categories-work, residence, marriage and intimate relationships, family and children, friendship and social activities, finances, physical health, and legal matters. The LEQ yields a frequency score for each category and for total positive and negative events. The authors (JC and DH) of this protocol have previously created a simplified version of the LEQ that can be self-administered and has had success in employing this scale in other prospective natural history research conducted by mail [8]. The modified questionnaire uses a total count of negative and positive life events, rather than the 8 summary scales relating to the different domains of life events. Pilot data has shown that these subscales were highly intercorrelated with the total life events summary scale (correlations ranged from 0.34 to 0.68; $P<.001$ in all cases), making the use of these subscales largely redundant with the total negative and positive life events subscales.

#### The TSRQ

The TSRQ is a scale based on the Self-Determination Theory [17,18], which assesses the degree of autonomous self-regulation regarding why people engage or would engage in healthy behavior. The questionnaire has been designed to be adapted to a range of different health behaviors and is readily modifiable to ask about motivation for change in gambling. The questionnaire presents participants with a question such as "The reason I would stop gambling permanently or continue not to gamble heavily is…" and asks them to rate preselected responses on a 7-point Likert scale of strongly disagree to strongly agree. Typically 15 items are used, assessing external motivation (4 items; eg, "Because others would be upset with me if I gambled"), introjected motivation (3 items; eg, "Because I would feel bad about myself if I gambled"), identified motivation (4 items; eg, "Because I personally believe it is the best thing for my health"), integrated motivation (2 items; eg, "Because it is consistent with my life goals"), and amotivation (3 items; eg, "I don't really know why"). Autonomous or "internal" forms of motivation have been regarded as identified and integrated, whereas nonautonomous or controlled forms of motivation have been identified as external and introjected [17,19,25,26]. Amotivation on the other hand has been treated as a unitary concept that identifies a lack of an intent or a value in performing a given behavior [26]. Previous research using the TSRQ found that autonomous forms of motivation have been associated with behavioral outcomes such as active participation in an alcohol treatment program [27], long-term maintenance of weight-loss in a stringent program for patients who were initialy morbidly obese [28], change in tobacco use for adolescents [29], and long-term tobacco abstinence for adults [25], as well as adherence to medication regimens [30,31]. In contrast, nonautonomous motivation and amotivation have been linked to nonadherence to treatment and poorer health and well-being [19]. Reliability estimates for the autonomous and nonautonomous subscales have been shown to be excellent, with a mean Cronbachs alpha score of .91 and .82, respectively [32]. Other research further determined that across three different health-related behaviors (diet, exercise, smoking) the internal consistency for autonomous motivation subscales ranged from .85 and .93 and for nonautonomous motivation it ranged from .74 and .91 [19].

#### Shortened TOSCA-3

The shortened TOSCA-3 [20] will be used to measure participants' propensity to experience shame and guilt at baseline. The test uses 11 brief scenarios depicting situations that would commonly elicit shame and/or guilt. Although the shortened version of the TOSCA-3 drops positive scenarios to eliminate the pride scales, the shame and guilt scales correlate .94 and .93, respectively with their corresponding full versions, thus supporting the utility of the abbreviated form [20].

#### The AUDIT-C

The AUDIT-C is a brief 3-item questionnaire that assesses alcohol misuse and tests for heavy drinking, active alcohol abuse, or alcohol dependence [21]. The response options for each item are scored 0-4 points, and possible AUDIT-C scores range 0-12 points. The AUDIT-C has been modified to a 3-item questionnaire from the original 10-item Alcohol Use Disorder Identification Test. The questionnaire exhibited high validity and reliability in many population samples, and has been validated in several countries by the World Health Organization [33].



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### *Content of Follow-Up Surveys*

#### The First Four Follow-Up Surveys

The follow-up surveys will assess identical constructs as in the baseline survey, including the PGSI as the primary outcome measure. The point of reference for the first 4 follow-up surveys will be events that occurred in the last three months. In addition, the Process of Change (PoC) Questionnaire [22,23] modified for gambling will be administered to individuals in the action and maintenance stages of quitting gambling at follow-up to assess techniques and strategies used to quit or reduce gambling.

#### The Fifth and Final Follow-Up

The fifth and final follow-up survey will assess identical constructs as the other follow-up surveys, however the point of reference will be events in the last six months. The survey will also assess obstacles to change using the Barriers to Change Questionnaire [34] with participants who have not quit or experienced a significant reduction in their gambling during the study. Further, success at resolving gambling problems by gambling at low risk levels will be determined by criteria identified by Currie et al [35].

#### The PoC Questionnaire

The PoC Questionnaire [22], originally designed to measure the change processes of smoking cessation, provides highly reliable measures of 10 processes of change, labeled: (1) consciousness raising, (2) dramatic relief, (3) self-liberation, (4) social liberation, (5) counterconditioning, (6) stimulus control, (7) self-reevaluation, (8) environmental reevaluation, (9) reinforcement management, and (10) helping relationship. The questionnaire has since been modified for use in other problem areas, with the gambling-modified version developed in 2001 to reflect factors and strategies used by recently resolved and active problem gamblers throughout the process of recovery [23]. It consists of 30 items querying how often the person has used a process in helping change gambling behavior, rated on a 5-point scale (1 = never, 2 = seldom, 3 = occasionally, 4 = frequently, 5 = repeatedly).

#### Barriers to Change Questionnaire

The Barriers to Change Questionnaire is a 28-item questionnaire previously developed by the authors (JC and DH) to assess barriers to change and delays to seeking treatment in problem gamblers [34].

#### The Low-Risk Threshold

In an effort to examine the relationship between gambling behaviors and gambling-related harm, Currie et al [35] conducted risk-curve analysis of the Canadian Community Health Survey - Mental Health and Well-being (Cycle 1.2) [36] to establish low-risk gambling limits. It was determined that the optimal low-risk threshold for gambling was gambling no more than three times per month, spending no more than $1000 CDN per year, and 1% of gross family income. This low-risk threshold did not change based on the definition of gambling-related harm; whether in terms of experiencing negative consequences or with a broader definition that included consequences and behavioral problems. The relationship between gambling activity and risk of harm has been further shown to be independent of gender, age, and socioeconomic status.

### Power and Sample Size

To determine the number of study participants required to identify factors related to successfully quitting or reducing problem gambling behavior, a series of Monte Carlo simulations (with 10,000 replications per target sample size) were carried out with PGSI total scores used as the primary outcome measure. We assume that baseline means and standard deviations are similar to those reported by Bagby et al [37] (Sample 2). We further assume that repeated measures taken on the same individual over time would show a moderate degree of correlation ($r$=.25). The effects of our predictors of interest in this investigation will be assessed using mixed models. Assuming 40% attrition over the course of the study, we will have sufficient power (>80%) to detect a relationship between PGSI total scores and one or more of our predictors of interest with a sample of 200 study participants provided that the combined impact of these predictors on gambling behavior is associated with a coefficient of determination $f^2$=0.02 or greater. Following the guidelines outlined by Cohen [38], this corresponds to a small effect size. Figure 2 shows that an initial sample of 200 study participants will provide us with sufficient power to detect a small effect even if attrition is higher than initially anticipated.



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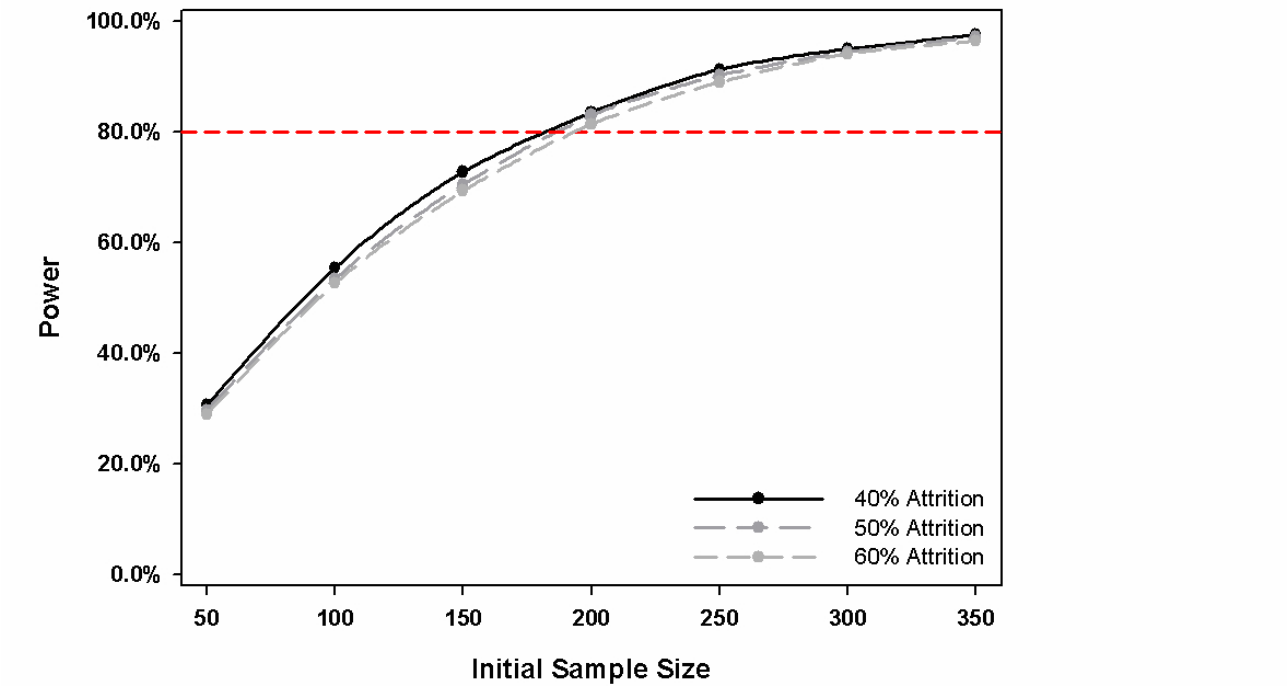
**Figure 2.** Initial sample size versus power.




### Data Analysis

All analyses will be two-tailed and will be carried out at an alpha level of .05 using the SAS System for Windows v.9.3 (The SAS Institute, Cary, NC). Prior to analysis, the data will be screened to ensure that the underlying assumptions for all subsequent statistical procedures are met. Preliminary analyses will include *t* tests, analyses of variance, and correlations and will examine the relationship between PGSI total scores and all predictors of interest. Should any continuous predictors be associated with PGSI total scores in a nonlinear manner, we will investigate appropriate transformations, categorizations, and viable thresholds for piecewise analyses. Any demographic characteristics (age, gender, education, marital status, employment status, household income) found to be associated with gambling severity will be included as covariates in all subsequent analyses.

Our three primary hypotheses will be addressed using linear mixed models. Unlike traditional analyses that typically assume independence of observations, mixed models allow observations to be correlated and are appropriate for use in longitudinal analyses where repeated measurements are taken on the same study participants over time. Additionally, these models use all available data in an efficient manner (ie, partial information derived from subjects lost to follow-up may be included in the analysis and it is not necessary to restrict the analysis to study completers only). The ratio of positive to negative life events, measures of motivation, use of treatment services, severity of gambling problems, amount of money spent on gambling, gambling frequency, time, and any relevant demographic characteristics identified through our preliminary analyses will be included in these models as predictor variables. We will also investigate potential interactions between time, treatment status, and all remaining predictor variables. We will use a purposeful selection of covariates approach [39] to select the subset of main effects and interactions to be included in our final model. Exploratory analyses will further examine whether potential interactions between predictor variables are associated with gender differences, thereby possibly requiring stratification by sex.

## Results

The study has commenced in May 2013 and is currently in the recruitment stage. The study is scheduled to conclude in 2016.

## Discussion

As this study will examine life circumstances and motivational factors that play a role in successful resolution from gambling problems, the results will inform ways of promoting change among the large number of problem gamblers who do not seek treatment as well as improve treatment for those who do seek help. If altered life circumstances are closely associated with successful change from gambling problems (ie, the first hypothesis is supported), then this will imply that treatment should focus on providing the tools to help the person change their life circumstance (eg, develop social support, move to a new location, change leisure activities). If initial motivation for change is autonomous and a significant predictor of successful change (ie, the second hypothesis is supported), then this will tell us that treatment interventions could most profitably be focused on increasing such motivation for change. The information gained could be used to inform problem gamblers who are unlikely to seek treatment, and reinforce self-help techniques currently in place, by outlining potential targets or factors associated with successful recovery for problem gamblers. In addition, the information may be instrumental in informing relapse prevention strategies and could be incorporated as part of brief-intervention strategies or complimentary to standard treatment.



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## Conflicts of Interest

None declared.

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## Abbreviations

**AUDIT-C:** Alcohol Use Disorder Identification Test-C
**LEQ:** Life Events Questionnaire
**PGSI:** Problem Gambling Severity Index
**PoC:** Process of Change
**TOSCA-3:** Test of Self-Conscious Affect, Version 3
**TSRQ:** Treatment Self-Regulation Scale
**TTM:** transtheoretical model



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Protocol

# Risk Prediction in Sexual Health Contexts: Protocol

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## Abstract

**Background:** In British Columbia (BC), we are developing Get Checked Online (GCO), an Internet-based testing program that provides Web-based access to sexually transmitted infections (STI) testing. Much is still unknown about how to implement risk assessment and recommend tests in Web-based settings. Prediction tools have been shown to successfully increase efficiency and cost-effectiveness of STI case finding in the following settings.

**Objective:** This project was designed with three main objectives: (1) to derive a risk prediction rule for screening chlamydia and gonorrhea among clients attending two public sexual health clinics between 2000 and 2006 in Vancouver, BC, (2) to assess the temporal generalizability of the prediction rule among more recent visits in the Vancouver clinics (2007-2012), and (3) to assess the geographical generalizability of the rule in seven additional clinics in BC.

**Methods:** This study is a population-based, cross-sectional analysis of electronic records of visits collected at nine publicly funded STI clinics in BC between 2000 and 2012. We will derive a risk score from the multivariate logistic regression of clinic visit data between 2000 and 2006 at two clinics in Vancouver using newly diagnosed chlamydia and gonorrhea infections as the outcome. The area under the receiver operating characteristic curve (AUC) and the Hosmer-Lemeshow statistic will examine the model's discrimination and calibration, respectively. We will also examine the sensitivity and proportion of patients that would need to be screened at different cutoffs of the risk score. Temporal and geographical validation will be assessed using patient visit data from more recent visits (2007-2012) at the Vancouver clinics and at clinics in the rest of BC, respectively. Statistical analyses will be performed using SAS, version 9.3.

**Results:** This is an ongoing research project with initial results expected in 2014.

**Conclusions:** The results from this research will have important implications for scaling up of Internet-based testing in BC. If a prediction rule with good calibration, discrimination, and high sensitivity to detect infection is found during this project, the prediction rule could be programmed into GCO so that the program offers individualized testing recommendations to clients. Further, the prediction rule could be adapted into educational materials to inform other Web-based content by creating awareness about STI risk factors, which may stimulate health care seeking behavior among individuals accessing the website.

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**KEYWORDS**

prediction models; Internet-based testing; sexually transmitted infections



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## Introduction

### Getting Checked Online

There has been considerable interest in the adoption of information and communication technology for prioritizing resources in sexually transmitted infections (STI) service delivery [1,2]. In British Columbia (BC), we are developing Get Checked Online (GCO), an Internet-based testing program that provides Web-based access to STI testing [3]. The overall goal of GCO is to reduce barriers to accessing appropriate sexual health services, and ultimately to decrease the overall burden of STI/human immunodeficiency virus (HIV) in BC. Clients accessing GCO will complete a risk assessment module, download a test requisition (if appropriate), provide blood and/or urine specimens at designated specimen collection sites, and retrieve negative results on the Internet or positive results in-person or by telephone [3]. By selectively triaging asymptomatic and other low risk GCO clients for laboratory testing only, the hope is to most efficiently identify infections. Universal screening is not likely to be cost-effective in a population with relatively low STI/HIV prevalence, including the general population of BC. Selective screening based on risk assessment may optimize cost-effectiveness and limit the number of individuals confronted with unnecessary tests [4].

### Implementing Risk Assessment

Much is still unknown about how to implement risk assessment and recommend tests in Web-based settings. In traditional sexual health service settings (such as STI clinics), screening guidelines or recommendations provide clinicians with assistance in distilling and applying the scientific literature to recommend specific STI tests and prioritize patient groups. Prediction tools have been shown to successfully increase efficiency and cost-effectiveness of STI case finding in the following settings-HIV screening [5], Internet-based testing [4,6], and partner notification [7-9]. These tools, broadly termed *clinical prediction rules*, use combinations of risk factors that have been statistically demonstrated to be meaningful predictors to calculate a numerical probability of the presence of a specific condition or likelihood of an outcome [10,11].

### The Methodological Framework

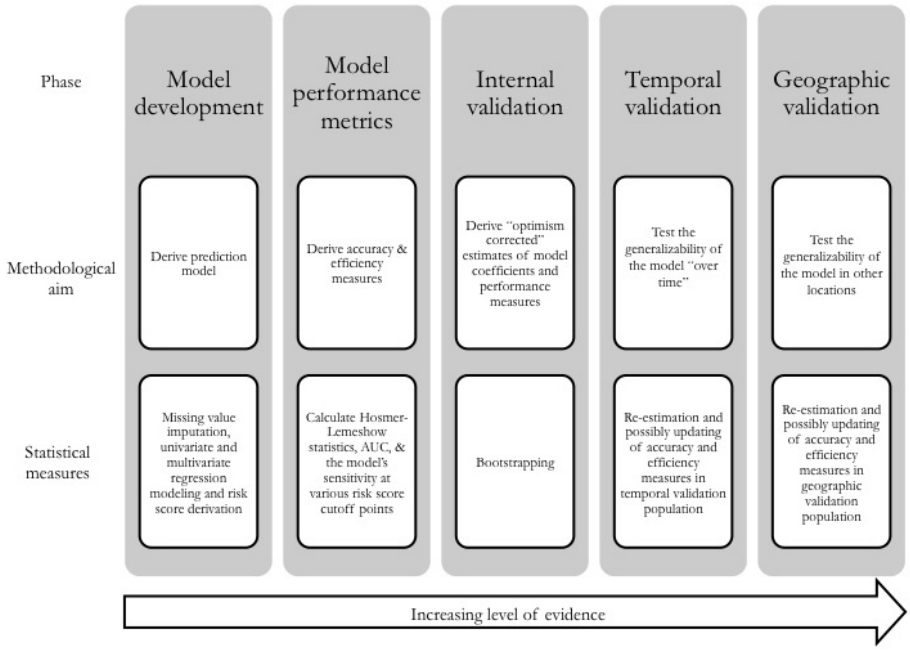
While acknowledging important early initiatives [4-6], the methodology for evaluation of STI prediction rules is not yet as crystallized as the methodologies associated with prediction rules used for chronic disease management (eg, the Framingham risk score for estimating cardiovascular disease). There has also been little discussion of practical considerations, especially issues associated with the formal validity of prediction tools that are particularly salient for STI service delivery. In this study, we describe the methodological framework for using electronic health records to develop and validate a multivariable risk prediction rule among clients attending STI clinics in BC. Specifically, this project was designed with three main objectives: (1) to derive a risk prediction rule for screening chlamydia and gonorrhea among clients attending two public sexual health clinics between 2000 and 2006 in Vancouver, BC, (2) to assess the temporal generalizability of the prediction rule among more recent visits in the Vancouver clinics (2007-2012), and (3) to assess the geographical generalizability of the rule in seven additional clinics in BC.

## Methods

### The Prediction Rule

Figure 1 shows the methodological framework for the derivation and validation of the prediction rule.

**Figure 1.** Methodological framework for the derivation and validation of the prediction rule.



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## Study Populations

This study will involve a population-based, cross-sectional analysis of electronic records of patients visits collected at publicly funded STI clinics that offer physical examination and treatment for STIs in BC. Data from each new client consultation between 2000 and 2012 among women and men who have sex with women will be included in this study. This analysis will be limited to asymptomatic clinic visits that are not sexual contacts of known STI cases. Repeat visits within 30 days of a previous clinical visit will also be excluded to avoid including clients receiving confirmatory diagnoses. The prediction rule will be created using the data gathered from the *development population* and the generalizability of the criteria will be tested in the *validation populations*. The *development population* is comprised of patient visits at the 12$^{th}$ Avenue and Bute Street clinics in Vancouver (n=10,471; chlamydia and/or gonorrhea prevalence is, 1.76%). These are low-threshold (free of charge and, if preferred, pseudonymously), outpatient clinics run by the BC Center for Disease Control (BCCDC). They provide STI assessment and management services, including HIV testing, for clients from throughout the Vancouver area. Chlamydia, gonorrhea, syphilis, and HIV tests are offered to all sexually active clients at each clinic visit.

The external validity of the model, known as the performance in different populations (also labeled “generalizability” or “transportability”), will also be tested. Temporal validity is generally considered the first line of generalizability ascertainment. This issue is particularly salient in STI testing because of the shift towards more sensitive diagnostic tests over this time period. The *temporal validation population* will include more recent visits at the Vancouver clinics between 2007 and 2012 (n=15,107; chlamydia and/or gonorrhea prevalence is, 2.23%).

The *geographical validation populations* will include clinic visits in publicly funded sexual health clinics located in the following geographical locations in BC–Penticton, Kelowna, Kamloops, New Westminster, Boundary, Courtenay, and Prince George. The proposed study will analyze computerized records from clients attending these clinics between 2000 and 2012 (n=10,529; chlamydia and/or gonorrhea prevalence is, 5.37%). These public sexual health clinics in BC use the same electronic charting as the BCCDC clinics, thus, the consistent nature of the data collection methods across the clinics allows for the direct comparison of data between individuals attending the clinics.

## Conceptual Framework of Variables and Measures

Risk modeling studies can benefit from the identification of a coherent conceptual framework at the outset of the analysis [12]. This project will adopt the proximate-determinant framework in the selection, operationalization, and interpretation of explanatory variables [13]. To help clarify the relative strength or importance of each STI predictor, we categorized the predictors into two groups based on the proximate-determinants framework: (1) distal determinants, which are demographic, social, or economic variables distally related to STIs, and (2) proximate determinants, which are directly associated with an individual’s probability of exposure to STIs and the efficiency of STI transmission (Table 1).

The proximate-determinants framework hypothesizes that after adjustment for the proximate determinants or sociobehavioral predictors, relationships between the underlying or sociodemographic characteristics should be nonsignificant [13]. Underlying determinants included in the analytical framework are-age, gender, race/ethnicity, sex work, drug use, and residence. Proximate determinants included indices of sexual activity (number of sexual partners in the past six months, number of lifetime sex partners) and partner characteristics (sex work, Internet partners). Other variables included condom use, previous STI diagnosis, type of sex (anal, oral, vaginal), and gender of sex partners. Statistical analysis in this study will take advantage of the multilevel structure outlined in the framework to understand estimates of the associations between the determinants and acquisition of STIs.



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**Table 1.** Candidate predictor and outcome variables for STI prediction rule modeling.

| Variable | Description | Type |
|---|---|---|
| **Underlying determinants** | | |
| Age | Age in years | Interval |
| Gender | Female/male/transgender | Categorical |
| Race/ethnicity | Unspecified Aboriginal/Arab/Asian/Black/First Nations/Hispanic/Inuit/Metis/South Asian/White | Categorical |
| Postal code | Self-reported postal code of residence | Categorical |
| Street involvement | Self-reported street involvement–reported as yes/no | Dichotomous |
| Sex trade worker | Self-reported sex trade worker–reported as yes/no | Dichotomous |
| IDU[a] | Self-reported current or previous injection drug use–reported as yes/no | Dichotomous |
| **Proximate determinants** | | |
| Gender of sex partners | Female/male/both | Categorical |
| Number of sex partners 6 months | Number of sexual partners in previous 6 months | Interval |
| Number of sex partners lifetime | Number of sexual partners in lifetime | Interval |
| Sex partner of IDU[a] | Yes/no/unknown | Categorical |
| Type of sex | Anatomical sites reported by client as exposed to partner during recent sexual activity–reported as genital/insertive rectal/receptive rectal/throat | Categorical |
| Number of Internet partners | Number of sexual partners met on Internet sites in previous 6 months | Interval |
| Needle sharing | Self-reported sharing of needles for injection drug use–reported as yes/no | Dichotomous |
| Sex partner of sex worker | Yes/no/unknown | Categorical |
| Prior STI | Yes/no | Dichotomous |
| Condom use | Self-reported condom use–reported as yes/no/sometimes | Categorical |
| **Health outcomes** | | |
| Chlamydia test result | Positive versus negative based on NAAT[b] result | Dichotomous |
| Gonorrhea test result | Positive versus negative based on NAAT[b] result | Dichotomous |

[a]Injection drug use

[b]nucleic acid amplification test

## Outcome Variables

The outcomes measured in this study will be diagnosis with chlamydia and/or gonorrhea infection [14]. Practitioners at sexual health clinics may order the following specimens-urine specimens and swabs (cervical, vaginal, urethral, rectal, oral swabs), which are tested using the nucleic acid amplification test (NAAT) or culture (gonorrhea only) [14]. We chose to examine chlamydia and/or gonorrhea as a composite outcome because most laboratories use multiplex assays that test for both infections simultaneously [15].

## Data Quality

The presence of missing data is a frequently encountered problem in the derivation and validation of prediction rules [16]. The default strategy is to delete all incomplete observations from the analysis; however, this is often a precarious and wasteful approach as variables are rarely missing at random. In this study, variables such as race/ethnicity, condom use, and number of sexual partners in previous 6 months have rates of missingness ranging from 8.92% (n=36,107) to 42.24% (n=36,107). Imputation techniques, especially multiple imputations, have been increasingly advocated to address the issue of missing values [17]. This study will impute missing values using IVEware, a software application that performs multiple imputations of missing values using the Sequential Regression Imputation Method [18]. In this method, imputations for each missing variable are produced based on a regression model using other variables as predictors in a cyclic manner [19].

## Sample Size

In prediction modeling, statistical precision is dependent on the number of individuals who experience the outcome of interest. Some authors have recommended that at least 10 individuals having the outcome of interest are needed per variable to allow for accurate prediction modeling (ie, events per variable-EPV) [11,17]. In this study, the derivation, temporal and geographical validation populations are sufficiently powered, having 11, 20, and 33 EPV, respectively.



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## Analytic Plan

Descriptive statistics will be used to determine the frequency and distribution of each independent variable. All data analyses will be conducted using SAS v9.3. The primary outcome is chlamydia and or/gonorrhea diagnosis between 2000 and 2012. Continuous variables will be categorized based on clinically and epidemiologically relevant cutoff points [9]. The association between each predictor and the outcome will be examined using unadjusted prevalence odds ratios with the associated 95% confidence intervals. A stepwise technique will be used with variables selected for inclusion in the model on the basis of a significant change in the log likelihood ($P$<.05). We will initially explore separate models for males and females.

A score will be calculated by multiplying the regression coefficients of each variable by 5 in the final regression model, with rounding to simplify the calculation. These scores are an immediate reflection of the logarithm of the odds of infection [4]; they will be added into a sum score for each individual. To identify an optimal strategy to identify STI cases, a cutoff for the predicted probability will be calculated. Patients with predictions above the cutoff will be classified as positive; those under the cutoff as negative. Specifically, the performance of the prediction rule will be assessed on the basis of cases detected (sensitivity) and the number of clients who have been tested (efficiency) [20]. We will explore optimal risk score cutoff points that identify the most cases (a high percentage for sensitivity), while testing the fewest number of people (low percentage for efficiency) [6,21].

## Assessment of Model Performance Measures

We will explore two measures of model accuracy-calibration and discrimination. Calibration (or "reliability") refers to the agreement of predicted and observed predictions [22]. Calibration will be tested using the Hosmer-Lemeshow goodness-of-fit test [20]. This test divides individuals into groups based on percentiles of their predicted probabilities of having an infection and then calculates within each group the expected number of positive and negative individuals [22]. These will then be compared with the observed values for the groups and the Pearson chi-squared statistic will be used to test for differences; $P$<.05 casts doubt on the fit of the model [20]. Calibration will also be assessed graphically by plotting observed frequencies of infection against predicted probabilities by a decile of predictions, drawing a line of regression through the points, and assessing the calibration slope [23]. The ideal calibration slope of a well-discriminating model is 1 [23].

Discrimination refers to the model's ability to distinguish low risk from high risk individuals [6]. Discrimination will be quantified by the area under the receiver operating characteristic curve (AUC) or the *c*-statistic which will be constructed by graphing sensitivity against 1-specificity for different cutoff points of the predicted STI risk [4]. The AUC lies between zero and one and provides a measure of the ability of the model to discriminate between those who have an STI diagnosis and those who do not. A value of 0.5 suggests no discrimination, such that the model is no better than a random guess, whereas a value of 1.0 suggests perfect discrimination [20].

## Evaluation of Internal Validity

Internal validation is important to obtain an honest estimate of performance for patients that are similar to those in the training sample. Also, internal validation indicates an upper limit to the expected performance in other settings [23]. Evaluating the performance of the model on the same data used to create the model usually leads to an optimistically biased assessment or overfitting [23]. We will use bootstrap validation techniques to correct for the optimism bias. Random bootstrap samples will be drawn with replacement from the full sample (200 replications) and the performance of the developed model will be tested in similar populations as the derivation population [24]. This method will be used to estimate the overoptimism of the derived model and to, subsequently, adjust the measures of performance and the estimated regression coefficients in the final model for overfitting [17,24].

## Examining the External Validity of the Prediction Rule in Other Populations

Even when internal validation methods are used to correct for overfitting and optimism, the accuracy of prediction rules can be considerably lower in new populations compared to the accuracy found in the derivation population [25]. External validation is a stronger test of model performance, and will be determined in other populations that are plausibly related to the derivation population. We will assess the performance of the prediction rule in different temporal and geographical settings; these settings may be different from the derivation population due to, for example, variation in prevalence, diagnostic tests, access to sexual health care services, core groups, or sexual networks. These validation settings may also differ due to documentation or charting practices. The predicted probability for STI diagnosis in the *validation populations* will be calculated according to the previously calculated risk scores. The discriminative ability of the risk scores will be assessed by calculating the AUC and conducting the Hosmer-Lemeshow test as described above [6].

When the accuracy of the prediction rule in the *validation population* is poor, researchers often discard the rule and directly pursue deriving new rules with the data of the *validation population* only [25]. In this scenario, when every new setting leads to a new prediction rule, prior information captured in previously derived prediction rules would be neglected; this is counterintuitive as scientific inferences should be based on data of as many individuals as possible and also violates the scientific principle of updating prior knowledge from previous studies [25]. Several approaches for updating previously developed rules have been suggested in the literature [23,25]. In this study, we anticipate that due to the higher prevalence of infection in the validation datasets, the calibration of the rule in the *validation populations* may be poor as a result of systematically too low predicted probabilities [26]. The intercept, which reflects the risk of the outcome not explained by the predictors in the prediction model, will be adjusted such that the mean predicted risk equals the observed prevalence in the STI clinics outside of Vancouver [26,27]; thus, in updating the intercept, potentially poor calibration will be improved [26].



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### Ethics

Ethics approval for the proposed thesis project has been obtained from the University of British Columbia Research Ethics Board prior to the start of any research activities. The BCCDC clinic data will be captured from existing program databases and will be considered chart review, which do not require informed consent. The stewards of these databases are BCCDC staff and the data will be safeguarded according to the Freedom of Information and Privacy Act.

## Results

This is an ongoing research project with initial results expected in 2014.

## Discussion

### Implications for the Scaling Up of Get Checked Online

The results from this research will have important implications for scaling up of Internet-based testing in BC. This analysis will focus on the development of screening criteria for asymptomatic heterosexuals, a population often targeted by screening recommendations issued by public health organizations. Several organizations recommend the screening of all sexually active men and women 25 years or younger for chlamydia. This recommendation could prove to be cost prohibitive in settings where individuals in this age group comprise the highest proportion of clinic visits and in low prevalence settings, whose STI epidemic could be characterized as concentrated, with low prevalence rates in the general population [4]. For example, there are increasing concerns about this recommendation, particularly in the United Kingdom, which has fully endorsed and committed funding to universal screening of young people (16 to 24 years) in the form of the National Chlamydia Screening Programme, an initiative reported to be facing implementation obstacles, low participation rates, and lack of demonstrable cost effectiveness [28].

### Improving on Screening Recommendations

Screening recommendations could be improved by tailoring risk assessment to the specific circumstances of the patient [29]. If a prediction rule with good calibration, discrimination, and high sensitivity to detect infection is found during this project, the prediction rule could be programmed into GCO so that the program offers individualized testing recommendations to clients. Further, the prediction rule could be adapted into educational materials to inform other Web-based content by creating awareness about STI risk factors which may stimulate health care seeking behavior among individuals accessing the website. For example, a potential use could be the creation of a Web-based risk assessment tool for individuals. The risk scores developed for the prediction rule also have important implications for risk communication and testing motivation because they can increase risk perception by creating tailored risk messages to different groups.

We also anticipate the prediction rule could potentially facilitate decision-making in traditional clinical encounters where clinicians could enter basic demographic and behavioral data directly into the client's computerized medical record during the consultation. The prediction rule could be used to display an alert on the computer screen to prompt clinicians to offer specific STI tests to those at increased risk of infection. This would standardize both STI Web-based testing and at the clinics, ensuring those at greatest risk are tested and reduce unnecessary testing. Moreover, the results will be used to inform ongoing clinical recommendations related to selective screening of STI clients in BC, potentially enabling targeted testing to higher risk individuals, thereby reducing the unnecessary testing of those without the infection and saving costs.

### Study Strengths and Limitations

This study has several strengths. To our knowledge, this will be the first study to derive and validate a locally specific risk assessment tool to quantify STI risk in a Canadian setting. Risk assessment tools ideally should be derived from large representative samples [30]. Our study will include 13 years of electronic health records comprising more than 35,000 clinical visits to publicly funded STI clinics in BC, representing a high proportion of the population of individuals using this service in the province. One major limitation of this research project is that the validity of the predictive variables depends on the accuracy of the self-reported health behaviors. There is a risk of recall and social desirability biases because of the self-reported nature of stigmatized activities and behaviors. There is also the risk of overreporting of perceived normative behaviors such as condom use. Such reporting biases would artificially inflate the relationships between infection and risk factors. However, because the clinical risk assessment interviews are confidential and are conducted by clinicians who are typically not acquainted with the respondents, strong motivations to self-present are unlikely. Moreover, the outcome variables do not rely on self-report and thus are not subject to recall or social desirability biases. Another limitation is the limited generalizability of our prediction rule to the general population or people seeking care in settings other than STI clinics.

The ultimate goal of the proposed project is to use research evidence to inform policy and program development, and through providing more effective services, strengthen sexual health care provision in BC, including the optimal scaling up of GCO across BC (including in rural and northern communities). The investigators involved in this project are members of two GCO working groups; and, thus we are in positions to integrate knowledge translation as the data analyses progress and we examine preliminary findings [31]. The scholarly products developed as a result of the study (eg, manuscripts submitted to peer-reviewed journals, including open-access journals, presentations at conferences) will make theoretical and empirical contributions toward more effectively using the characteristics of sexual health clinic clients to predict STI.



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## Acknowledgments

The authors gratefully acknowledge the Canadian Institutes of Health Research for funding part of this research (see Multimedia Appendix 1).

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Canadian Institutes of Health Research decision letters for the project as well as the reviewer comments.

[PDF File (Adobe PDF File), 348KB - resprot_v2i2e57_app1.pdf ]

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## Abbreviations

**BC:** British Columbia
**BCCDC:** BC Center for Disease Control
**EPV:** events per variable
**GCO:** Get Checked Online
**HIV:** human immunodeficiency virus
**NAAT:** nucleic acid amplification test
**STI:** sexually transmitted infections


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Original Paper

# Nutritional Education Through Internet-Delivered Menu Plans Among Adults With Type 2 Diabetes Mellitus: Pilot Study

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## Abstract

**Background:** A potential barrier to weight loss and vascular risk reduction is difficulty in operationalizing dietary education into a concrete plan. Although a variety of Internet-based software tools are now available to address this issue, there has been little formal evaluation of these tools.

**Objective:** The aim of this single-arm pilot study is to determine the effect of a 24-week Internet-based menu-planning program, by examining pre- to postintervention changes in the body weight, blood pressure, and glycemia, specifically among overweight adults with type 2 diabetes mellitus (DM2), a clinical population at high risk for vascular diseases.

**Methods:** A total of 33 adults with DM2 were recruited by collaborating registered dietitians to a 24-week Internet-based menu-planning program. Individualized dietary prescriptions were operationalized into weekly Internet-delivered menu plans through an adapted version of a commercially available service. Adherence was defined as logging into the program at least once per week for a minimum of 18 of the 24 weeks. Multiple imputations were used for missing data. Using baseline and postintervention assessments, we calculated the weight changes (mean, 95% CI) and investigated the corresponding effects (linear regression models) on blood pressure (systolic, diastolic) and hemoglobin A1C (ie, glycemia).

**Results:** The mean age was 58 (SD 7) years and the mean baseline body mass index was 34.4 (SD 4.6) kg/m$^2$. The results of this study showed that ≥5% weight reduction was achieved by 6/33 participants (18%) and by 5/18 adherent participants (28%). A mean weight change of −2.0% (95% CI −2.6 to −1.4) was observed, with changes occurring in the adherent (−3.6%, 95% CI −4.5 to −2.8) but not in the nonadherent (0%, 95% CI −0.6 to 0.7). It was found that each 1% reduction in body weight was associated with a −2.4 mmHg change in systolic (95% CI −3.5 to −1.2) and a −0.8 mmHg change in diastolic blood pressure (95% CI −1.4 to −0.2). Percent weight change was not found to be related to changes in A1C.

**Conclusions:** In adults with DM2, an Internet-based menu-planning program has the potential to lead to clinically important weight reductions in more than one quarter of those who adhere, with corresponding improvements in blood pressure.

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**KEYWORDS**

weight loss; obesity; hemoglobin A1C; blood pressure; Internet; Web; type 2 diabetes mellitus; diet; menu



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## Introduction

Although many adults with type 2 diabetes mellitus (DM2) tend to be overweight, loss of 5% of total body weight leads to improvements in vascular risk factors [1,2] and loss of 2-5% of weight may confer benefits [3]. Difficulty in translation of dietary education and advice into a concrete operational plan (ie, grocery lists, recipe selection, time management, and budgeting) is a potential weight loss barrier. Indeed, assistance with menu planning has been demonstrated to be effective in overweight individuals to achieve weight loss [4]. Unfortunately, because of time constraints and client volume, clinicians are generally unable to provide daily meal plans and recipes.

Several investigators have recently attempted to circumvent the menu-planning barrier through the use of prepared meals. This approach has been demonstrated to be highly effective in realizing the benefits associated with weight loss. For example, in a clinical trial conducted among overweight women, weight losses were greater among participants who received free Jenny Craig prepared meals (n=167; 42-67% of their total energy intake), with a net 10.9% loss compared to a 2.6% loss in the control group (n=111) who followed dietary guidelines [5]. More than 60% of the intervention arm participants achieved a≥5% weight loss. Others have opted to examine the use of meal replacements in the form of shakes and bars, which is potentially a less expensive option. Impressively, in adults with DM2, the Look AHEAD trial incorporated meal replacements to achieve a 7% or greater weight loss in 1 year, and the mean reduction in the intervention arm (n=2570) was 8.6% [6].

An ongoing reliance on prepared meals and/or meal replacements, however, may not be financially realistic or appealing to some individuals. Such individuals may benefit from menu-planning services delivered through the Internet. These plans may be generated through specialized software that integrates “dietary prescriptions” with banks of recipes and food items locally available. However, while the Internet is now emerging as a source of many menu-planning tools, there has been little formal evaluation of their effectiveness. An Internet-based menu-planning strategy, known as eDiets, has been previously implemented in overweight individuals [7,8]. Among completers (n=48) of the eDiets study of Gold and colleagues, a weight loss of 5% or greater was seen in 18 (37%) of the participants. No previous studies to our knowledge have been conducted in overweight persons with DM2. We report herein the results of our 24-week intervention in overweight adults with DM2 who received dietary education from a registered dietitian and were then given weekly individualized menu plans via the Internet, through an adapted version of an existing program [9]. We evaluated pre- and postintervention changes in weight and dietary intake, as well as the corresponding effects of weight change on glycemic control and blood pressure.

## Methods

### Design

We conducted a single-arm pilot interventional study to determine the effect of a 24-week Internet-based menu-planning program by examining pre- to postintervention changes. This design permits each participant to act as his or her own control, to potentially reduce confounding and increase the precision of estimates in smaller pilot studies. In contrast, small randomized controlled trials (RCTs) risk unbalanced treatment arms and limited scope for statistical adjustments. The McGill Faculty of Medicine Institutional Review Board (Montreal, Canada) approved all study procedures, as did the participating institutions.

### Participants

Recruitment of participants and data collection occurred over a 52-week period (ie, from June 2009 to June 2010). Potential candidates were identified by registered dietitians working in diabetes outpatient clinics in Montreal, affiliated with McGill University (McGill University Health Centre, Jewish General Hospital, and St. Mary’s Hospital Center). Dietitians invited all potentially eligible patients to participate. Those who indicated interest were referred to the study coordinator. To be eligible to participate in the study, participants were required to meet the following inclusion criteria: diagnosis of DM2, a body mass index of 25 to 45 kg/m$^2$, and regular access to computer and Internet services. Participants were deemed ineligible if they met any of the following exclusion criteria: history of any significant comorbid illness (eg, malignancy, renal failure, or liver disease), taking medications (eg, orlistat, steroids) that could affect weight, smoking during the last 12 months, or pregnant or planning to become pregnant within the next 12 months.

### Intervention

We tested an adapted version of a commercially available Internet-based menu program (SOSCuisine; Multimedia Appendix 1). The program offers Internet-based menu-planning services, with some services free of cost (eg, five dinner menus weekly) and others paid (eg, complete menu plan each day). In the present study, a website, without third-party advertisements, was specifically developed for evaluation purposes. Costs of the services were covered through a research grant that incurred no costs to participants.

Following informed consent and baseline assessment by research personnel, the collaborating referring dietitians shared their assessments and recommendations with the SOSCusine dietitian through telephone discussion. The measures included for the discussion were diabetes history, socioeconomic status, medication use, usual dietary intake, food habits, weight history, energy requirement for weight loss, sample meal pattern, and macronutrient distribution. The nutritional requirements were added on SOSCuisine software to develop an individualized menu plan. The software allowed alignment of the “dietary prescription” with the SOSCuisine menu bank (over 62,000 recipes) as well as weekly specials from local grocery stores in Montreal and the number of individuals within the household. Participants received weekly menu plans, recipes, a grocery list, ingredients’ cost with and without grocery store specials, and a step-by-step action plan to reduce meal preparation time [9].

Macronutrient distribution for the management of diabetes among overweight adults followed 2008 Canadian Diabetes



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Association guidelines (eg, carbohydrate intake accounted for 45-60% of total energy intake, protein for 15-20%, and fat for less than 35%) [10]. Other nutritional considerations included decreased sodium intake, increased whole grain intake, including an intake of 25-50 g of dietary fiber per day, and restricted saturated fat intake to less than 7% of total daily energy intake. A detailed nutritional facts table and servings from each food group based on Eating Well With Canada's Food Guide [10] were generated for each meal.

### Assessments

Assessments were completed at baseline (week 0) and following the intervention (ie, at 25-26 weeks) by research personnel at the Division of General Internal Medicine, Montreal General Hospital site, McGill University Health Centre. Demographic data including sex, marital status, occupation, place of birth, ethnicity, education, and income, were obtained at the baseline assessment. Baseline and follow-up measures included body weight (postvoid in light clothes without shoes to nearest 0.1 kg, using a SECA 882 electronic scale), height (head in Frankfurt horizontal plane position to nearest 0.1 cm, without shoes using a SECA 214 stadiometer), waist circumference (standing position, midway between the lateral lower ribs and the iliac crests after a moderate expiration), hip circumference (widest level, over the greater trochanters), and blood pressure (following 5-minute rest, two measures 2 minutes apart, using an Omron HEM-747 IC). Venous blood was sampled for A1C measurements (BioRad Variant II high-performance liquid chromatography system). A1C level reflects an overall glucose control during the previous 2- to 3-month period, with a target AIC level of approximately 7% in DM2. Prescription medications were recorded.

Dietary intake was estimated using a validated food frequency questionnaire [11]. Physical activity was measured using a validated self-administered International Physical Activity Questionnaire (IPAQ)—short form [12] that assesses physical activity for the prior 7 days. Participants' stage of change was assessed using the Weight Stages of Change—short form [13]. The usage of the website usage was tracked electronically.

### Statistical Analyses

Descriptive statistics at baseline were presented as means and SDs for all continuous variables and proportions for categorical variables. These statistics were generated both for the cohort overall and stratified by adherence. Adherence in this study was defined as having logged in at least once per week for 18 of the 24 weeks (ie, 75% of total weeks). Implausible dietary intake values were excluded (ie, outside the range of 500-3500 kcal/d for women and 800-4000 kcal/d for men [14]), as were implausible physical activity values, in accordance with the IPAQ scoring protocol. Mean changes and 95% CIs were calculated for change in weight and other anthropometric measurements, such as clinical parameters, changes in dietary food intake, and changes in physical activity in MET-min/week, both overall and stratified by adherence.

Linear regression models were constructed to estimate whether reduced weight was associated with changes in systolic and diastolic blood pressure, and A1C. Multiple imputation was used to adjust for missing data [15]. Because of sample size constraints, a maximum of three variables could be included concurrently in our adjusted models. In all cases, we present age- and sex-adjusted models. For systolic and diastolic blood pressure, separate adjustments for season of baseline assessment and change in physical activity were included in our analyses. Data were analyzed using SAS version 9.2.

## Results

### General Results

Prospective participants' recruitment and data collection occurred over a 52-week period (ie, from June 2009 to June 2010). A total of 33 participants were enrolled, and 26 (79%) completed final assessments (Figure 1).

Participants recruited for the study were middle-aged to elderly with a mean age of 57.8 (7.4) years. Of all the participants, 16/33 participants (49%) were women (Table 1). Participants were predominantly married, Europid, and educated beyond high school graduation. A total of 14/33 participants (42%) were retired or not seeking work. They were on average in obese class 1 level, with elevated waist circumference and waist-to-hip ratio. Most participants were in the "action" phase of the weight-loss stage of change at baseline, and reported confidence in their ability to prepare meals. Baseline average daily energy intake was found to be approximately 2070 kcals. Of this energy intake, 100 g (19.4%) came from protein, 91 g (39.8%) from fat, including 28 g (12%) from saturated fat, and 211 g (40.8%) from carbohydrate. The mean sodium intake of 3.1 g/d (1.6 g) was also found to be above recommendations, while mean dietary fiber intake of 21.6 g/d (10.7 g) was slightly lower than daily recommendations of 25-50 g/d [10]. Participants were classified as being mainly low or moderately active. Average duration of diabetes was close to 8 years. Mean A1C and blood pressure values were slightly higher than recommended targets [10]. Antihypertensive, antihyperglycemic, and lipid-lowering medications were commonly used by participants (75.8%, 97.0%, and 81.8%, respectively).



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**Table 1.** Baseline characteristics, both overall and stratified by adherence.

| Variables | | Total (N=33) | Nonadherent (n=15) | Adherent (n=18) |
|---|---|---|---|---|
| Age in years, mean (SD) | | 57.8 (7.4) | 55.7 (8.5) | 59.6 (6.1) |
| Women, n (%) | | 16 (48) | 5 (33) | 11 (61) |
| Marital status (single), n (%) | | 6 (18) | 4 (27) | 2 (11) |
| Ethnicity (Europid), n (%) | | 27 (82) | 11 (73) | 16 (89) |
| Education (high school or less), n (%) | | 11 (33) | 0 (33) | 6 (33) |
| Occupational status (retired or not seeking work), n (%) | | 14 (42) | 4 (27) | 10 (56) |
| Weight in kg, mean (SD) | | 95.5 (14.3) | 94.3 (9.7) | 96.5 (17.5) |
| BMI in kg/m$^2$, mean (SD) | | 34.4 (4.6) | 33.3 (4.2) | 35.3 (4.8) |
| **Waist in cm, mean (SD)** | | | | |
| | Women | 103.3 (8.4) | 103.0 (8.0) | 103.4 (9.0) |
| | Men | 110.5 (7.6) | 108.3 (5.5) | 113.7 (9.5) |
| **WHR, mean (SD)** | | | | |
| | Women | 0.85 (0.05) | 0.85 (0.06) | 0.85 (0.05) |
| | Men | 0.99 (0.05) | 1.0 (0.04) | 0.99 (0.06) |
| **Weight—stage of change, n (%)** | | | | |
| | Precontemplation | 0 (0) | 0 (0) | 0 (0) |
| | Contemplation | 5 (15) | 3 (20) | 2 (11) |
| | Action | 23 (70) | 10 (67) | 13 (72) |
| | Maintenance | 5 (15) | 2 (13) | 3 (17) |
| **Cooking skills, n (%)** | | | | |
| | Prepares simple meals | 6 (18) | 3 (20) | 3 (17) |
| | Cooks with a recipe | 6 (18) | 4 (27) | 2 (11) |
| | Competent cook | 17 (52) | 5 (33) | 12 (67) |
| | Expert cook | 3 (9) | 2 (13) | 1 (6) |
| | Not applicable (as it is not my role to cook) | 1 (3) | 1 (7) | 0 (0) |
| **Dietary intake in grams/day, mean (SD)** | | | | |
| | Energy[a] | 2071 (699) | 2022 (503) | 2112 (829) |
| | Protein | 100.2 (35.5) | 100.4 (30.9) | 100.2 (39.1) |
| | Carbohydrate | 210.8 (81.9) | 219.8 (76.8) | 201.1 (85.4) |
| | Fat | 90.6 (40.6) | 83.2 (34.9) | 96.7 (44.0) |
| | Fiber | 21.6 (10.7) | 23.2 (9.4) | 20.3 (11.6) |
| | Sodium | 3.1 (1.6) | 2.7 (1.0) | 3.4 (1.9) |
| | Saturated fat | 27.8 (13.3) | 28.0 (14.2) | 27.6 (12.6) |
| **Physical activity, n (%)** [b] | | | | |
| | Low | 11 (37) | 7 (47) | 4 (27) |
| | Moderate | 12 (40) | 5 (33) | 7 (47) |
| | High | 7 (23) | 3 (20) | 4 (27) |
| DM2 duration in years, mean (SD) | | 7.6 (6.1) | 7.0 (5.2) | 8.0 (7.0) |
| A1C (%), mean (SD) | | 8.1 (1.5) | 8.6 (1.8) | 7.7 (1.1) |
| **Blood pressure in mmHg, mean (SD)** | | | | |



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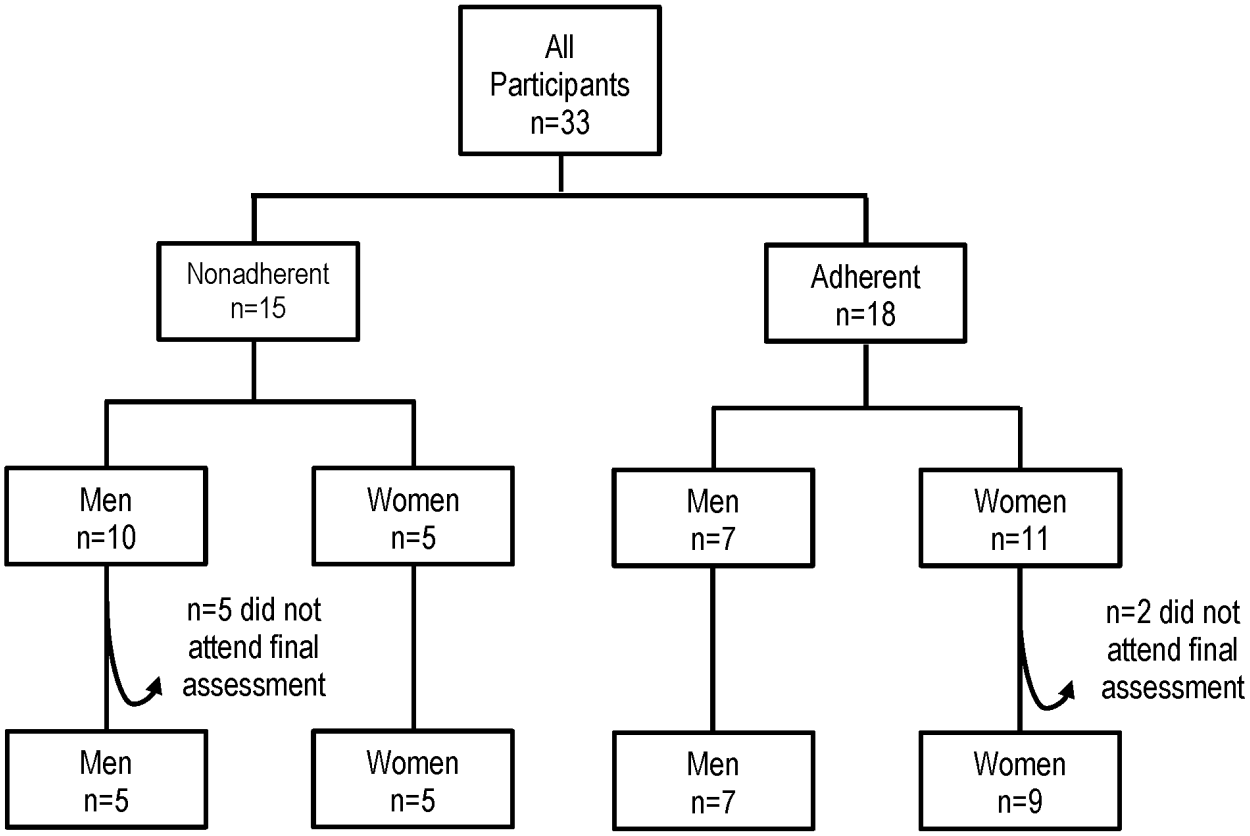
| Variables | | Total (N=33) | Nonadherent (n=15) | Adherent (n=18) |
|---|---|---|---|---|
| | Systolic | 137 (14) | 138 (11) | 136 (16) |
| | Diastolic | 83 (8) | 82 (8) | 84 (9) |

[a]Energy intake in kilocalories/day.

[b]Adherence is defined as logging into the Internet-based menu program at least once per week for a minimum of 18 weeks of the 24-week intervention (ie, 75% of weeks).

**Figure 1.** Flow diagram of the participants from enrollment to final assessment.




## Evaluation Outcomes

Of the total 33 participants, 18 (54%) of them were adherent (Figure 1) by our definition. On average, participants logged into the Internet-based menu program at least once per week for 14.7 weeks (9.9 weeks). Among the adherent group (Table 1), a higher proportion of participants were women, Europid, retired, and reported being a competent cook, were in the action stage of change, and reported a high level of physical activity.

Participants' change in weight at 24 weeks ranged from −12.4% to +4.0%, with a mean change of −2.0% (95% CI −2.6 to −1.4) overall and −3.6% (95% CI −4.4 to −2.2) in the adherent group (Table 2). A 5% or greater weight reduction was achieved by 6/33 participants (18%) overall and 5/18 participants (27.8%) in the adherent group. Only 1/33 participants (3%) overall and 1/18 adherent participants (6%) achieved a weight reduction of ≥10%. This one participant was successful in achieving a 12.4% net weight loss.

A reduction in A1C levels was found among participants (A1C change −0.4%, 95% CI −0.6 to −0.2), with the significant reduction observed in the nonadherent group. The A1C changes were not related to weight changes. It was found that excluding the 7 participants with changes in antihyperglycemic medications during the study period did not alter the direction of overall findings (ie, A1C change −0.3%, 95% CI −0.9 to 0.3).

Reductions in systolic and diastolic blood pressure were also observed (systolic change −2.1 mmHg, 95% CI −4.3 to 0.2; diastolic change −0.6 mmHg, 95% CI −1.7 to 0.5), with the adherent demonstrating a systolic change of −6.1 mmHg (95% CI −9.3 to −2.8) and diastolic change of −1.7 mmHg (95% CI −3.5 to 0.1 mmHg). There were reductions in dietary intakes of total energy, protein, carbohydrate, fat, saturated fat, fiber, and sodium. Improvements in physical activity were observed at 24 weeks, with a mean increase of 319 MET-min/week (95% CI −53 to 690).

The relationship between changes in weight and blood pressure is shown in Table 3. After adjustment for age and sex, the



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change of 1 kg unit for a weight (equivalent to a 1% weight change) was associated with a systolic blood pressure change of −2.2 mmHg (95% CI −3.1 to −0.6) and a diastolic blood pressure change of −0.8 mmHg (95% CI −1.4 to −0.1). It was also found that excluding the 6 patients with changes in antihypertensive medications did not alter findings. There were no clear relationships between modifications in carbohydrate intake and A1C change or between reductions in sodium intake and change in blood pressure. An increase of 100 MET-min/week resulted in −0.2 mmHg (95% CI −0.3 to −0.1) change in systolic blood pressure and −0.1 mmHg (95% CI −0.1 to −0.02) in diastolic blood pressure. Changes in physical activity did not appear to be a predictor of change in weight or A1C level.

**Table 2.** Changes overall and stratified by adherence and sex.

| Variables | | Mean (95% CI) Total (N=33) | Nonadherent (n=15) | Adherent (n=18) |
|---|---|---|---|---|
| Weight loss of ≥5%, n (%) | | 6 (18) | 1 (7) | 5 (28) |
| Weight (kg) | | −2.0 (−2.6 to −1.4) | 0 (−0.6 to 0.6) | −3.6 (−4.4 to −2.8) |
| % Weight | | −2.0 (−2.6 to −1.4) | 0 (−0.6 to 0.7) | −3.6 (−4.5 to −2.8) |
| BMI[a] (kg/m$^2$) | | −0.7 (−0.9 to −0.5) | 0.1 (−0.2 to 0.3) | −1.3 (−1.6 to −1.0) |
| **Waist (cm)** | | | | |
| | All | −2.2 (−3.0 to −1.4) | −1.7 (−2.4 to −0.9) | −2.7 (−3.9 to −1.4) |
| | Women | −2.6 (−3.3 to −2.0) | −0.58 (−1.6 to −0.5) | −2.3 (−4.3 to −0.2) |
| | Men | −1.7 (−3.2 to −0.3) | −2.0 (−3.2 to −1.2) | −3.3 (−4.1 to −2.4) |
| **Hip (cm)** | | | | |
| | All | −2.9 (−3.6 to −2.1) | −1.4 (−2.4 to −0.4) | −4.1 (−5.1 to −3.1) |
| | Women | −4.1 (−5.4 to −2.8) | −1.9 (−4.6 to 0.8) | −5.1 (−6.6 to −3.6) |
| | Men | −1.7 (−2.3 to −1.1) | −1.1 (−1.9 to −0.3) | −2.6 (−3.5 to −1.7) |
| **WHR** [a] | | | | |
| | All | 0 (−0.01 to 0.01) | 0 (−0.02 to 0) | 0.01 (−0.01 to 0.02) |
| | Women | 0.01 (0 to 0.02) | 0.01 (−0.01 to 0.02) | 0.01 (0 to 0.03) |
| | Men | −0.01 (−0.02 to −0.07) | −0.02 (−0.03 to −0.01) | −0.01 (−0.02 to 0) |
| A1C (%) | | −0.4 (−0.6 to −0.2) | −0.7 (−1.0 to −0.3) | −0.2 (−0.5 to 0.1) |
| **Blood pressure (mmHg)** | | | | |
| | Systolic | −2.1 (−4.3 to 0.2) | 2.7 (−0.1 to 5.5) | −6.1 (−9.3 to −2.8) |
| | Diastolic | −0.6 (−1.7 to 0.5) | 0.9 (−0.4 to 2.2) | −1.8 (−3.5 to −0.1) |
| Physical activity[b] (MET-min/week) | | 319 (−53 to 690) | −407 (−845 to 30) | 924 (371 to 1476) |
| Energy intake | | −418 (−518 to −318) | −463 (−584 to −343) | −380 (−536 to −224) |
| **Dietary intake (grams/day)** | | | | |
| | Protein | −22.7 (−27.9 to −17.5) | −27.2 (−32.7 to −21.7) | −19.0 (−27.4 to −10.6) |
| | Carbohydrate | −38.0 (−51.4 to −24.6) | −54.9 (−74.2 to −35.6) | −23.9 (−42.2 to −5.6) |
| | Fat | −20.2 (−25.6 to −14.7) | −20.1 (−27.3 to −12.9) | −20.2 (−28.3 to −12.1) |
| | Fiber | −3.9 (−5.6 to −2.2) | −6.8 (−9.0 to −4.7) | −1.5 (−3.9 to 1.0) |
| | Sodium | −0.7 (−0.9 to −0.5) | −0.6 (−0.8 to −0.4) | −0.7 (−1.0 to −0.4) |
| | Saturated fat | −7.9 (−9.6 to −6.1) | −9.1 (−11.6 to −6.5) | −9.8 (−9.3 to −4.4) |

[a]BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); WHR, waist-to-hip ratio (calculated as waist circumference divided by hip circumference.

[b]Adherence is defined as logging into the Internet-based menu program at least once per week for a minimum of 18 weeks of the 24-week intervention (ie, 75% of weeks).



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**Table 3.** Linear regression models examining relationships between weight change and changes in blood pressure and hemoglobin A1C.

| Model | | Change in outcome variable of interest per 1 kg unit decrease in weight | 95% CI |
|---|---|---|---|
| **Systolic (mmHg)** | | | |
| | Weight change | −2.30 | −3.50 to −1.11 |
| | Weight change, age, sex | −2.20 | −3.14 to −0.61 |
| | Weight change, baseline season | −2.17 | −3.41 to −0.93 |
| | Weight change, change in PA | −2.17 | −3.27 to −1.08 |
| **Diastolic (mmHg)** | | | |
| | Weight change | −0.76 | −1.40 to −0.13 |
| | Weight change, age, sex | −0.75 | −1.41 to −0.10 |
| | Weight change, baseline season | −0.76 | −1.43 to −0.10 |
| | Weight change, change in PA | −0.72 | −1.35 to −0.10 |
| **A1C (%)** | | | |
| | Weight change | 0 | −0.14 to 0.15 |
| | Weight change, age, sex | 0 | −0.15 to 0.15 |

## Discussion

### Principal Results

In a middle-aged to elderly cohort of adults with DM2 who consulted a registered dietitian, we determined that a 24-week program of Internet-based menu planning led to a 5% or more net weight reduction in approximately one fifth (6/33, 18%) of those who enrolled and over one fourth (5/18, 28%) of those who logged on weekly (mean 2% net weight reduction overall, 3.6% in adherent). Overall energy intake decreased and physical activity increased. There was an overall A1C reduction in this cohort (−0.4%), although it was not related to weight change. In contrast, there were significant reductions in blood pressure in the adherent group (systolic −6.1 mmHg; diastolic −1.8 mmHg); such a reduction, if sustained, is sufficient to lower the risk of future vascular complications. Blood pressure reductions overall were related to reductions in weight and increases in physical activity. These findings provide some evidence for potential effectiveness of an Internet-based menu-planning strategy (weekly plans, grocery lists, menus, and recipes) when the treating dietitian is involved in the structure of the plan, as was the case in our study. Conducting an RCT appears to be justified, based on our results.

### Comparison With Prior Work

As noted previously, two other groups of investigators have examined the effects of an Internet-based menu-planning strategy, “eDiets program” [7,8]. The weight change observed in the eDiets Internet-based menu-planning program was greater than that observed in our pilot study: among completers (n=48) of the eDiets study of Gold and colleagues, a weight loss of 5% or more was seen in 18 (37%) of the participants. However, the eDiets population included overweight individuals rather than overweight individuals with DM2. A previous study by Wing and colleagues suggests that individuals with DM2 have greater difficulty losing weight: weight loss was lower in overweight persons with DM2 compared to their overweight spouses who followed the same diet or exercise program [16]. In more recent studies, Wing and colleagues have achieved much greater weight losses in individuals with DM2 through a dietary intervention that incorporates meal replacements and strong behavioral therapy elements [17]. However, not all individuals with DM2 may be willing to use meal replacements. Therefore, for these individuals, an Internet-delivered menu plan may be a useful option, based on our findings.

Food frequency information suggested that our participants induced a caloric deficit of 418 kcal/day. Although such a deficit might be expected to result in a weight loss of 8.6 kg over a 24-week period, the actual weight loss observed was lower than this. Following the intervention, energy from fat and saturated fat intake remained 3.8% and 4.0% above recommendations for DM2, respectively [10]. Incorporating complex and low-glycemic index carbohydrates and dietary fiber is associated with lower prevalence of cardiovascular diseases and better glycemic control [10,18,19]. Overall, mean carbohydrate intake of participants at baseline was lower than recommendations and decreased by 3.9 g at final assessment.

The reduction in sodium intake was found to be 0.7 g/d overall. Sodium intake at final assessment was 2.3 g/d, which is an amount associated with reduced blood pressure in previous studies using DASH menus [20]. A relationship between the reduction in sodium intake and change in blood pressure was not established, however, in our study, perhaps because of sample size limitations.

Overall, clinically important changes in A1C were observed but reductions were more pronounced in nonadherent participants. Notably, however, baseline A1C values were roughly 1.0% greater among nonadherent participants compared to those who adhered (Table 1); this could have contributed to the greater A1C change noted in the nonadherent group (ie, greater “room” to decline).



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Further, we observed reductions in blood pressure among adherent participants. Blood pressure changes corresponded to weight changes. In our study, a 1 kg loss of body weight was associated with 2.2 mmHg decrease in systolic blood pressure (95% CI −3.1 to −0.6); thus, a 10 kg reduction might be extrapolated to lead to a 20 mmHg decrease. This relationship between weight change and systolic blood pressure change is in agreement with what would be expected from previous studies [21]. In our study, increased physical activity was associated with improvements in both systolic and diastolic blood pressure. These results are also consistent with previous literature [21]. We would note that while participants were encouraged to engage in regular physical activity by their dietitians and on the website, this was not a specific focus of the intervention.

### Limitations

The limitation of our study is its small sample size, but, as noted above, precise estimates (ie, narrow CIs) of effect measures were obtained. Due to funding limitations, the study involved comparisons of pre- and postintervention values rather than a randomized controlled design with an intervention and control group. However, we would note that we endeavored to link the program with changes by assessing the relationship between weight changes and changes in glycemia and blood pressure. With respect to the intervention itself, it may have been strengthened by greater emphasis on self-monitoring [7,8,22,23] and motivational messages to increase the frequency of logging into the program and to improve patient adherence to dietary recommendations. We opted not to further modify the existing program because we wanted to evaluate a "real-life" program, as such a program would potentially be accessible for use even after the study. At the time of the final evaluation, several participants endorsed the utility of the Internet-based tools; however, timelines and funding precluded a systematic qualitative assessment. We acknowledge this as a limitation, and note that we have performed such assessments in other examinations of behavioral interventions [24,25].

### Conclusions

Our pilot study findings indicate that in adults with DM2, recruited from standard care clinics, nutritional prescriptions operationalized through an Internet-delivered menu-planning strategy may improve the vascular risk profile of an important proportion of participants who log in regularly. This appears to occur through weight changes that lead to blood pressure reductions, even in the context of antihypertensive therapy. The effects on glycemic control, however, are not clear. The strategy could be strengthened through greater emphasis on self-monitoring and motivational support.

Internet-based tools have the advantage of ease of access to a large number of individuals at their own convenience. Our study adds to the evidence base that this type of strategy may be a modern adjunct to diabetes care in those with Internet access who log in regularly. Behavioral nutrition approaches may be conceptualized as ranging from less structured to more structured approaches. These range from gaining familiarity with general nutritional principles, acquiring a planning framework (eg, carbohydrate exchanges, "points"), receiving plans, and planning tools to using meal replacements or prepared meals. Internet-based tools lie in the midrange of this spectrum, providing plans and tools, but still allowing consumption of home-cooked meals. In combination with reliable dietary education, our study suggests that these tools may have some beneficial effects. Our findings may be used to inform an RCT to definitively test this possibility.

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### Authors' Contributions

Peer-reviewed funding for this study was obtained by KD from Diabète Québec and the Vice Principal Research Office of McGill University. KD designed the study with important input from RG, LJ, and DD. KD supervised data collection and study procedures. AB conducted the analyses under the supervision of KD, LJ, and RG. AB and KD wrote the manuscript with critical input from LJ, RG, and DD.

### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Sample of a 1-day diabetes menu plan.

[PPTX File, 530KB - resprot_v2i2e41_app1.pptx ]

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## Abbreviations

**DM2:** type 2 diabetes mellitus
**IPAQ:** International Physical Activity Questionnaire
**RCT:** randomized controlled trial

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Short Paper

# Feasibility and Effectiveness of an Automated Bilingual Text Message Intervention for Weight Loss: Pilot Study

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## Abstract

**Background:** Little is known about the feasibility and acceptability of tailored text message based weight loss programs for English and Spanish-language speakers.

**Objective:** This pilot study evaluated the feasibility, acceptability, and estimated impact of a tailored text message based weight loss program for English and Spanish-language speakers. The purpose of this pilot study was to inform the development of a full-scale randomized trial.

**Methods:** There were 20 overweight or obese participants (mean age 40.10, SD 8.05; 8/20, 40% male; 9/20, 45% Spanish-speakers) that were recruited in San Diego, California, from March to May 2011 and evaluated in a one-group pre/post clinical trial. For 8 weeks, participants received and responded to 3-5 text messages daily sent from a fully automated text messaging system. They also received printed weight loss materials and brief 10-15 minute weekly counseling calls. To estimate the impact of the program, the primary outcome was weight (kg) measured during face-to-face measurement visits by trained research staff. Pre and post differences in weight were analyzed with a one-way repeated measures analysis of variance. Differences by language preference at both time points were analyzed with *t* tests. Body mass index and weight management behaviors also were examined. Feasibility and acceptability were determined by recruitment success, adherence (ie, percentage of replies to interactive text messages and attrition), and participant satisfaction.

**Results:** Participants who completed the final assessment (N=18) decreased body weight by 1.85 kg ($F_{1,17}$=10.80, $P$=.004, $CI_{\Delta}$ 0.66-3.03, $\eta^2$=0.39). At both time points, there were no differences in weight by language preference. Participants responded to 88.04% (986/1120) of interactive text messages, attrition rate was 10% (2/20), and 94% (19/20) of participants reported satisfaction with the program.

**Conclusions:** This fully automated text message based weight program was feasible with English and Spanish-speakers and may have promoted modest weight loss over an 8-week period.

**Trial Registration:** Clinicaltrials.gov NCT01171586; http://clinicaltrials.gov/ct2/show/NCT01171586 (Archived by WebCite at http://www.webcitation.org/6Ksr6dl7n).

***(JMIR Res Protoc 2013;2(2):e48)*** doi:10.2196/resprot.2789



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**KEYWORDS**

physical activity; diet; obesity; health behavior; Hispanic Americans; weight loss; cellular phone; text messaging

## Introduction

Text message based programs to promote behavior change are a rapidly growing area of research. This inexpensive, instantaneous, two-way communication of brief written messages via a mobile phone has many capabilities that may be useful for promoting weight loss. For example, texting features can support important constructs in behavior change theories such as cues to action, reinforcement, goal setting, goal reminders, and feedback. Text messages can be used as a stand-alone program [1-4] or can be integrated easily with other wireless or networked technologies [5,6]. Studies have demonstrated that text messages promote improved diet [5], increased physical activity (PA) [4,7-10], behavioral strategies like self-monitoring [3], and weight loss [1,2,6,11,12]. However, more research is needed regarding long-term efficacy and best practices of these programs, in particular in diverse populations.

This pilot study evaluated feasibility and acceptability of a tailored text message based weight loss program for English and Spanish-language speakers and enabled an estimate as to its impact on weight status. The purpose of this pilot study was to inform the development of a full-scale randomized trial.

## Methods

### Unblinded One-Group Pre/Post Design

We used an unblinded one-group pre/post design. The Institutional Review Board of University of California, San Diego (UCSD) approved this study. This manuscript is in accordance with the CONSORT-EHEALTH checklist [13] and is a registered trial (NCT01171586).

### Recruitment

Participants were recruited in San Diego, California, from March to May 2011 via newspapers, flyers, online announcements, and participant recommendations. The first 20 individuals who met the eligibility criteria were enrolled, with a goal of 40% (8/20) male and 50% (10/20) self-identified Spanish-speaking. Bilingual speakers choose language-message preference.

Eligible individuals were 21-60 years of age, had a body mass index (BMI) of 27.0-39.9, had a cellphone capable of sending and receiving text messages, were current users of texting or willing/able to learn, and could communicate in English or Spanish. Participants were excluded if they could not engage in moderate intensity PA, were pregnant or intended to become pregnant during the study, had a history of substance abuse or psychiatric disorders that would impair compliance, were using weight-altering medications, or were enrolled in another weight loss program. At baseline, potential participants were screened for inclusion and exclusion criteria and underwent written informed consent. Participants were compensated $75 for participation and $10 for a text message plan.

### Intervention

Social cognitive theory [14], control theory [15], and ecological theory [16] informed the intervention. It integrated these theoretical approaches with evidence-based behavioral strategies for improving diet and PA. Strategies include self-monitoring, intention formation, goal setting, goal review, feedback on performance, self-efficacy, benefits, barriers, problem-solving, social support, and tailoring.

The 8-week intervention included: (1) 3-5 automatically scheduled and tailored text messages per day. Message content focused on diet and PA weight management behaviors and strategies; (2) a printed weight loss binder organized by weekly weight management topics such as portion control, increasing PA, reducing sedentary behavior, and self-monitoring; and (3) brief weekly 10-15 minute counseling calls to provide encouragement and reinforcement. A database was developed of more than 3000 text messages. The research group translated and culturally tailored the messages to Spanish-speakers to ensure linguistic and cultural equivalence. Approximately one-quarter of messages requested a reply, with the balance providing tips, suggestions, and positive reinforcement or encouragement for improved behaviors. The following shows sample messages sent and received from ConTxt (San Diego, CA 2011): (1) ConTxt–What is your weight today?, (2) Participant–220, (3) ConTxt–Congratulations! You have lost 5 lbs since starting ConTxt, (4) ConTxt–Here's a healthy tip, put your pedometer on your nightstand so you can remember to put it on in the morning, (5) ConTxt–Work on your goal of reducing portion sizes this week by buying single serving pre-packaged snacks, and (6) ConTxt–Thank you. Your response has been recorded. A total of 1500 rules were added to control what message was sent based on the weekly behavioral strategy, day of the week, and time of day, as well as other parameters such as self-reported weight management behaviors and pedometer step count. A baseline dietary assessment of weight management behaviors was conducted using the Weight Behavior Inventory (WBI) to identify unique diet and PA behavior challenges for each participant contributing to high-energy intake and low-energy expenditure. A computerized expert system processed these data to create individualized goals based on predetermined logic rules. Goals were presented to the user via text message to serve as prompts for behavioral improvements. The system is designed so participants who show rapid and sustained progress can advance through content, while those experiencing difficulties can receive additional tips and suggestions.

### Measures

Outcomes were measured at baseline and 8 weeks by trained research staff at UCSD research offices during face-to-face visits. The primary outcome was weight (kg) measured using a calibrated scale. Secondary measures included BMI calculated as $kg/m^2$ and weight management behaviors associated with weight loss measured with the 35-item WBI (validation study under review, Kolodziejczyk et al 2013). The WBI was adapted



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from the validated Eating Behavior Inventory [17,18]. Each behavior on the WBI is rated on a five-point scale. Total scores are averaged and can range from 1-5. Sample items include "I keep one or two raw vegetables available for snacks" and "I decide ahead of time what I will eat for meals and snacks."

Feasibility and acceptability were measured by recruitment success, adherence, and participant satisfaction. Recruitment was deemed successful if we achieved our enrollment goal of 20 participants in two months. Adherence was measured by percentage of replies to interactive text messages (ie, text messages requesting a reply) and attrition rate. Satisfaction was measured using a Likert scale that asked about level of satisfaction with the program, as well as program components. In addition, we asked open-ended questions about elements of the program such as what they liked the least and best.

### Statistical Analysis

Pre and post differences between weight, BMI, and WBI scores were analyzed with one-way repeated measures analysis of variance. WBI score differences between gender and language preference at each time point were analyzed with independent sample *t* tests. Analyses used an alpha level <.05 and were conducted using SPSS Statistics 17.0 (SPSS Inc, Chicago, Illinois).

## Results

### Participants

A total of 18 out of the 20 participants completed all measures (ie, two participants completed the program but did not show for their final assessment). On average, the sample was obese and had approximately equal percentages of participants across demographic categories. Table 1 displays participant demographics.

**Table 1.** Demographic characteristics of the ConTxt pilot participants (N=20).

| Demographic variables | | Overall sample |
|---|---|---|
| Age at study entry in years, mean (SD) | | 40.10 (8.05) |
| BMI (kg/m$^2$), mean (SD) | | 33.67 (4.00) |
| Female, n (%) | | 12 (60) |
| **Education, n (%)** | | |
| | Trade or technical school | 6 (30) |
| | Some college | 2 (10) |
| | College graduate | 3 (15) |
| | Graduate degree | 7 (35) |
| | "Prefer not to answer" | 2 (10) |
| Married, n (%) | | 11 (55) |
| **Race/ethnicity, n (%)** [a] | | |
| | Hispanic | 15 (75) |
| | White non-Hispanic | 13 (65) |
| | Asian | 2 (10) |
| | "Prefer not to answer" | 4 (20) |
| **Language preference, n (%)** | | |
| | English | 11 (55) |
| | Spanish | 9 (45) |
| **Monthly income, n (%)** | | |
| | $1,000-1,999 | 5 (25) |
| | $2,000-3,999 | 5 (25) |
| | $4,000-5,999 | 6 (30) |
| | ≥ $6,000 | 3 (15) |
| "Don't know/prefer not to answer" | | 1 (5) |

[a]More than one race category may apply



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### Participants' Body Weight

Participants decreased body weight by 1.85 kg ($F_{1,17}$=10.80, $P$=.004, $CI_{\Delta}$ 0.66-3.03, $\eta^2$=0.39), decreased BMI by 0.70 kg/m$^2$ ($F_{1,17}$=13.21, $P$=.002, $CI_{\Delta}$ 0.29-1.11, $\eta^2$=0.44), and increased WBI scores by 0.56 points ($F_{1,17}$=14.51, $P$=.001, $CI_{\Delta}$ 0.25-0.87, $\eta^2$=0.46) (Table 2). At baseline, there were no differences in WBI scores by gender ($t_{18}$=0.71, $P$=.48, $CI_{\Delta}$ −0.31 to 0.62). There were no baseline differences by language preference and weight ($t_{18}$=0.14, $P$=.89, $CI_{\Delta}$ −15.44 to 17.60), BMI ($t_{18}$= −0.51, $P$=.61, $CI_{\Delta}$ −4.80 to 2.91), or WBI scores ($t_{18}$=1.01, $P$=.33, $CI_{\Delta}$ −0.23 to 0.67). At 8 weeks, there were no differences in WBI scores by gender ($t_{16}$=0.81, $P$=.43, $CI_{\Delta}$ −0.54 to 0.24), but participants preferring Spanish language had higher WBI scores (mean 2.87, SD 0.33) than English-preference participants (mean 2.48, SD 0.32; $t_{16}$=−2.60, $P$=.02, $CI_{\Delta}$ −0.72 to −0.07). There were no differences at 8 weeks by language preference and weight ($t_{16}$=0.07, $P$=.95, $CI_{\Delta}$ −19.16 to 20.47) or BMI ($t_{16}$=−0.36, $P$=.73, $CI_{\Delta}$ −5.34 to 3.80).

**Table 2.** Weight, BMI, and WBI from the ConTxt pilot study (San Diego, CA 2011) at baseline and 8 weeks (N=18).

| Outcome | Baseline | 8 weeks | % Change |
|---|---|---|---|
| Weight (kg)[a], mean (SD) | 92.96 (39.65) | 91.11 (42.41)[b] | -1.99 |
| BMI (kg/m$^2$), mean (SD) | 33.78 (4.16) | 33.07 (4.45)[b] | -2.10 |
| WBI score (points) | 2.11 (0.49) | 2.67 (0.37)[c] | 26.54 |

[a]kg= kilograms

[b]$P$<.01

[c]$P$<.001

### Participant Interest

There was considerable interest in the study, as the recruitment goal of enrolling 20 participants in two months was achieved quickly after receiving 123 inquiries. Participants responded to 88.04% (986/1120) of interactive text messages, and there was a low 10% (2/20) attrition rate. Most participants (94%, 19/20) reported satisfaction with the program. Participants also reported the program helped motivate and reinforce healthier habits and choices (n=5), encouraged portion control and awareness of energy intake (n=4), and taught how to be more active (n=5). Some challenges participants reported included feelings of withdrawal after the program ended (n=7) and technical issues with their phone, which sometimes hindered message response (n=4).

## Discussion

### The Weight Loss Program

An 8-week text message based weight loss program was found to be both feasible and acceptable in terms of recruitment interest, participant adherence, and satisfaction. The program may have had positive effects on weight management behaviors and weight outcomes, although this needs to be confirmed in a study with a stronger design. These results are consistent with previous text message based weight loss studies [1,2,11]. Based on information we received from this pilot, some changes to be implemented in the full-scale trial include user-initiated messages (eg, suggestions for restaurant meals, PA), more message personalization (eg, names of social supporters, PA locations), a greater focus on participant message preference (eg, participants will be able to set text message preferences through the use of a like/unlike system), inclusion of "milestone" and "competitive" messages based on weight and pedometer step count (eg, when a participant reaches a certain milestone, such as five pounds lost, he or she will receive a congratulatory message, and the system will compare the participant's weight loss with the groups' weight loss), and improvements to system programming to reduce technical errors (eg, a participant not receiving the correct follow-up message). In addition, based on feedback from the Spanish-language speaking participants, we made some of the Spanish materials clearer (eg, more pictures, simpler language).

### Study Limitations

Study limitations include a small sample, a short time frame, and a one-group pre/post design. Therefore, our findings are suggestive rather than conclusive. Based upon these pilot study findings a full-scale randomized controlled trial currently is underway enrolling 298 participants for a one-year intervention.

### Acknowledgments

The National Cancer Institute (R01CA138730; Clinical Trial Registration: NCT01171586) supported this project. We gratefully acknowledge the support of everyone at the Center for Wireless & Population Health Systems.

### Conflicts of Interest

Dr Patrick is co-owner of Santech, Inc, which is developing products related to the research described in this paper. Terms of this arrangement have been reviewed and approved by University of California, San Diego in accordance with their respective conflict of interest policies. Dr Norman, Dr Rock, and Mr Raab have received consulting income from Santech, Inc.



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## Abbreviations

**BMI:** body mass index
**PA:** physical activity
**UCSD:** University of California, San Diego
**WBI:** Weight Behavior Inventory



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Original Paper

# A Rehabilitation Tool Designed for Intensive Web-Based Cognitive Training: Description and Usability Study

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## Abstract

**Background:** Cognitive deficits are among the most disabling of neurological diseases and have a serious impact on the quality of life of patients and families. Cognitive training has been proven successful in improving or compensating for neuropsychological deficits after acute brain injury, but its efficacy highly depends on the intensity of treatment over an extended period of time. Therefore, cognitive training indicates expensive human resources and renders the rehabilitation process vulnerable to physical and economic barriers for the majority of patients.

**Objective:** The aim of this study was to develop and test a new Web-based rehabilitation tool that provides intensive cognitive training at home under clinical prescription and monitoring, at affordable costs.

**Methods:** From a pool of 60 original exercises, designed and used over the past 10 years for cognitive training at our center, we developed 27 exercises on a computer game format, with automatic increase or decrease of difficulty levels. These exercises were assembled in a clean, user-friendly design and covered various cognitive domains such as attention (n=4), memory (n=11), language (n=3), calculus (n=3), praxis (n=2), and executive functions (n=3). A Web 2.0 platform was also designed to provide medical prescription of cognitive training sessions, performed at the patient's home. These sessions included continuous monitoring of compliance, performance, and evolution; algorithms for automatic adjustment and long-term learning through use, and database recording of all activities. The end-user interaction test included 80 patients from our memory clinic from several groups including subjective memory complaints (n=20), traumatic brain injury (n=20), stroke and other static brain lesions (n=20), and mild Alzheimer's disease (n=20). During a 1-hour session, patients and their relatives were taught to use the system and allowed to practice using it. At the end of the session, they were asked to complete a questionnaire.

**Results:** A total of 48/80 patients (60%) attended the training session. The mean age of the patients was 60 years (SD 13.3, range 41-78), and the mean level of formal education was 6 years (range 4-16). Of all the participants, 32/48 patients (66%) have previously used a computer. All patients and their relatives made a positive evaluation of the cognitive training tool. Only 2/48 patients (4%) were not interested in performing the exercises at home; 19/48 patients (39%) mentioned the need for further coaching from a relative or health care professional. The patients who mentioned difficulties in performing the exercises have not used the computer earlier.

**Conclusions:** This new Web-based system was very well accepted by patients and their relatives, who showed high levels of motivation to use it on a daily basis at home. The simplicity of its use and comfort were especially outlined. This tool will have



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an important effect on human resource management, in increasing the patient access to specialized health care and improving the quality and national health system costs of rehabilitation programs.

*(JMIR Res Protoc 2013;2(2):e59)* doi:10.2196/resprot.2899

**KEYWORDS**

cognitive training; cognitive deficits; neurorehabilitation; Web-based applications; eHealth systems; usability test

## Introduction

### Overview

Neurological disorders are commonly associated with a variety of cognitive and motor deficits that result in an ever increasing demand for health services. Among all major groups of diseases, neurological disorders constitute 6.3% of the global burden of diseases worldwide [1]. This value may be as high as 10.9% for high-income countries and 11.2% in the European region, which corresponds to 15-30 years of life lost adjusted for disability per 1000 inhabitants each year [1]. Irrespective of the cause (eg, stroke, brain injury, or dementia), people with cognitive impairments rarely recover spontaneously or completely [2].

Once established, brain damage is difficult to revert and pharmacological tools with a confirmed positive result are scarce [3-5]. The recovery process is typically slow, relies on the remaining plastic properties of brain tissue, and is highly dependent on complex and intensive assisted rehabilitation programs [6]. Similar to other rehabilitation processes, the results of the recovery process also depend on the timely onset, intensity, and specificity of the treatments [7,8].

The neurorehabilitation programs have proven efficacious in the compensation, improvement, and stabilization of cognitive deficits in several diseases and nosological models [9-17]. However, despite being accepted as a fundamental component of current treatment plans, these programs often impose strong restrictions on the patients' access to such treatments [18,19]. These programs commonly require multidisciplinary teams and are usually performed in hospital settings, away from the patient's home, in the presence of a relative (a huge effort by patients, families, and institutions). Classic cognitive training in particular requires pencil-and-paper tasks and object manipulation under specialized supervision. These characteristics result in a large economic burden to both the health system and families [20,21]. Furthermore, they limit the efficacy of the treatment by increasing the difficulty in coping with rehabilitation sessions in due time (soon after injury) and in attaining the high intensity of treatment necessary to foster nervous system plasticity [8,22].

The computer has emerged as a tool for the training and educating patients with brain injury, thus reducing the large demand for human resources and increasing the motivation of these patients [9,23]. However, the use of informatics programs in cognitive training is a recent approach; hence well-designed clinical trials are scarce, and the majority of them are inadequate for efficient integration in current clinical practice [18,24]. Therefore, the sole reliance on repeated exposure to computer-based tasks without some involvement and intervention by a therapist is not recommended [9].

To address these problems, we decided to develop a new integrative Web-based tool "COGWEB" for home-based cognitive training, centered not only on the patients' needs but also on professionals and institutional requests. This instrument takes advantage of the growing knowledge on computerized training protocols for cognitive rehabilitation [18,25-29] and combines a Web-based platform with computer exercises developed over the last few years in an outpatient memory clinic. The aim of this tool is to increase the quality and overall intensity of cognitive training programs.

This paper presents the main characteristics of the developed system and the results of a usability testing of the online system performed by patients suffering from highly prevalent neurological diseases, and their relatives.

### Previous Approaches

Over the past few years, several solutions have been proposed to increase the availability of cognitive training. In fact, the market is flooded with commercial brain exercise programs that claim to improve cognition, have diagnostic abilities, and even replace the role of specialized health professionals along the way [30]. However, extensive clinical validation is still lacking and only a few programs have undergone scientific inquiry [26,27,31-33].

Previous approaches to cognitive training can be summarized into 3 categories: (1) cognitive domain-specific programs, (2) neuropsychological software programs, and (3) video games.

Cognitive domain-specific programs train specific cognitive capacities, usually under professional guidance at a health institution, and rely on the repetition of standardized tasks on a computer. Training of reaction time [34], processing speed [35], selective attention [36], and working memory [37,38] are some examples of these applications.

Neuropsychological software programs are designed to train several cognitive domains using a variety of tasks. These programs rely on immediate feedback and allow individuals to evolve based on their performance. Most studies with these tools analyze multiple cognitive domain interventions, either in the lab or remotely, for example, the Posit Science Brain Fitness Program [39], the Integrated Cognitive Stimulation and Training Program [40], the Neuropsychological Training [41], the CogniFit Personal Coach [42], and Lumosity [29]. Most of these programs are commercially available and especially designed for older people, as this age group is their biggest target market [30]. Nonetheless, there is a specific growing group dedicated to children and academic performance, usually under the format of tutorials [43].



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Video games include computer or other electronic games where the players are enrolled in a set of activities oriented toward achieving a specific goal. Patients are given immediate feedback, and these games allow for an automatic progression between different levels of difficulty according to performance. The cognitive domains in this category are more difficult to individualize [18,44]. This category includes games originally designed to improve cognition like Nintendo's Big Brain Academy for Wii [45], classics like Pac Man, Donkey Kong, or Tetris that were studied for processing speed [46], and recent commercial successes like Rise of Nations [47] and Medal of Honor [48] that were assessed for attention, memory, executive function, and visuospatial abilities.

### Unmet Needs and Problems

Computerized cognitive training offers several advantages over traditional pencil-and-paper tasks mediated by a psychologist or therapist at a health institution. The human resource costs per patient treated and the treatment time decrease, and home-bound or remotely located persons can have easier access to the treatment. In spite of all the available alternatives, several important needs remain unanswered [49]. Most of the programs available have a reductionist approach to brain conditioning or rehabilitation, discourage human relations in favor of self-executed exercises at home, and increase the distance between individuals or patients and specialized health professionals [30]. Furthermore, although all individuals may benefit from the use of novel technologies, the acquisition of regular training routines and computer skills is not straightforward for older people or patients with cognitive problems if we want to have an inclusive approach.

From the scientific point of view, research studies lack well-conducted randomized clinical trials, and most importantly, a clear definition of what a placebo is in these trials [50,51]. Furthermore, there is an absence of dose-finding studies that could assess what is necessary to obtain effects on other cognitive domains or improvement of daily living activities. Another major concern is the lack of studies to determine the possible side effects of these interventions. Noninvasive brain stimulation and cognitive enhancement strategies may have a mental cost on some abilities [52]. This feature is of utmost importance to deal with brain injury models like stroke or traumatic brain injury, where the rehabilitation of several brain functions competes for the uninjured cortex plastic and metabolic properties. Side effects are also important in neurodegenerative disease models where intensive training activities may have undesired effects if not controlled, monitored, or integrated in the social life and networks of individuals [30,44,49].

## Methods

### End-User Interaction Study Design

#### *Clinical Settings for Using COGWEB*

Patients with changes in cognition attend different specialized medical appointments, where their medical and therapeutic needs are identified and assessed. Normally in the diagnosis procedure, besides other examinations, the patient is frequently submitted to neuropsychological assessments. Therapeutic plans for cognitive intervention are defined in this multidisciplinary clinical environment. The COGWEB appears in this context as a work tool, and the practitioner is responsible to manage and use the system, according to the clinical context and the patient's characteristics (Figure 1, Table 1). The mandatory prerequisites for using the COGWEB are the existence of a medical diagnosis, a detailed neuropsychological characterization of the cognitive impairments, and a health professional willing to manage the treatment program, essential for a quality analysis of the system. The therapist that handles the system plays a central role in defining the degree of supervision and the type of patient exposure to the treatment and the Web-based system. The management of objectives, areas of cognitive intervention, individual composition of training sessions, and duration and intensity of treatment are all under the responsibility of the health professional. Although the presence of therapists is not continuously necessary for the training, they can actively direct all activities via online interaction and periodic (eg, daily, weekly, or monthly) meetings or telephone contact with the patient and caregiver (Multimedia Appendix 1).



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**Figure 1.** Clinical context in which COGWEB was developed.

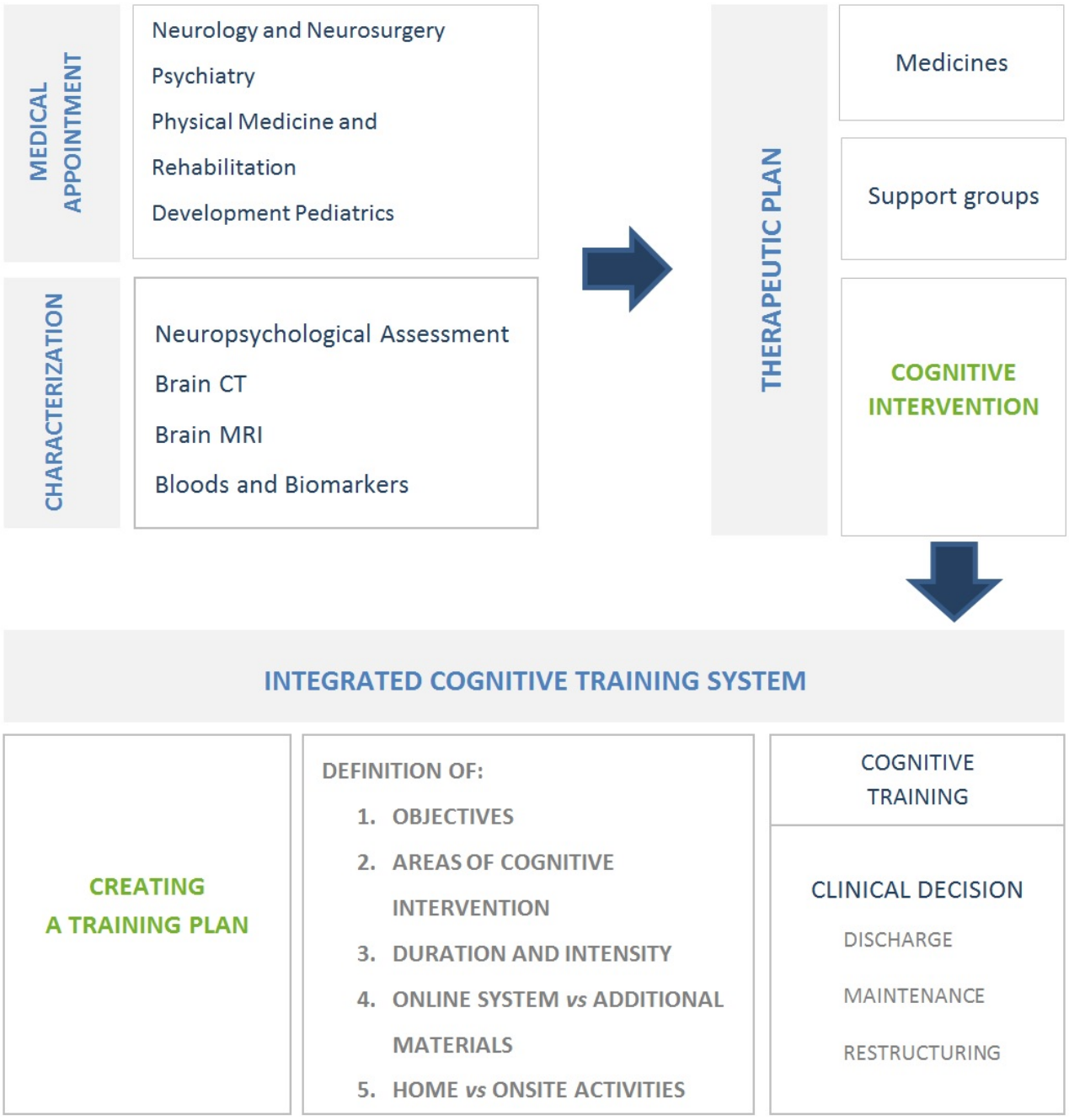




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**Table 1.** Target neurological conditions of the COGWEB system.

| Major subgroups of diseases | Most important diseases |
|---|---|
| Non progressive structural lesions | Traumatic brain injury |
| | Stroke |
| | Sequels of brain paralysis, anoxia, radiotherapy, encephalitis, brain surgery, and other static brain lesions |
| Neurodegenerative diseases at an initial stage | Mild cognitive impairment |
| | Alzheimer's disease |
| | Parkinson's disease |
| | Vascular dementia |
| Cognitive dysfunction of functional nature | Subjective memory complaints |
| | Depression |
| | Normal aging and active aging strategies |
| Other nosological models | Multiple sclerosis |
| | Schizophrenia |
| | Hyperactivity and attention deficit (adults and children) |

### *Patient Selection*

A group of 80 consecutive patients from our outpatient memory clinic were selected and grouped equally into 4 nosological groups: 20/80 (25%) with subjective memory complaints, 25% with traumatic brain injury, 25% with stroke and other static brain lesions, and 25% with mild Alzheimer's disease. The recruitment process took 3 months, and the following cumulative selection criteria were included: (1) a medical diagnosis compatible with 1 of the 4 groups, (2) 4 years of formal education completed, (3) favorable opinion of the attending neurologist, (4) no sensorial or physical deficiency preventing the use of regular computers unaided (eg, blindness, hemiplegia, or amputation), and (5) informed consent from both the patient and relative.

### *Group Sessions, Procedures, and Usability Questionnaire*

Patients and caregivers (n≤20) were scheduled for psychoeducational group sessions at the hospital in a room with 10 computers with the Internet access. Two attempts per patient were performed to schedule the sessions at working hours. The sessions were structured into 3 parts (20 minutes each): (1) a psychologist provided an overview about the program and individual credentials for each patient to assess the online system; (2) the pair patient-caregiver was allowed to experiment with the program unaided on 1 of the 10 computers in the room; and (3) after completing a regular training session with 8 different exercises, an opinion questionnaire on the easiness of use and motivation for using it at home was answered anonymously by both the patient and caregiver in the absence of the psychologist (Table 2).

**Table 2.** Opinion questionnaire.

| Question | | Possible answers |
|---|---|---|
| Q1 | Were the instructions easy to follow? | Yes/No |
| Q2 | Were the exercises interesting to you? | Yes/No |
| Q3 | Did you find the training useful to you? | Yes/No |
| Q4 | Are you motivated to use it at home? | Yes/No |
| Q5 | Having completed this training session, do you feel already independent to use it, or do you need additional training? | Independent/Additional training |

### *Ethical Issues*

All patients and caregivers understood the purpose of the study and provided written informed consent. An approval from the referring neurologist was also obtained to guarantee that patient and caregiver expectations were properly managed after the usability test. This study was approved by the hospital review board and ethics commission.

## Rehabilitation Tool

### *Main Characteristics*

The Integrated Cognitive Training System is composed of 2 components: (1) an online platform, COGWEB and (2) a series of tools in the classic format of exercise books [53,54].

First, the COGWEB allows for the implementation of personalized cognitive training programs remotely, in the patient's living environment. The tool is implemented through the professionally supervised prescription of exercise sessions,



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in computer game format, targeted to various cognitive functions, such as attention, executive functions, memory, language, praxis, gnosis, and calculus. Supervision is conducted by specialized practitioners without the loss of human contact or management (Figure 2).

Second, the exercise books were designed in parallel with the online platform and are useful during the initial stages of the training (Table 3). They can also be used to switch between stimulation methodologies if deemed necessary by the health professional, and to help people who, for various reasons, have no regular access to the Internet. Thus, people who face difficulty in using computers can start their training activities with paper and pencil, acquire routines, and then move up to a more intensive system (Multimedia Appendix 2).

Both system components are meant to be used as support for a wide range of cognitive interventional approaches, or at distance, under supervision with the neuropsychologist, being more or less present depending on the case (Figure 1, Table 1). The main structure of the online system is described in Figure 2 and its principal functional characteristics, resulted from a set of usability requirements defined by a board of clinicians, and are explained in the following text.

The online system was structured for modular cognitive training, as exercises were grouped according to major cognitive function stimulated (Table 4). This system covers different degrees of impairment, from normal function to moderate deficits, given that all exercises have sequential levels of difficulty and were designed for use in a wide range of diseases and ages (Figure 3). The monitoring tools coupled with biostatistics and long-term system analysis tools and a storage system that records performance continuously are incorporated into the system to supervise clinical evolution and adjust programs according to the patients' progression. This system can be used in supervised group sessions with patients and can also be accessed at home or at any other place in the community with an Internet connection, only requiring a login information (without software installation or updates).

**Figure 2.** Global system scheme.

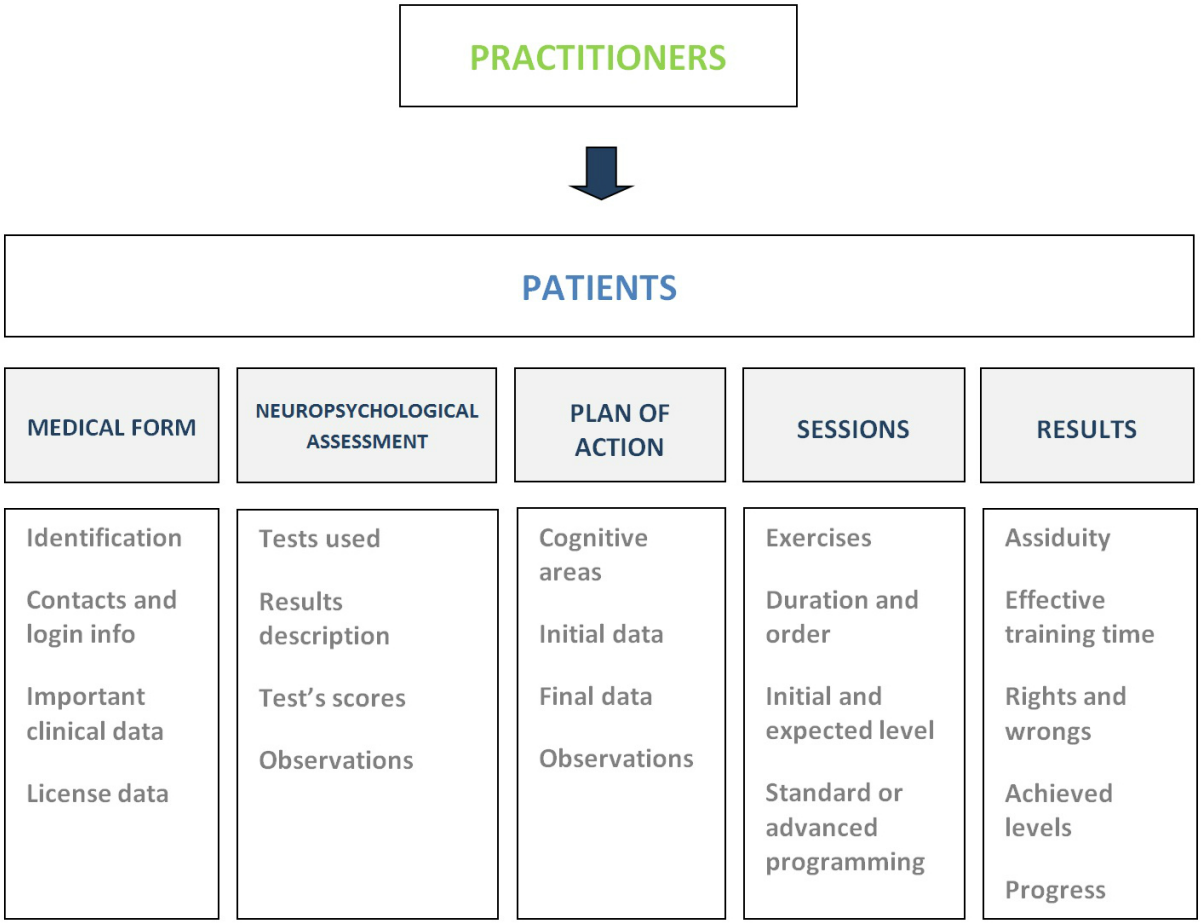




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**Table 3.** Exercise books available and their target population.

| Exercise books | Active ageing | Degenerative diseases | | | Static brain lesions | |
|---|---|---|---|---|---|---|
| | | MCI[a] | Mild dementia | Moderate dementia | Stroke | TBI[b] |
| Weekly notebooks, Volumes I to IV | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Monthly notebooks Level 3, Volumes I to III | ✓ | ✓ | | | ✓ | ✓ |
| Monthly notebooks Level 2, Volumes I to III | | | ✓ | | ✓ | ✓ |
| Monthly notebooks Level 1, Volumes I to III | | | | ✓ | ✓ | ✓ |
| COGWEB Art, 3D pieces | ✓ | ✓ | ✓ | | ✓ | ✓ |

[a]Mild cognitive impairment.

[b]Traumatic brain injury.

**Table 4.** Available exercises per cognitive domain.

| Cognitive domain | Exercise | Levels (N) |
|---|---|---|
| Attention | Attention to the letter | 5 |
| | Attention to the number | 5 |
| | Find the letter | 9 |
| | Water colors | 10 |
| Memory | Attention to the news | 3 |
| | Fast eye | 8 |
| | Fast memory | 8 |
| | Long memory | 14 |
| | Numbers in order | 8 |
| | Restless cubes | 7 |
| | Reverse the stars | 7 |
| | Supermarket | 8 |
| | Who moved | 7 |
| | Worms | 7 |
| | Where were they | 8 |
| Language | Arrange the words | 6 |
| | Follow the orders | 9 |
| | Starts with | 8 |
| Executive functions | Match the color | 3 |
| | Contrary | 7 |
| | Inside or out | 9 |
| | Logic mind | 9 |
| Calculus | Fast mind | 5 |
| | Let’s go shopping | 3 |
| | Mathematical table | 6 |
| Constructive capacity | Puzzles | 6 |
| | COGWEB Art | 7 |



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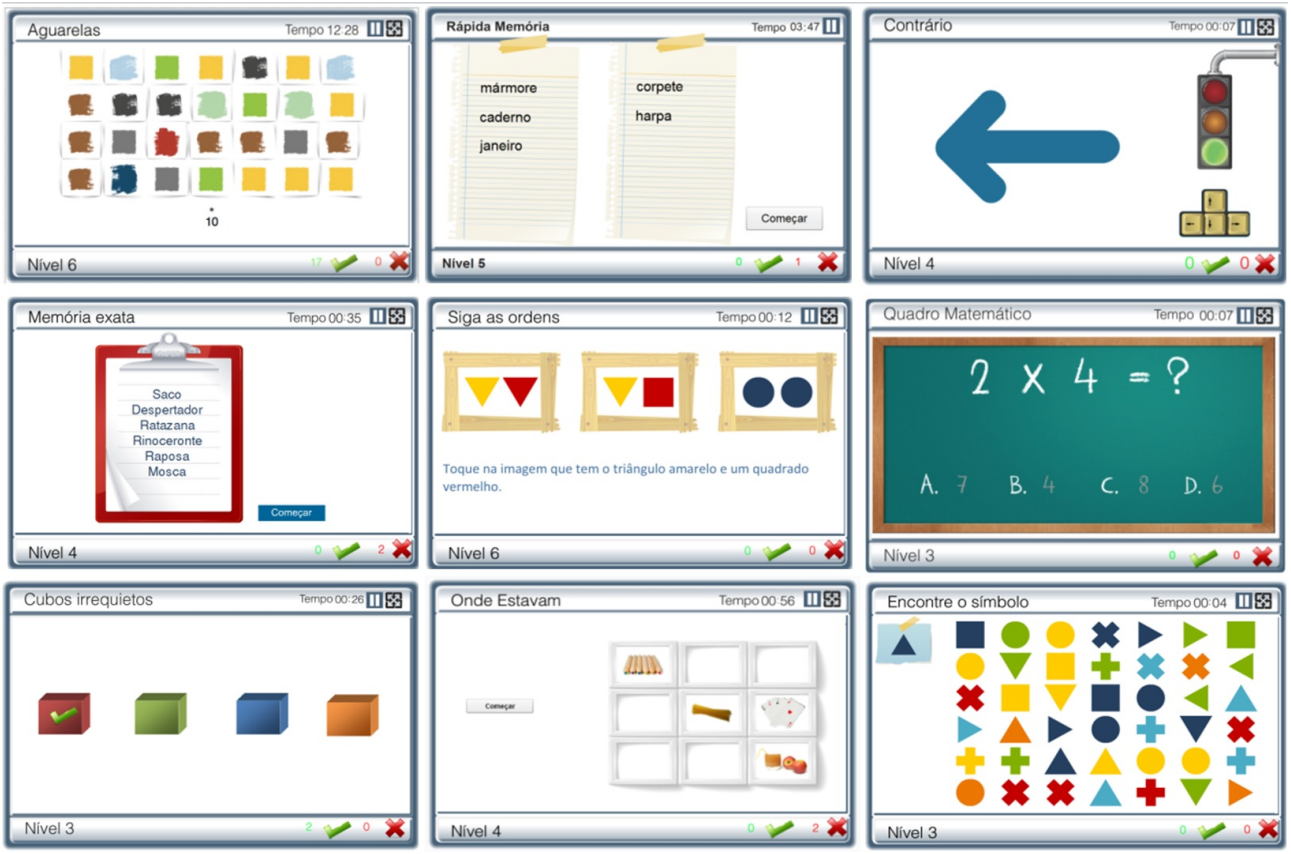
**Figure 3.** Examples of COGWEB exercises.




### *Online System Architecture*

The medical system, accessible via Internet browser, was designed to meet the requirements of health professionals and patients. Both groups need specialized and usable interfaces to access the system and introduce daily inputs. All data are centralized, recorded, and acceded on a health record system. During the cognitive training sessions performed by the patient, all of the data is updated continuously in real time via Web-based system and is saved on a remote database that furnishes all required information to be examined by the health professional. The database contains information of all patients and health professionals, and maintains a record of all training programs prescribed and patient performance. The system also includes a biostatistics analysis framework of unidentified data generated by the users of the system. The main purpose of the system is to analyze the quality of processes according to the standards established by a board of consulting clinicians. All data used for this computation remain unidentified and cannot be linked to the professional or patient who generated it. This policy was set according to the strict demands of the National Commission for Data Protection, established in accordance with European regulations (Directive 95/46/EC) [55]. The results from these computational operations are used to assess the application quality of the system by health professionals, to perform benchmarks of clinical outcomes, and to aid in the long-term improvement and context adaptation of the system. Some changes occur automatically, according to machine learning algorithms based on the internal statistical analysis. These tools provide additional evidence for the substitution of a useless exercise, the changing of system features that lead to errors, setting new automatisms like alert signs for some clinical situations, or the preparation of specific educational campaigns for professionals.

### *Network Operations and Coworking*

The system is designed to become accessible to a large number of people, through a network of centers and practitioners specialized in using it. Upon agreement by the professionals and patients, anonymous data on the treatments prescribed and clinical evolution are stored on a centralized application. The analysis of these data allows the depiction of the trends and the assessment of the quality of the tools and operative processes throughout the time. Thus, the system can be evolved and adapted to the needs of patients, professionals, and institutions. All agents can share useful information and guidelines on operational processes through a collaborative network. Furthermore, all neuropsychologists and practitioners who receive training on using the COGWEB system and share quality criteria in operating the system are stimulated to develop personal and team research projects. This step will improve the quality of the projects, increase the size of possible samples without incurring additional costs, and conduct multicenter trials while shortening the required time to complete them.

### *Professional Console*

#### Overview

The health professionals can access the rehabilitation program by entering their username and password on the website [56]. The website, in addition to allowing access to the online training area, contains educational content targeting the general population and a blog. The aim of the site is to provide scientific



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and pedagogical information about cognitive functioning and its changes, and the possibilities and indications for cognitive training [56].

The most important menu is the patient health record where the professional may add patient's information to the system and manage it later. The patient menu includes several submenus: medical form, neuropsychological assessment, intervention plans, session programming, and results.

### Medical Form

In this submenu, 3 types of data can be inserted: (1) identification data, (2) clinical data, and (3) data on the duration of the license to use the system and patients' credentials to access it.

### Neuropsychological Assessment

This menu, allowing the entry of neuropsychological assessment data on any patient, is organized into 2 parts. The first part records general descriptive data of the evaluation and the second part helps record each test and the quantitative results (preferably raw data) obtained in each neuropsychological test. Therefore, several evaluations can be recorded over time.

### Intervention Plans

Health professionals can use this option to enter the general information of the treatment plan, like duration, main cognitive domains, and the expected intensity of training. This option allows to entering information on as many intervention plans as needed. The data entered in this section can be used for the detailed evaluation of the quality of the tasks prescribed to the patient in the next session. If a decision is made to train working memory or attention, the system provides information on all of the exercises the patient is prescribed, in addition to their duration.

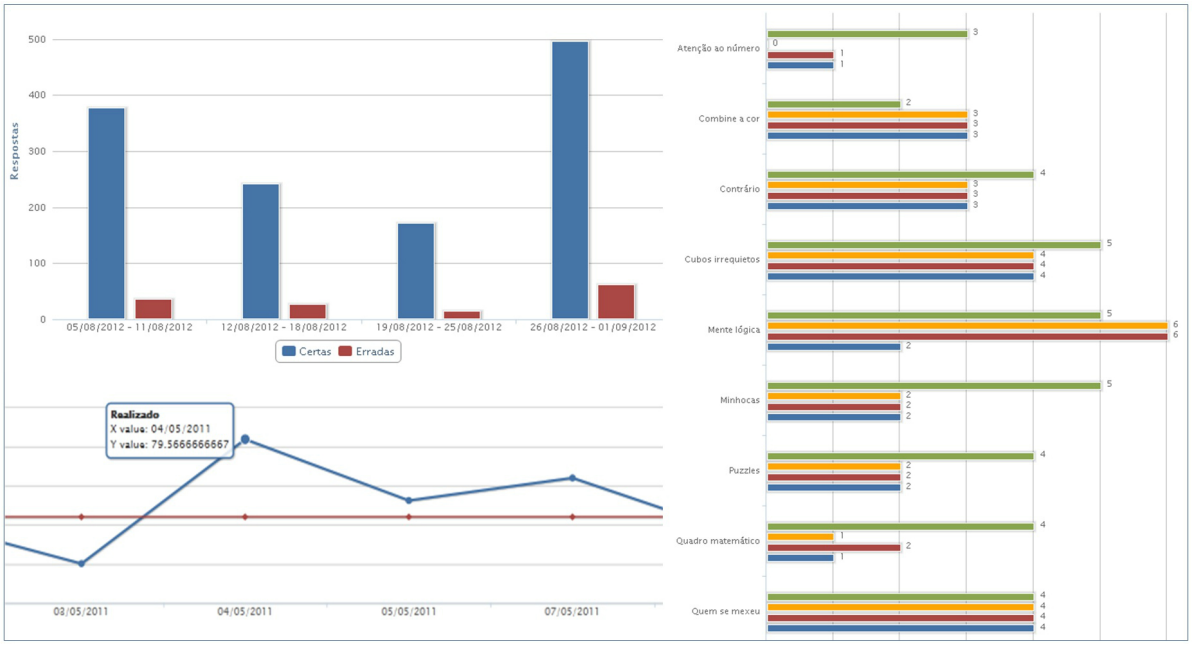
### Session Programming

The prescription system provides 2 ways to create sessions: (1) the standard mode and (2) the advanced mode. These two work modes share a set of prescription parameters, and the planning of each session requires the following parameters: the selection of exercises, their starting and completion dates, their order of appearance, the duration of exposure to each exercise, and the initial level and the level expected to be achieved at the end of the plan. These two modes, however, differ in defining and managing the training schedule. The standard mode is a faster and simpler way to plan sessions in which the patient conducts the same set of exercises in consecutive days. In the advanced prescription mode, the prescribing health professionals select the day on which they want a specific session to be active and the intended activation period, that is, morning, afternoon, or all day. Thus, the needs that currently exist in sophisticated and intensive rehabilitation or cognitive training methodologies in specific areas can be met.

### Results

The current system provides several kinds of progress graphs: right answers versus wrong answers, global training time (actual realized time vs planned time), game time in each exercise, concluded levels, accesses (realized accesses vs planned accesses), and a progress summary per exercise (expected performance vs real performance) (Figure 4).

**Figure 4.** Examples of progress graphs.




## *Patient Console*

### Overview

The COGWEB is accessed through the website, similar to the professional's login [56]. The entire login dynamic is identical in both the consoles with the only difference in the attributes and areas associated to the username/password.

### Training Sessions

As soon as the patient credentials are introduced, the training session starts automatically. First, the patient views a welcome



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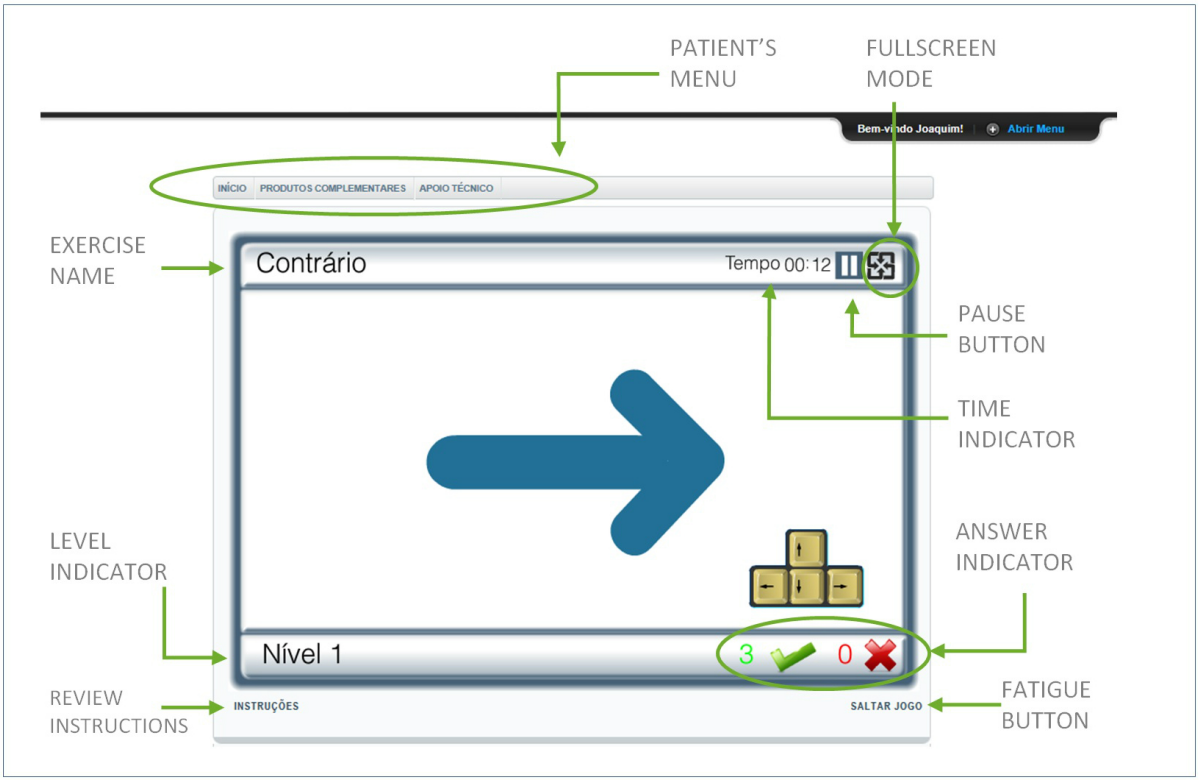
screen with the training session information (number of exercises prescribed, total duration, and other general instructions) and a start button. When the patient feels ready, the first exercise planned starts, with no need for additional clicks or menu navigation. The simplicity of accessing the program eliminates the obstacles that may hinder training program compliance. The training arena is presented, by default, in a normal sized window. However, for added convenience during the exercise, the user can switch to full screen, by pressing the signed button (Figure 5).

**Figure 5.** Screen appearance of the patient training area and principal features of the game arena.




### Game Arena

Each exercise starts with a set of instructions, written on the screen and spoken through the speakers, for 20 seconds before the onset of the exercise. Instructions can be viewed at any time, even during the exercise, by pressing the instructions button. After the instructions, the exercise starts and the game arena appears. However, as time is an important factor in some of the exercises (eg, trainings processing speed), it is crucial to guarantee the patient's attention to stimuli from the beginning. For that reason, there is a start button on the screen. The game arena is similar between various exercises making the learning and adaptation process easier. It comprises a central area, where the exercise takes place and the answers are given, with a frame around it. The exercise name is shown on the upper left hand corner of the frame, and the time remaining, the pause button, and the full screen activation button appear on the upper right hand corner. The lower left hand corner shows the level indicator and the bottom right the answer indicator (right and wrong) (Figure 5). The bottom of the screen displays 2 buttons: (1) the instructions button, which enables the patient to review the instructions even during the exercise and (2) the fatigue button (designated, skip game button), which can be activated if the patient feels tired or discouraged with a specific game.

The pause button allows the session to be stopped in case of unforeseen events that might distract the patient and hinder the performance. This button should be used exceptionally.

### Motivation Tools

Upon successful completion of each level, a support message appears that is expressed simultaneously on the screen and in audio. When the performance by the end of the level does not fulfill the criteria for progression, the level is either maintained or decreased, depending on the progression rules for each game (see description of exercises). In this case, no information is given to the patient, the instructions for that level are just repeated, and the game continues. During the last exercise of each session, at the bottom of the game arena, the buttons that restart the session and end the session appear, which allow the patient to repeat the session, if they feel up to it, or end the session, in case they already feel fatigued. At the end of the session, this information is presented again.

## *Cognitive Exercises*

### Overview

The COGWEB system is composed of 27 independent exercises, distributed by different cognitive areas (Table 4). All exercises were first developed in a classic format including paper, pencil, cards, and other physical materials. Before being converted to the current computer game format, which took a period of more than 5 years, a pool of 60 original exercises were subject to



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extensive clinical use, validation, and refinement at our outpatient memory clinic [53,54]. These exercises share some important characteristics.

### Functional Organization

Each exercise is organized around the stimulation of a specific cognitive area. However, one exercise does not train only one area, as other additional areas are also involved in solving the tasks. This multiplicity of tasks is intimately related to the integrated function characteristics of the human cognition.

### Levels of Difficulty

The exercises were developed to train various degrees of cognitive defects, from mild to more severe impairments. Exercise progression is automatic, by levels, becoming more difficult or easier in response to the patient's performance, both inside the same session or in consecutive sessions. The different degrees of difficulty, depending on each game, are obtained through manipulation of some of the features, either alone or in combination: the number of items per level, their complexity, and the interval between stimuli within the same level (game vs patient's paced rhythms). For choosing the stimuli for each exercise (words, figures), special attention was given to various aspects that contribute to the complexity of the items, such as the extension of words, their degree of imageability, semantic proximity, or, in the case of figures, the number of graphic elements or graphic composition.

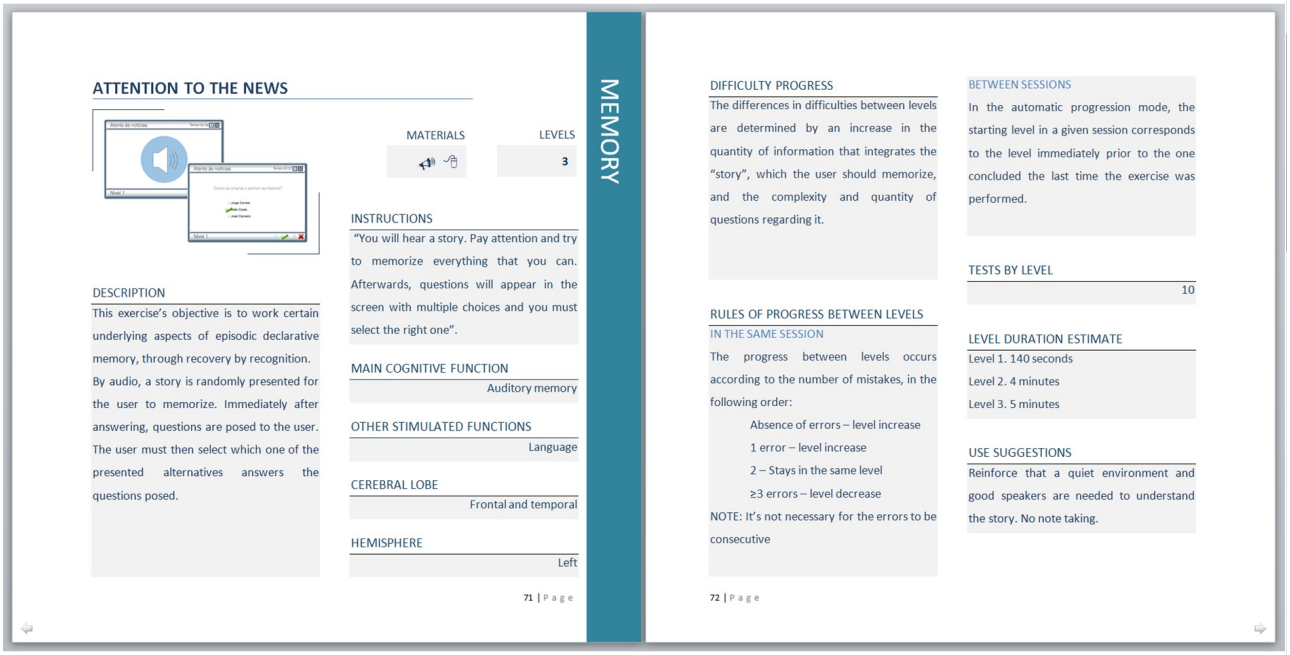
### Random Stimuli

The structure of the exercises, at its base, is composed of sets of stimuli grouped by difficulty. On the same level of an exercise, the stimuli always appear in a random, nonsequential way to prevent memorization.

### Information Sheets

For each exercise, the prescribing health professional has access to an individual sheet including the following parameters: general description, patient instructions, and multimedia requirements; main cognitive function that the game stimulates and other secondary stimulated functions; cortical areas recruited, according to anatomic-functional models of bibliographic basis; principles behind the choice of items that compose the game and the organization of their level of difficulty; the number of levels for each game, rules of progression between different levels and the number of tests in each level; estimated average time required for a normal individual to complete levels 1, 2, and 3 of each game (important for setting the minimum time of each game in sessions that might demand a level increase); and special use suggestions (Figure 6).

**Figure 6.** Example of an information sheet for the game exercise "Attention to the news".




## Results

Of the 80 patients initially selected, 48 patients (60%) attended the psychoeducational group sessions and completed the usability test proposed. The mean age of the respondents was 60 years (SD 13.3, range 41-78). A total of 21/48 participants (44%) were female. The mean level of formal education was 6 years (SD 4.3, range 4-17). Previous use of the computer was shown by 32/48 patients (66%). Of all the participants, 32 patients (66%) did not complete the study because they were not able to attend the assessment sessions at the hospital. However, this did not differed between groups ($P$=.12).

As shown in Figure 7, all patients in the presence of their caregivers understood the instructions given in the training session and during the execution of the 8 different exercises (Q1). All patients found the exercises used in the training sessions interesting to them (Q2). Only 2 of the 48 participants (4%) did not find the exercises useful for their clinical condition (Q3). The same percentage of respondents was not motivated to use the system on their own at home (Q4). After the first



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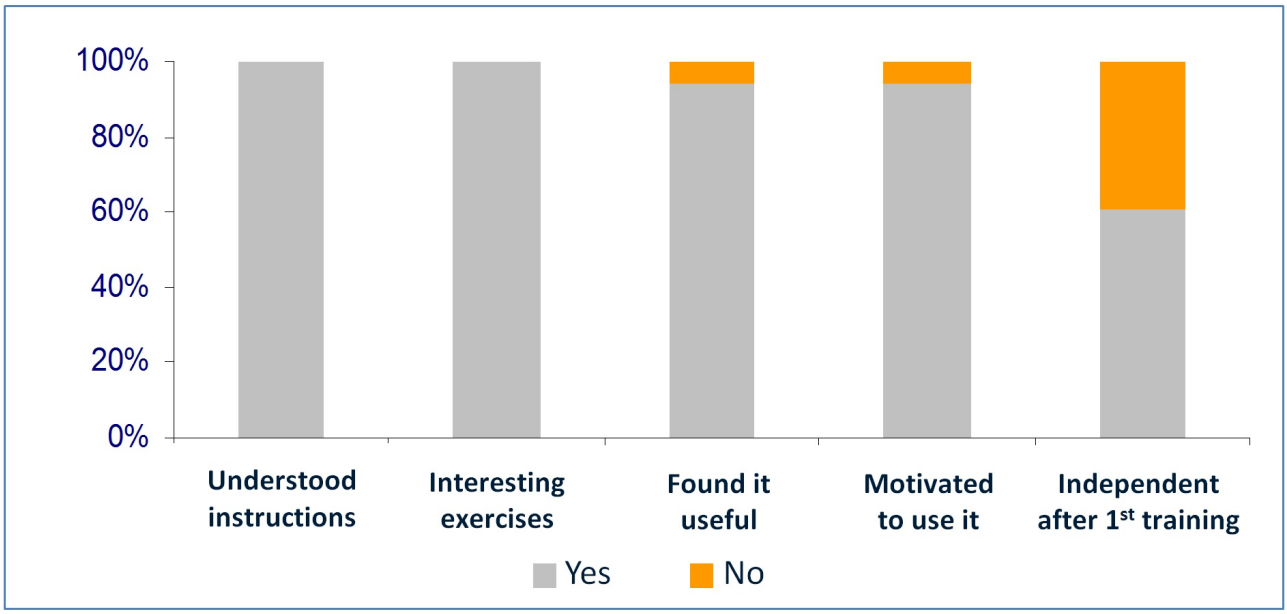
training session, 19/48 patients (39%) indicated the need for further help from the caregiver to use it at home (Q5).

In the group of patients that mentioned the need for additional training (n=19), 74% (14/19) were male, 79% (15/19) have not used the computer earlier, and 16% (3/19) had only sporadic exposure to computers.

**Figure 7.** Answers to the opinion questionnaire (Q1-5) (%).




## Discussion

### Principal Findings

This new system was very well received by patients and their relatives, who showed high levels of motivation to use it on a daily basis at home. The simplicity of its use and comfort were especially emphasized. Considering the mean age, the level of instruction, and the cognitive deficits of the patients enrolled, 19/48 patients (39%) required some kind of coaching to achieve independent use of the system. The formal evaluation of usability by both professionals and patients will be given further attention in future studies.

### Optimized Approaches

Compared to most related technologies available [18,43], COGWEB characteristics were defined after thorough study of existing cognitive training procedures in an outpatient memory clinic. The improvement of the quality and access to treatment by the patient were very important. Nonetheless, the system has the rehabilitation professional at its core as is recommended [9]. Ultimately, it is a specialized working tool that improves health decision making and time management per patient treated. A significant part of cognitive interventions can be done outside the health care units, by maintaining high quality levels of therapy through bidirectional communication between patients and professionals thus avoiding isolation. This step promotes patient comfort and treatment adhesion while eliminating economical and geographical barriers [30,44,49]. The impact of several degrees of personal presence of the therapist on the overall quality of training and outcomes are currently being evaluated in a prospective study.

Another significant feature of the system is its suitability for coworking and multicenter use in collaborative networks of professionals and institutions. This will foster investigation in the field and position COGWEB as one of the most prepared tools designed for clinical trials in cognitive interventional approaches. In the field of neurorehabilitation, high-quality scientific knowledge about several neurological and psychiatric diseases will be very important for treatment decision in the near future [5].

Finally, the incorporation of biostatistics and long-term system analysis tools are at the cornerstone of the system's ability to improve quality and to adapt either to professionals, patients, institutional, or various clinical context needs or trends. This is similar to what can be achieved with some of the most advanced medication management information technology [57].

### Conclusions

We are now able to start clinical trials to test and measure intensive cognitive training protocols and to evaluate its positive and also possibly negative effects on a variety of diseases and settings [52,58]. The quantification of the economic impact and health gains of these strategies for health systems is also a priority [1]. The system will continue to evolve, basically with the development of new exercises and features to accommodate the needs from diverse populations and clinical settings of operation.



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## Acknowledgments

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## Conflicts of Interest

VTC and JP are shareholders of Neuroinova, Lda, a company that commercializes COGWEB-related products.

## Multimedia Appendix 1

Web-based cognitive training system presentation for patients.

[MP4 File (MP4 Video), 3MB - resprot_v2i2e59_app1.mp4 ]

## Multimedia Appendix 2

Exercise books presentation for patients.

[MP4 File (MP4 Video), 3MB - resprot_v2i2e59_app2.mp4 ]

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## Abbreviations

**COGWEB:** Web-based cognitive training system



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Original Paper

# The Development of the Tobacco Tactics Website

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## Abstract

**Background:** Web-based cessation interventions have been shown to reduce tobacco use, be more efficacious than self-help booklets, be more efficacious if they provide tailored messages, and enhance quit rates in conjunction with nicotine replacement therapy.

**Objective:** The objective of this study was to usability test and pilot test the Tobacco Tactics website for veterans.

**Methods:** Both formative and summative evaluations were used across three small successive studies to develop and test the Tobacco Tactics website for veterans, which was based on a prior face-to-face smoking cessation intervention. Once the website was developed, the research team and Web developers usability tested the website with 5 veteran smokers and former smokers. Feedback from the veterans was collected as they navigated each webpage, then used to revise the website. In pilot study 1, 9 veteran smokers were provided access to the website, and given a baseline and 30-day follow-up survey. In pilot study 2, 18 veteran smokers, who were also motivated to quit smoking, were recruited and randomized to either the Tobacco Tactics website plus nicotine replacement therapy or to the 1-800-QUIT-NOW telephone line.

**Results:** As a result of usability testing, more than 27 modifications were made to improve the website. In pilot study 1, 50% (3/6) veterans who entered the website had cut down on the number of cigarettes and 83% (5/6) found the website enjoyable, easy to read, easy to navigate, and would recommend the website to others. In pilot study 2, which included only smokers motivated to quit and also offered nicotine replacement therapy, seven-day point prevalence abstinence at 30-day follow-up was 40% (4/10) in the intervention group compared to 13% (1/8) in the control group.

**Conclusions:** These preliminary results are promising and suggest the need for wider-scale testing of the Tobacco Tactics website for veterans.

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**KEYWORDS**

smoking cessation; Internet; intervention studies; health services accessibility

## Introduction

### Smoking in the Department of Veterans Affairs System

While smoking rates among veterans have decreased from 33% in 2001 to 22.2% in 2005, smoking remains especially pronounced among subgroups of veterans, such as returning Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans [1,2]. Compared to nonsmokers, smokers have twice as many hospital stays and longer hospitals stays, resulting in greater hospital expenses per admission [3]. Treatment of heart attacks and strokes is expensive, especially



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in the Department of Veterans Affairs (VA) system where patients have less social support and economic resources. Studies have shown that veterans are interested in quitting, but those who are inpatients, older, not married, unemployed, and living in rural areas are less likely to receive cessation services [4,5]. In fact, less than 7% of smokers in the VA receive smoking cessation pharmaceuticals and cessation medications—which accounts for less than 1% of the VA pharmacy budget [6]—yet smoking-related illnesses may account for up to 21% of all VA health care costs [7].

Within the VA, outpatient programs provide the majority of services to smokers, in accordance with the Agency for Healthcare Research and Quality (AHRQ) guidelines [8], yet outpatient smoking cessation programs are poorly attended and few smokers are reached [9]. More recently, VA primary care providers have been more aggressive in providing cessation interventions in primary care clinics and inpatient units, but factors such as provider time, training, and competing demands limit their effectiveness [10]. The Committee on Smoking Cessation in Military and Veteran Populations and the Institute of Medicine recommended the development of a VA smoking cessation website for veterans [11]. VA cessation providers met in Atlanta in December 2007 and one recommendation was to develop a cessation website for veterans [12]. Since the face-to-face Tobacco Tactics intervention was found to be efficacious in a clinical trial [13], the intervention was developed into a website for smokers and usability tested and pilot tested among veterans.

## Theoretical Framework

Social marketing theory, which was used to design and refine the Tobacco Tactics website, is the planning and implementation of programs designed to bring about social change. Social marketing uses concepts from commercial marketing including the "4 Ps": (1) create an enticing "Product" (ie, the package of benefits associated with the desired action such as the tailored Tobacco Tactics website), (2) minimize the "Price" the target audience believes it must pay in the exchange, such as easy access to the website and cessation medications, (3) make the exchange available in "Places" that reach the audience and fit its lifestyles, such as accessing the website from home or public libraries, and (4) "Promote" the exchange opportunity with creativity and through channels and tactics that maximize desired responses such as a tailored, multimedia, interactive website enhanced with medications and follow-up [14]. A central component of social marketing is listening to the needs and desires of the target audience and building the program based on their feedback. In social marketing, it is also important to evaluate the competition or rival offerings, such as competing cessation programs.

## Studies Leading to the Development of the Tobacco Tactics Website (Product)

The Tobacco Tactics website was based on the face-to-face Tobacco Tactics intervention (VA IIR 98-500), which was tested among head and neck cancer patients and showed a significant difference in 6-month smoking cessation rates when compared to an enhanced usual care group [13]. Having packaged the Tobacco Tactics intervention into a toolkit, a VA implementation study (VA SDP 06-003) [15] brought the face-to-face intervention to veteran inpatient smokers and found a significant improvement in 6-month quit rates. Social marketing techniques were used to engage veterans to assist in the development of the image-based VA Tobacco Tactics program logo and campaign character (VA Public Health Grant) [16].

## Efficacy of Internet Cessation Interventions (Product)

Web-based cessation interventions have been shown to reduce tobacco use [17-19], be more efficacious than self-help booklets [20], be more efficacious if they provide tailored messages [21], and enhance quit rates in conjunction with nicotine replacement therapy (NRT) [20-22]. A recent 2009 meta-analysis [23] reviewing 22 Web-based randomized control trials for smoking cessation yielded an abstinence rate about 1.5 times higher than the control group (intervention group 9.9%, control group 5.7%). Web-based cessation interventions can be further enhanced if they include tailored messages [21] and medications such as NRT [20-22].

## Advantages of Web-Based Interventions (Price/Place)

The Internet is a valuable tool for providing health education and support given its 24-hour accessibility, growing number of Internet users, potential to reach thousands of individuals, and potential cost-effectiveness [24]. The computer's availability, enormous memory, versatile means of expression, and low cost make it a valuable adjunct in patient education and support [25]. *Tailored modules* are a superior alternative to "surfing the net" [22,24,26] because the message is adapted to the prior knowledge and characteristics of each individual, and hence contains more relevant information that increases attentiveness and limits defensiveness toward the intervention content [27]. *Interactivity* allows patient tailoring, increases engagement in decision making, improves learning, increases program attractiveness, and enhances the influence of online services [28]. *Multimedia* programming refers to "text, graphics, audio and video with links and tools that allow the user to navigate, interact, create and communicate" [29].

## Competitive Cessation Internet Interventions (Promotion)

While smoking cessation websites are already available, many Internet users encounter frustrations on sites that are poorly designed. A study of 202 cessation websites found that only 46 provided actual cessation treatment, and only 5 of those received high rankings for usability based on evidence-based guidelines [30]. There were readability problems, no coverage of key components of recommended guidelines, and failure to provide interactive exercises and tailored messages [30]. Navigational issues, content layout, and information location are common problems [31]. Many require detailed profiles before entering the site. The two most frequently visited sites were owned by tobacco companies and perceived by respondents as unhelpful [32]. Seventy-two percent (13/18) of the most popular websites were for profit and several promoted unproven methods. The US Government's Smokefree website [33] was ranked above average for helpfulness, but was strictly informational without interactive exercises. QuitNet provides some free information,



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but requires payment for use of the site for specialized services, which may be a barrier to participation [34]. The VA's My HealtheVet website does provide some information about the benefits of quitting smoking, tips for quitting, and weight gain, but it is not a comprehensive intervention, and has limited interactivity and tailoring. The Department of Defense has a smoking cessation website that veterans can access [35]; however, we are not aware of any published studies on the efficacy of the website. A Google search for "quit smoking" did not reveal some of the most efficacious cessation websites. Hence, tobacco users who search the Internet for cessation assistance are unlikely to find high-quality, evidence-based treatment resources. Thus, the Tobacco Tactics website was developed in conjunction with a graphic design company, Allen Wayne, LTD (VA SHP 08-197).

## Methods

### Design

Both formative (process) and summative (outcome) evaluation were used across three small successive studies to develop and test the Tobacco Tactics website for veterans. Formative evaluation was conducted with a small group of veterans to "test run" the Tobacco Tactics website, obtain feedback, and then revise the website. Summative evaluation was conducted to determine if the website did what it was designed to do in two small pilot studies. Human studies approval was obtained from the VA Ann Arbor Healthcare System and the University of Michigan.

### Sample/Setting (Place)

The sample for all three studies consisted of veteran smokers and former smokers who had access to the Internet. The samples for the usability test and first pilot study were recruited at the VA Ann Arbor Healthcare System and were not necessarily smokers who were interested in quitting (usability testing included former smokers) while pilot study 2 consisted of all motivated smokers.

### Procedures (Promotion)

#### *Usability Testing*

Based on modules used in our prior studies, the Tobacco Tactics website was built with our website developers, Allen Wayne, LTD. First, the research team and website developers sat individually with 5 VA smokers and former smokers (employees or volunteers from Voluntary Services) for one hour as they navigated each successive webpage and requested feedback on: (1) ability to accomplish tasks, (2) ability to accomplish goals with skill and speed, (3) ability to operate the system, and (4) satisfaction with the website. Then, based on the feedback, the website was revised for pilot testing.

#### *Pilot Study 1*

Using the revised website, 9 veteran smokers (patients) who had computer access and were willing to test the website at home were recruited from the smoking shelter. Veterans were given a baseline survey and a 30-day follow-up survey to request information about their smoking habits and other covariates that can influence smoking.

#### *Pilot Study 2*

To further test the website among smokers motivated to quit who also received NRT, 18 veteran smokers who had computer access and were interested in quitting were recruited from Operating Engineers Locals 324 Training Center as part of a larger funded study. This is a registered randomized controlled study (clinicaltrials.gov NCT01124110). Veterans were randomized to the Tobacco Tactics website plus mailed NRT (ie, patch, gum, or lozenge) or the 1-800-QUIT-NOW telephone line, which also mailed NRT for those without insurance. The specific type of NRT was given based on the number of cigarettes the veteran smoked as well as his/her previous experience with NRT and personal preferences. Veterans were given a baseline survey and a 30-day follow-up survey to request information about their smoking habits and other covariates.

### Measures

#### *Usability Testing*

The questions for the usability testing were open-ended. Examples of the open-ended questions were: Why did you click on that? or Why did you skip that exercise?

#### *Pilot Tests*

The outcome of interest was self-reported seven-day point prevalence abstinence at 30-day follow-up. To be considered as having quit, the patient had to self-report on their 30-day follow-up survey that they had "not used any tobacco products, even a single puff of a cigarette, in the past 7 days." Variables known to be associated with smoking and cessation were measured on the survey using previously validated tools including: (1) the Fagerström Test for Nicotine Dependence (FTND), (2) the Alcohol Use Disorders Identification Test (AUDIT), (3) the abbreviated Center for Epidemiologic Studies Depression Scale (CESD) [36], and (4) "self-rated health" [37]. Demographic variables included age, gender, race, education, marital status, and employment status. Comorbidity information was self-reported by patients.

### Description of Tobacco Tactics Website Intervention (Product)

#### *General Description*

The Tobacco Tactics website was developed based on prior work and is in keeping with guideline recommendations for treatment of tobacco addiction [38]. The content is written at an eighth grade reading level. Veterans can sign onto the website with a unique ID and user generated password. The Tobacco Tactics website [39] can currently be viewed with a test user login of "test" and password "testpass."

#### *Home Page*

As seen in Figure 1, the home page includes a video from General Barry McCaffrey who provides a compelling, emotionally charged message about the General's personal story of smoking in the military and how he managed to quit. The left side of the home page has "buttons" that link to specific cessation modules including "General Information", "Are You Ready for a Change?", and the "Change Plan" button which has



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an interactive calculator that will assess the amount of money that can be saved from quitting (see Figure 2).

### *Medications*

Treatment links review the medications available to assist with cessation, including NRT (gum, patch, spray and lozenge), Zyban, and Chantix. An interactive exercise provides a tailored medication protocol and contraindications assessment (see Figure 2). On the Medications Tab, veterans can indicate whether they would like a pharmacist to contact them to provide medications and if so, they provide their name, email or phone number, and best time to be contacted. This information can be transmitted to the Pharmacy Administration webpage, which is part of the administrative section of the website, not accessible to patients. Pharmacists can routinely check the Pharmacy Administration webpage to see who has requested medications, review information on the website and the patients' medical record, call, or email the patient to further assess, enter the medication request into the Computerized Patient Record System, and mail the prescription to the veteran. See Figure 3 for a screenshot of the Pharmacy Administration webpage.

**Figure 1.** Sample Tobacco Tactics for veterans home page.

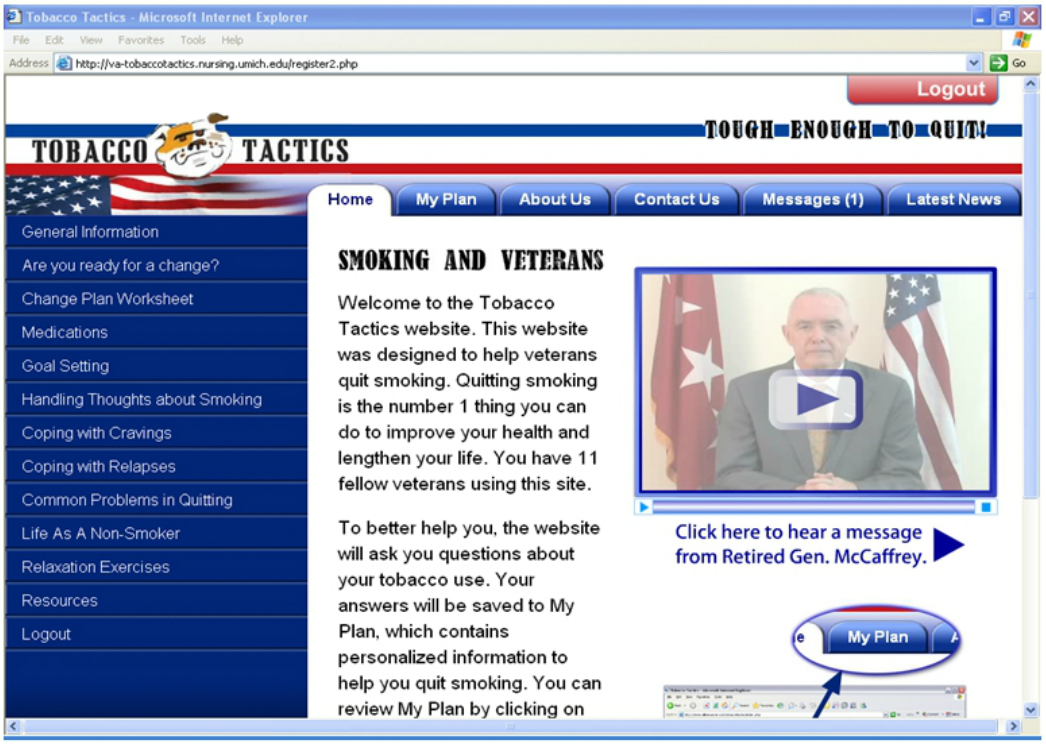


**Figure 2.** Sample Tobacco Tactics for veterans webpages.


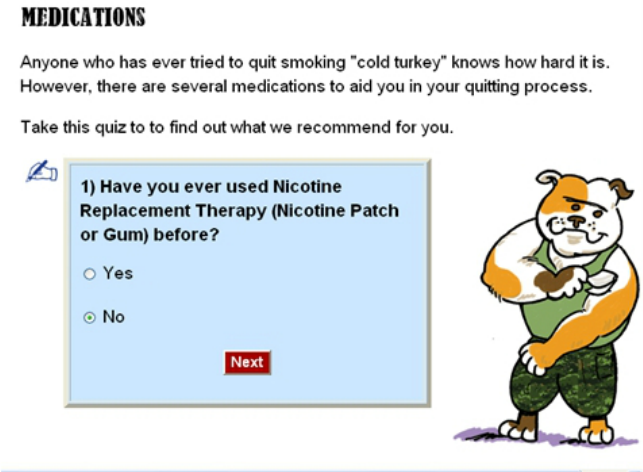




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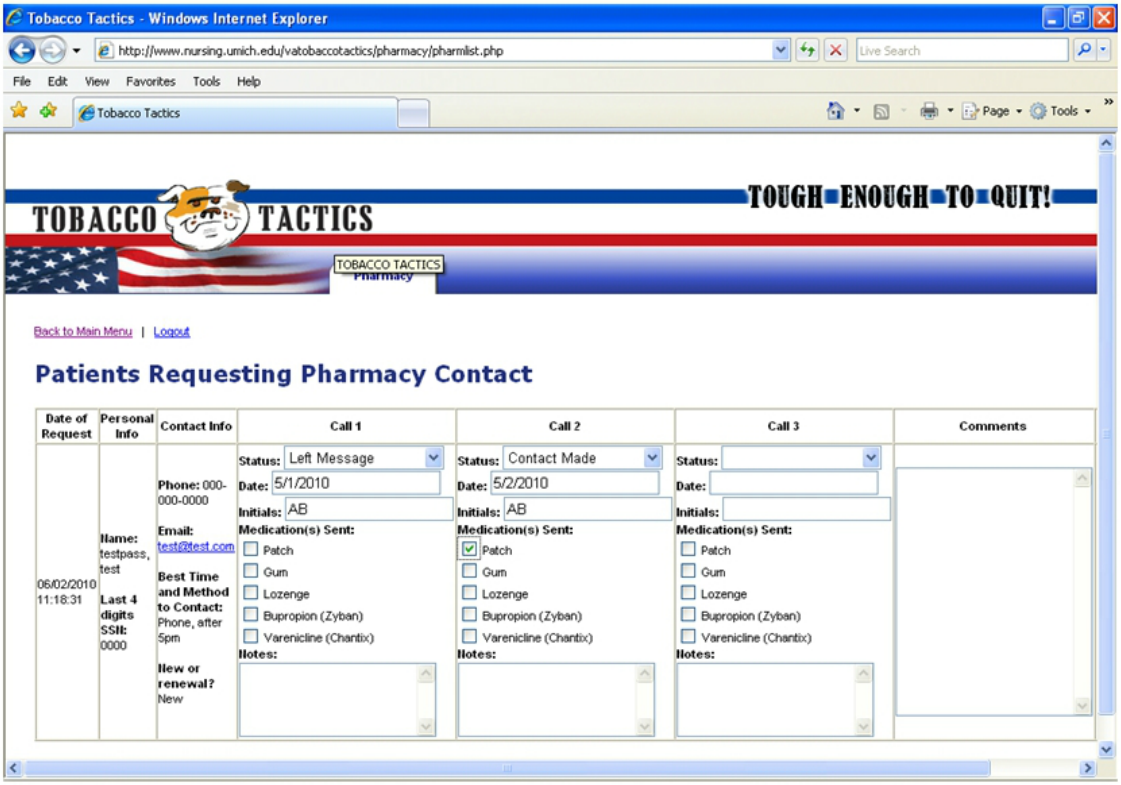
**Figure 3.** Sample Tobacco Tactics for veterans webpage for pharmacists.




### *Additional Buttons*

Additional buttons on the left side of the home page include “Goal Setting”, “Handling Thoughts About Smoking”, “Coping With Cravings”, “Coping With Relapses”, “Common Problems in Quitting”, “Life As A Nonsmoker”, and buttons that provide relaxation exercises and resources. Tabs across the top of the home page include “About Us”, “Messages”, “Latest News”, and a tab for an e-community (chat room).

### *Interactivity and Tailoring*

Extensive programming has resulted in the highly interactive exercises with tailored messages that save data to “My Plan” so users can monitor their progress over time. For example, a cost calculator depicts the amount of money that can be saved by quitting smoking. The e-community feature of the website consists of a three-day per week (one morning and two evenings), nurse-moderated forum that allows participants to conduct text-based discussions.

### *Graphics*

The artwork and logo were developed using social marketing techniques based on prior work by Duffy [40], and lessons learned from advertising noting the use of animal cartoons (eg, Joe Camel, AFLAC duck, Smokey the Bear) as some of the most successful campaigns in attracting attention and selling products [41]. The development of the artwork is described in another paper [16] which describes how a graphic design firm, Allen Wayne, LTD, was hired to illustrate the logo and character for the VA Tobacco Tactics program. Initially, the firm developed thumb sketches of 4 logos and 10 variations of a character that would be portrayed doing different activities related to quitting smoking. Four rounds of formative evaluation were conducted by distributing surveys to veterans, visitors, and staff to elicit comments about the art work until there was high agreement from respondents that the logo, illustrations, and color were “good” or “excellent”.

### *Proactive/Warm Transfer Telephone Component and Email Reminders*

Veterans who use the Tobacco Tactics website received a follow-up telephone call encouraging them to use the website and these calls also provided additional counseling. Proactive/warm transfer calls have been used to introduce patients to interventions in other studies [42] as well as business situations [43]. Veterans also received automated motivational emails to encourage them to use the website.

## Results

### Usability Testing

As a result of usability testing, more than 27 modifications were made including, but not limited to: (1) moving the user login box to the top of the page, (2) making the play button for the video more visible, (3) changing the font color of selected headings from blue so as not to confuse them with a URL link, (4) making the scrolling list of chemicals slower, (5) enlarging the calendar icon when setting a quit date, and (6) changing the wording to be more veteran-centric (eg, “Smoking causes more deaths than all Americans killed in World War I, World War II, and the Korean and Vietnam wars combined”).



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### Pilot Study 1

Thirteen veteran smokers were approached to recruit 9 who had computer access and were willing to test the website at home. The 9 smokers were not necessarily motivated to quit nor were they provided any cessation medications. Sixty-seven percent (6/9) of veterans accessed the website with prompting by a follow-up telephone call. Overall, the average age was 48 years, 67% (6/9) were male, and 67% (6/9) were white. Sixty-seven percent (6/9) had some college education and 33% (3/9) had less than a high school degree or a high school diploma/GED. One-third of the sample was never married, 22% (2/9) were married, and the remainder were separated, widowed, or divorced. Forty-four percent (4/9) were unemployed. At 30-day follow-up, none of the 6 responders had quit, however, 1 had attempted to quit. Fifty percent (3/6) had cut down on the number of cigarettes, averaging a reduction of 7 cigarettes per day. Most found the website easy to read (n=5), enjoyable (n=4), and easy to navigate (n=4), rated the website highly on pictures, illustrations, and colors, and indicated that they would recommend the website to others (n=5).

### Pilot Study 2

To further pilot test the Tobacco Tactics website with veteran smokers who were motivated to quit, 18 veterans recruited from a population of Operating Engineers (heavy equipment operators) were randomized to the Tobacco Tactics website plus NRT versus the 1-800-QUIT-NOW telephone line. Groups were similar on baseline variables. At 30-day follow-up, 80% (8/10) intervention participants responded, while 63% (5/8) control condition responded. Using an intent-to-treat analysis (assuming non-responders in the control group were smokers and did not use NRT), Table 1 shows that seven-day point prevalence abstinence at 30-day follow-up was 40% (4/10) in the intervention group compared to 13% (1/8) in the control group. Seventy percent (7/10) of veterans in the intervention group used NRT compared to 13% (1/8) in the control group. The average participant accessed the website 2.5 times (range 1-6).

**Table 1.** Characteristics and smoking quit rates for Veteran Operating Engineers randomized to the Tobacco Tactics website intervention compared to control subjects (N=18).

| | | Baseline | |
|---|---|---|---|
| | | Intervention (N=10) | Control (N=8) |
| | | Mean (SD) or Frequency (%) | Mean (SD) or Frequency (%) |
| **Characteristics** | | | |
| | Age | 45.6 (7.5) | 46.3 (8.1) |
| | Male | 10 (100%) | 8 (100%) |
| | White | 10 (100%) | 6 (75%) |
| | High school or less than high school | 7 (70%) | 4 (50%) |
| | Marital status | 7 (70%) | 5 (71%) |
| | Nicotine dependence [a] | 5.0 (2.6) | 3.9 (3.0) |
| | Baseline Problem Drinking (AUDIT) [b] | 8.9 (4.6) | 10.6 (8.2) |
| | Baseline Probable Depression (CES-D) [c] | 12.1 (10.2) | 10.3 (8.5) |
| **30-day follow-up** | | | |
| | Quit Rate | 4 (40%) | 1 (13%) |
| | NRT use | 7 (70%) | 1 (13%) |

[a]The Fagerström Test for Nicotine Dependence ranges from 0-10; a score ≥ 8 is considered nicotine dependent.

[b]The AUDIT ranges from 0-40; a score ≥ 8 is considered problem drinking.

[c]The CES-D ranges from 0-60; a score of 16 or higher is indicative of significant or mild depressive symptomatology.

## Discussion

### Principal Findings

The two pilot studies showed that veterans were able to change their smoking behavior after exposure to the Tobacco Tactics website. The poor quit rate in the first pilot study was not particularly surprising in that none of the veterans were actively seeking cessation services and none received cessation medications. Nonetheless, 17% (1/6) of veterans had attempted to quit and the reduction in cigarettes per day was substantial for 50% (3/6) of the veterans. Moreover, participants rated the website highly. Albeit the study was underpowered, the seven-day point prevalence abstinence at 30-day follow-up in the second pilot study was more than three times as high in the intervention group compared to the control group as it included smokers motivated to quit who were also given NRT along with the website compared to the 1-800-QUIT-NOW telephone line where they may also have obtained NRT. These preliminary results are promising and suggest the need for wider-scale testing of the Tobacco Tactics website for veterans.



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Most of the veterans who used the Tobacco Tactics website found it to be enjoyable, easy to read, easy to navigate, rated the website highly on pictures, illustrations, and colors, and indicated that they would recommend the website to others. This is likely due to the extensive usability testing that was conducted and subsequent revisions that were made. These revisions likely enhanced engagement and reduced navigational problems common on other websites [31].

Similar to other populations [44], about two-thirds of veterans have access to the Internet and were able to log on to the website with a proactive/warm transfer telephone call. Web-based cessation interventions, which have been shown to be efficacious [17-19], may allow smokers to quit on their own, reach veterans in rural areas, and may be more popular among younger, more Internet savvy OEF/OIF veterans, among whom smoking is especially pronounced [1,2]. The great advantage of the Tobacco Tactics website is that it can allow Veteran smokers to access cessation treatment, including medications, without ever leaving their home, reducing barriers in access to care. An additional advantage of the Tobacco Tactics website is that it could be broadly disseminated to veterans across the country extending the reach of cessation services in the VA. In addition to being convenient for veterans, it may in fact reduce face-to-face provider-veteran time.

The major barrier to implementation is that VA data security policies are such that there are several layers of "red tape" in order to house interactive websites on VA servers. Thus, currently the Tobacco Tactics website is housed on a secure University of Michigan server. For the moment, the VA is partnering with another website program [35] to service veterans. Nonetheless, with a grant from the Blue Cross Blue Shield of Michigan Foundation, we have redesigned the website for Operating Engineers (heavy equipment operators), which include a high proportion of veterans (20%) and are mostly men, similar to the veteran population. In a funded National Institutes of Health (NIH) R21 for Exploratory Grants for Behavioral Research in Cancer Control (R21 CA152247-01) randomized control trial, the Tobacco Tactics website for Operating Engineers is being compared to the 1-800-QUIT-NOW state-supported quit line (see Figure 4).

**Figure 4.** Sample Tobacco Tactics for Operating Engineers webpage.


## Limitations

The sample sizes for pilot studies 1 and 2 were small which may limit generalizability. Given that these were pilot studies, there was limited time for longer follow-up intervals as well as biochemical verification. Contact between participants and the research team may have influenced participants' reports about the website. While data on the number of times the participants accessed the website was collected, no information was collected on the number of times they accessed particular exercises. The slightly higher differential drop out in pilot study 2 control subjects has implications for interpretation of the results, and may imply less engagement, as more intervention participants responded. Veterans assigned to the Tobacco Tactics website were given ready access to NRT while those assigned to the 1-800-QUIT-NOW group *may* have been able to obtain NRT.

## Conclusion

The preliminary results show that the Tobacco Tactics website has the potential to be an efficacious intervention for veterans trying to quit smoking. Moreover, the website has the potential to increase the reach of smoking cessation interventions to veterans who may have difficulty accessing services for younger OEF/OIF veterans who prefer the Internet. An efficacious tobacco cessation intervention that has the ability to reach a large number of veterans has the potential to increase smoking cessation rates and decrease morbidity and mortality in the VA.



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## Acknowledgments

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## Conflicts of Interest

None declared.

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## Abbreviations

**NIH:** National Institutes of Health
**NRT:** Nicotine Replacement Therapy



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**VA:** Veterans Affairs
**OEF:** Operation Enduring Freedom
**OIF:** Operation Iraqi Freedom
**AHRQ:** Agency for Healthcare Research and Quality
**FTND:** Fagerström Test for Nicotine Dependence
**AUDIT:** Alcohol Use Disorders Identification Test
**CESD:** Center for Epidemiologic Studies Depression Scale

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Viewpoint

# EBMPracticeNet: A Bilingual National Electronic Point-Of-Care Project for Retrieval of Evidence-Based Clinical Guideline Information and Decision Support

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## Abstract

**Background:** In Belgium, the construction of a national electronic point-of-care information service, EBMPracticeNet, was initiated in 2011 to optimize quality of care by promoting evidence-based decision-making. The collaboration of the government, health care providers, evidence-based medicine (EBM) partners, and vendors of electronic health records (EHR) is unique to this project. All Belgian health care professionals get free access to an up-to-date database of validated Belgian and nearly 1000 international guidelines, incorporated in a portal that also provides EBM information from other sources than guidelines, including computerized clinical decision support that is integrated in the EHRs.

**Objective:** The objective of this paper was to describe the development strategy, the overall content, and the management of EBMPracticeNet which may be of relevance to other health organizations creating national or regional electronic point-of-care information services.

**Methods:** Several candidate providers of comprehensive guideline solutions were evaluated and one database was selected. Translation of the guidelines to Dutch and French was done with translation software, post-editing by translators and medical proofreading. A strategy is determined to adapt the guideline content to the Belgian context. Acceptance of the computerized clinical decision support tool has been tested and a randomized controlled trial is planned to evaluate the effect on process and patient outcomes.

**Results:** Currently, EBMPracticeNet is in "work in progress" state. Reference is made to the results of a pilot study and to further planned research including a randomized controlled trial.

**Conclusions:** The collaboration of government, health care providers, EBM partners, and vendors of EHRs is unique. The potential value of the project is great. The link between all the EHRs from different vendors and a national database held on a single platform that is controlled by all EBM organizations in Belgium are the strengths of EBMPracticeNet.

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**KEYWORDS**

evidence-based medicine; practice guidelines as topic; decision support systems; clinical; point-of-care systems; biomedical technology; medical informatics; information storage and retrieval; information management; ambulatory care information systems

## Introduction

There has been an explosive growth in scientific evidence, with 75 trials and 11 systematic reviews being published a day [1]. However, the use of literature remains suboptimal because health care providers do not have the time to search actively for information or have difficulty finding the relevant evidence [2]. Too often, clinical decisions are based only upon experience, unsubstantiated routine, and opinions of experts [3,4].

Properly designed information retrieval and clinical decision support systems are now being promoted as a Global Positioning System to prevent health care providers from getting lost in clinical practice [4-6]. Such systems either use technologies, where users can pull clinical information from a database or use services that push information through reminders or alerts [7,8].

Structured clinical guidelines and computerized clinical decision support systems have the potential for improving the quality of care [9-13]. However, most of these evaluative studies focused on physician behavior or process of care rather than on the evaluation of effects on patient outcomes. Despite modern technology, it remains an important challenge to implement such systems effectively [6,14]. To be successful, it is essential that systems make clinical decision-making easier by integrating it in the clinician's workflow the moment the clinician meets the patient. Recommendations should be generated on the fly and be action-oriented rather than mere assessments [14]. Above all, alert fatigue has to be avoided [15].

In Belgium, the construction of a national electronic point-of-care information service, EBMPracticeNet, was initiated in September 2011 to optimize quality of care by promoting evidence-based decision-making [16]. All Belgian health care professionals get free access to an up-to-date database of validated Belgian and international guidelines incorporated in a portal that also provides Evidence-based medicine (EBM) information from other sources than guidelines, including a computerized clinical decision support linked to the electronic health record (EHR). The primary focus is on general practitioners at this moment. In the second phase, there will also be a multidisciplinary focus on allied health personnel and specialist physicians. The platform is also available to patients, albeit for now not in layman's language.

The aim of this paper is to describe the development strategy, the overall content, and the management of EBMPracticeNet.

## Methods

### Overview

EBMPracticeNet was officially founded as a non-profit organization in 2011, and originated from grass roots gathering of EBM-producing organizations. This integrative cooperation project was inspired by CEBAM, the Belgian Centre for EBM and the Belgian branch of the Dutch Cochrane Collaboration. EBMPracticeNet is open to four types of organizations, namely independent producers of EBM information, disseminator organizations, user organizations, and governmental public health departments. Funding comes from the national health insurance institute (National Institute for Health and Disability Insurance, INAMI-RIZIV). The project fits within the broader range of eHealth initiatives in Belgium. The goal is to share national or adapted international EBM guidelines on one certified and secured platform (eHealth), easily accessible to different vendors of EHRs. The information structure of EBMPracticeNet is presented in Figure 1.

The guidelines database is a mix of national and international guidelines. First of all it entails about 50 Belgian guidelines, regularly updated by local Belgian Guideline producers. We supplemented this with a comprehensive database of international clinical guidelines, with the intention to adapt the content to the Belgian context. Several candidate providers of comprehensive guideline solutions were evaluated on the basis of a published review [17]. The EBM Guidelines of Duodecim Medical Publications was selected [18]. The main advantages include the strong EBM methodology, the large number of guidelines, the quality of keywords indexation, the focus on the first line level of health care, the good editorial quality, and efforts to keep the database up-to-date [17,19]. An additional argument was the formal accreditation by the UK National Health Service (NHS) of the Duodecim approach to the production of guidelines, after a formal evaluation based on the AGREE criteria [20-22]. The latter is important to demonstrate that the recommendations are trustworthy [23,24]. For the same reason, all Belgian guidelines need to be formally validated by the Belgian Centre for EBM (CEBAM), before they can be published in the database.



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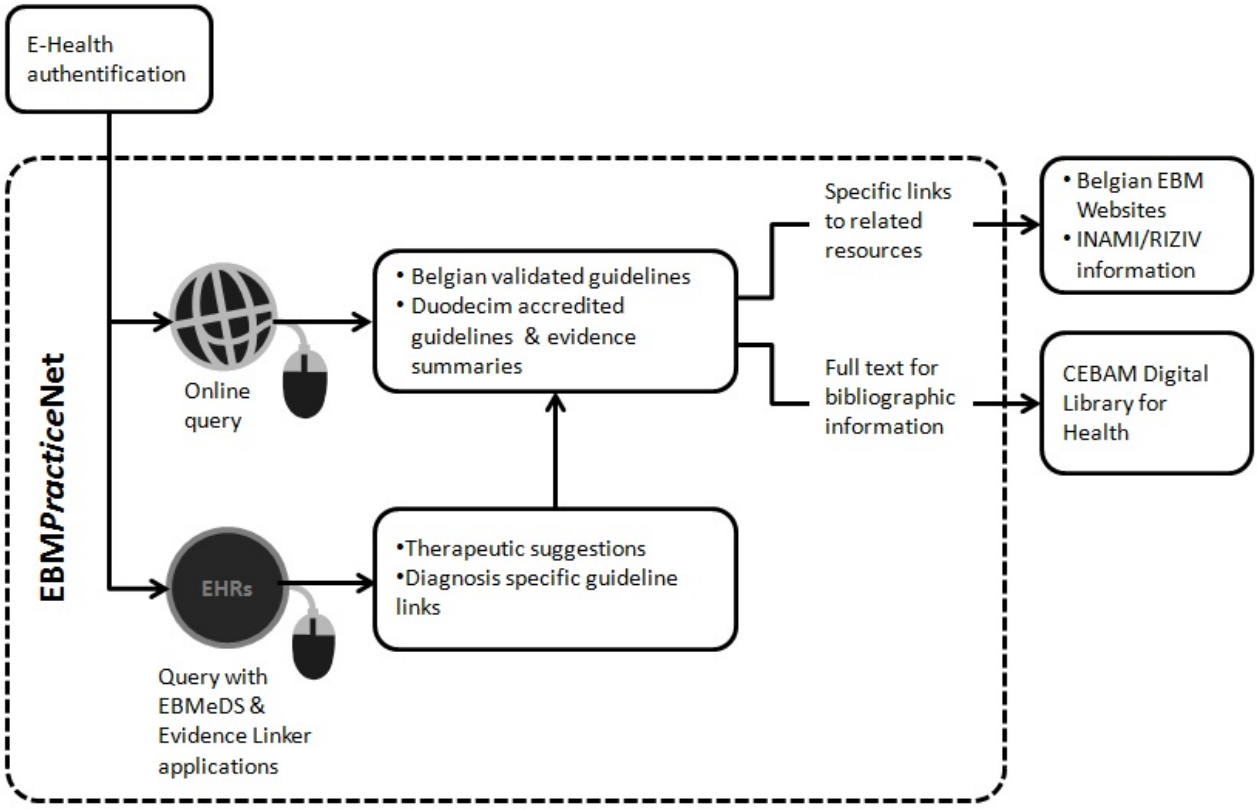
**Figure 1.** EBMPracticeNet information structure.




## Translation and Adaptation to Belgian Context

Duodecim EBM Guidelines comprise of nearly 1000 clinical guidelines and one million words. Translating this comprehensive set and adapting it to the Belgian context posed a huge challenge for EBMPracticeNet. Our first step in this process involved the translation from English to Dutch and French, two official languages of Belgium. This translation project was undertaken in cooperation with our technical partner, Iscientia IVS, a broker company for scientific information, and provider of technical platforms for scientific bibliographic information. The process was supervised by an academic institution of Applied Language Studies (Hogeschool Gent). First, the translation software, SDL Trados Studio, produced a machine translation, which was then post-edited by a human translator, a medical proofreader and a validator [25]. Machine translation was supported by a translation memory database and a terminology management system to ensure the consistent use of terms. The terminology management system used multi-term files, based on MeSH translations developed within the faculty of Applied Language Studies and based on medical glossaries available with the faculty [26]. Apart from the terminology system, the translators also consulted the InterActive Terminology for Europe multilingual term base from the European Union [27]. The post-editing of the human translators was captured in the translation memory, which increased the efficiency throughout the process. It took approximately 2000 translation hours, 500 proofreading hours and 200 validation hours per language, spread over 15 months, to accomplish the translation of the full set of guidelines. The validated versions of the translated guidelines were re-entered in the translation memory database, which will improve the quality of the translation when future updates of the international guidelines have to be translated.

Next is the adaptation of the Duodecim EBM Guidelines to the Belgian context. This process was guided by a preliminary prioritization effort. First, an inventory was made of 50 validated Belgian guidelines. The content of these Belgian guidelines was transformed in the format of the Duodecim EBM guidelines to replace the International guidelines. This involved a two-step transformation with first the production of a structured summary, and then legacy conversion into the EBM Guideline Extensible Markup Language format. Second, an additional priority list of 50 clinical topics was drafted by taking into account clinical information need (based on user surveys and epidemiological reason-for-encounter data in sentinel practice networks) and priority areas indicated by key stakeholders. The relevant guidelines for this list of priority clinical topics are now screened in close consultation with the core community of experts from the Belgian producers of EBM information [28]. The guidelines are categorized in three groups: no need for adaptation for guidelines that are trustworthy and in accordance with the Belgian context, and guidelines requiring minor or major adaptation. The guidelines requiring contextual adaptation will undergo a tailored ADAPTE procedure in collaboration with the Belgian experts [29]. Content-related remarks are followed up by Duodecim experts and editors so that the Belgian process of adaptation is synchronized with the Finnish updating cycle. We also reached out to the Belgian University Centers for Primary Care, responsible for Vocational training in General Practice, to involve a substantial group of General Practice



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trainees in the screening and adaptation process of additional guidelines as part of their thesis.

For the screening of the larger set of low-priority guidelines, we have invited stakeholder organizations and volunteers to screen the remaining guidelines only with regard to their compliance with the Belgian context. This process of screening and adaptation has to be completed by the end of 2015. Meanwhile, all the guidelines will be published with an explicit indication that adaptation to the Belgian context is under way. This indication will be removed when the screening (and if necessary the adaptation) is performed.

The Duodecim EBM Guidelines are revised continuously at a rate of 80 updated guidelines each trimester. This means that we need to keep up that pace of translating the updated information and screening when, and if, updated recommendations need adapting.

### Content Organization and Navigation

The user can search for information with a search engine or can browse for information using a navigation menu based on the conditions included in the database. The content and search engine are organized in such a way that they can be used during the patient encounter in a minimum of time. Implementation of direct access to the EBMPracticeNet is now a criterion in the accreditation of EHR software in Belgium.

The information in the original Duodecim EBM Guidelines database is indexed with the International Classification of Primary Care, Second edition (ICPC-2) and the International Classification of Diseases, Tenth revision (ICD-10) codes and Medical Subject Headings (MeSH) terms. The available ICD-10 and ICPC-2 codes were submitted to scrutiny and validated for the diagnostic part of the guidelines. However, additional coding is needed for process and outcome aspects. An available translation of MeSH terms in Dutch and French will be used to translate the English MeSH terms [30,31].

Based on the 1000 clinical guidelines, we will build a multilingual terminology database. Selected words and phrases will be attributed to each guideline to create an effective search engine to search the database in Dutch, French, and English.

### Portal for Other Evidence-Based Medicine Information

In addition to rapid access to practical recommendations at the point-of-care, this portal also organizes the flow of the clinical information in a chain of evidences that allows users with specific clinical questions to move efficiently from guidelines to systematic reviews and primary studies. As the time invested in these searches increase, they will typically be accessed outside the patient consultation.

- With the Duodecim EBM guidelines comes a collection of more than 4000 evidence summaries. These evidence summaries are graded statements with a short description of systematic reviews or original research [18]. In addition, the EBM guidelines information corpus includes images and videos, which are helpful in making diagnoses and carrying out procedures.
- Each guideline in the database will be linked to specific information on the websites of Belgian EBM producers. Although the Belgian EBM information is scattered across various websites, this will make it possible for the user to surf the relevant links on the site of the producers, through the EBMPracticeNet. Likewise, the guidelines will be linked to information from INAMI-RIZIV.
- Integration with the CEBAM Digital Library for Health enables the users to move from the bibliographic information provided on EBMPracticeNet to the full text of original research or systematic reviews, either in the Cochrane Library or in the large collection of scientific journals, subscribed to by the Digital Library [32,33].

### Computerized Clinical Decision Support

The computerized clinical decision support component uses the Evidence Linker technology and the Evidence-based Medicine electronic Decision Support (EBMeDS) system. The Evidence Linker is a new tool developed by the CEBAM with two General Practice trainees supervised at the KU Leuven (by BA), that provides a direct link between patient data from the EHR and guidelines for general practitioners [34].

The EBMeDS system was developed by Duodecim and its content development process is also accredited as such by the United Kingdom NHS [22,35]. The EBMeDS system receives structured patient data from EHRs and returns therapeutic suggestions and diagnosis-specific links to guidelines for a full spectrum of clinical topics.

### Promoting Implementation

To promote use of the EBMPracticeNet services, we adopt a multifaceted strategy [36]. Representatives of all local groups of family doctors receive an invitation by mail to discuss the EBMPracticeNet services at their meetings and to send in their feedback. EBMPracticeNet partners pay attention to the services in their respective publications, and organizers of EBM courses train participants in using it. Outreach visits to clinicians by the staff of an EBMPracticeNet member (ie, FARMAKA) are foreseen to give further explanations on the use of the services. Patient specific information, linked to the caregiver guidelines, will be developed in order to increase adherence to the counseling and to empower patient self-care.

### Management

The building and management of EBMPracticeNet is coordinated by a project leader, an editor-in-chief, five editors, and a secretary, all working part-time on this project and representing two full-time equivalents. The processes are being implemented in collaboration with the Belgian EBM producers, technical experts, and volunteers. Finding competent volunteers that are motivated to participate in these processes is a key factor in the sustainability of this project. The use of volunteers can include taking on the responsibility for one or several guidelines to ensure that the recommendations and their updates are in accordance with the Belgian context.

The project involves many working processes such as: information collection, processing and validation, publication and updating of the published information, and usage monitoring. An important initial effort was to describe all the key processes in Business Process Model and Notation (BPMN).



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The BPMN is a standard graphical notation that describes working processes in flowcharts and enables the management team to clarify and optimize processes for all stakeholders, and ensure that processes are easily transferable within the team and to the partners. We developed these flowcharts in the Open Source software Bizagi, which allows exportation to automated work flows and task lists on our editorial platform (Microsoft Sharepoint). This proved to be vital to increase the manageability of the different working processes for a small project team, collaborating with a large group of partners and volunteers.

## Results

Currently, EBMPracticeNet is still in a "work in progress" state. The use of EBMPracticeNet will be monitored in order to better meet the needs of the users and for research purposes. For this purpose, routine statistical information will be collected, such as:

- Mechanism of information retrieval: search engine, navigation system, Evidence-Linker, EBMeDS scripts.
- Type of information: search terms used, documents opened, *click-through rates* to sites of EBM producers and to CEBAM Digital Library for Health.
- User profile: type of user (health care providers, general public), language group.
- Time of use: hour and day of use, time spent in a resource.

This information is general in nature and collected anonymously, in respect of privacy regulations.

A research agenda needs to be developed to evaluate the impact of EBMPracticeNet on the care provided by Belgian health care providers. The research will comprise user-centered evaluations to analyze factors associated with failure or success; content-centered evaluation to evaluate the EBM quality; and quality and safety of care evaluation.

Preliminary results include the pilot implementation of the EBMeDS system in the EHRs of a small group of Belgian general practitioners and a quantitative and qualitative assessment of acceptance of the system has already been performed. The early adopters that responded to this survey reported a positive attitude toward this system and definitely intended to continue using it [37]. A research protocol has now been ethically approved for a randomized controlled trial (RCT) with focus on diabetes management, and is registered in clinicaltrials.gov as NCT01830569. The RCT will assess the effectiveness of the use of the EBMeDS system among Belgian general practitioners compared to the usual care process. The primary outcome measure is adherence to each of the recommendations. Secondary outcome measures include process and patient outcomes as selected from a list of quality indicators.

## Discussion

### Principal Findings and Future Directions

The prerequisite for the functioning of seamless information flows is accurate and sophisticated recording of data in the EHRs, with structured data entry, facilitated by interface terminology systems, to bridge the gap between every day medical communication and international nomenclatures and classification systems [38]. A well functioning interface terminology system should be a hybrid combination end user terminologies and one reference terminology. The end user terminology part is a unilingual lexical terminological resource (one per language), containing a selection of often used words and phrases in daily medical communication, with a splitting of polysemous meaning if present, and tagging of possible synonyms, preferably linked to National Language Processing resources such as WORDNET. The reference terminology is a multilingual resource, containing the collected concepts pertaining to a core set for medical practice, their preferred terms (for physicians and for laymen) in the different languages, a semantic bridge (word sense to concept definition), and a string bridge (word or phrase to preferred term of a concept) to the unilingual end user resources. In addition, all concepts should be mapped to several international nomenclatures (SNOMED, UMLS), classifications (ICD, ICPC), and Thesauri (MeSH). The mappings to these external systems should be the result of an expert-validated mapping effort, with qualification of the nature of the mapping (exact match; nearly exact match; imperfect but closest possible match; and impossible to match within this system) [39]. Both types of terminological resources with the interface terminology system should be represented in ISO International Standards: Lexical Markup Framework (LMF).

The LMF is used for the unilingual end user terminology and Terminological Markup Framework (TMF) is used for the multilingual reference terminology. The two resources could be managed with a Web-based Semantic Media Wiki Application, and published in Linked Open Data. Correct medical registration will optimize the functioning of automated decision support alert systems by providing both correct triggering of alerts and comments, only when necessary, and not when known exceptions are present. The coding behind correct medical registration can also provide the pathway to focused clinical questions, when practice problems surface, which halt the routine flow of the consultation process. The answer to these clinical questions can then be seamlessly provided on the guideline platform.

To facilitate information retrieval for the users, we also planned additional tools such as:

- The development of a Patient-Intervention-Comparison-Outcome interface and the complex indexing of specific practice recommendations to make the database searchable for specific patient problems [40].
- The further elaboration of the navigation menu according to taxonomy of generic clinical questions and organization of the content as a strategy to route general user questions to more specific clinical questions and focused recommendations [41].
- Specialty-specific indexing of information for several groups of allied health personnel and medical specialists.

### Conclusions

The Institute of Medicine defines Health Care Quality as the extent to which health services provided to individuals and



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patient populations improve desired health outcomes [42]. The care should be based on the strongest clinical evidence and provided in a technically and culturally competent manner with good communication and shared decision-making. Six aims were designed for improving the delivery of care: safety, effectiveness, patient-centeredness, efficiency, timeliness, and equitability. Improving the quality of care requires action at the micro (individual), meso (practice setting and different disciplines in primary and hospital care), and macro levels (government).

Professional behavior of caregivers consists of evidence-based practice, reflecting on their own performance, accountability, and continuous professional education. Information and communication technology (ICT) plays an important supporting role in improving the quality of care. The ICT can increase efficiency through the efficient management of resources and administrative simplification. But ICT also plays a crucial role in the effective use of treatments and patient safety (evidence-based practice) in promoting the participation of the patient and may ensure better continuous professional development and education of the caregiver.

While EBMPracticeNet is currently in "work in progress" state, the potential value of the project is great. The link between all the EHRs from different vendors with a national database held on a single platform and controlled by all EBM organizations in Belgium is the strength of EBMPracticeNet. As yet, we are not aware of an identical project in the world. The collaboration of government, health care providers, EBM partners, and vendors of EHRs is unique. With the help of national leadership in standardization and the collaboration of medical software vendors, standards can be set to facilitate the integration of different types of evidence-based and clinical information. This collaboration stems from the free delivery of independent content by the government and EBM providers, and the creativity of software vendors in creating applications for this content. A mechanism for gradual improvement of the resulting systems is the accreditation process of medical software for EHRs in which the Belgian eHealth authorities verify if the EHR fulfills the certification criteria for EHR technology.

Since Belgian EBM organizations are now formally united in EBMPracticeNet, the potential for collaboration increases. This will help reduce duplication in efforts during the development of EBM information. International collaboration on evidence synthesis and guideline development methodology, standardization of data structures, and ontologies (terminologies and their relationships) for evidence, clinical questions, recommendations and decision support, facilitated sharing of knowledge resources, and tools for staying informed about evidence will further enhance the impact of EBMPracticeNet. In addition to the EBM guidelines and EBMeDS editorial teams in Finland and Austria, the collaborative network consists of the Cochrane Collaboration, Guidelines International Network, and the GRADE Working Group.

To sustain funding for this project the impact on the quality of care will need to be demonstrated, if possible on patient outcome. The development of a research agenda is needed to verify the impact on changing clinical practice.

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## Conflicts of Interest

RVS is the salaried Project Leader, SVDV is the salaried Editor-in-Chief, and AH is a salaried Editor for EBMPracticeNet. BA and SG are founding members of EBMPracticeNet. BF is president of the EBMPracticeNet board and is salaried editor of EBMPracticeNet. DR is board member of CEBAM. IK is the salaried Chief Editor of EBM Guidelines and EBMeDS decision support service.

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## Abbreviations

**BPMN:** Business Process Model and Notation
**CEBAM:** Belgian Centre for EBM
**EBM:** evidence-based medicine
**EBMeDS:** Evidence-Based Medicine electronic Decision Support
**EHR:** electronic health records
**ICD-10:** International Classification of Diseases, Tenth revision
**ICPC-2:** International Classification of Primary Care, Second edition
**ICT:** information and communication technology
**INAMI-RIZIV:** National Institute for Health and Disability Insurance
**LMF:** Lexical Markup Framework
**MeSH:** Medical Subject Headings
**NHS:** National Health Service
**RCT:** randomized controlled trial
**TMF:** Terminological Markup Framework



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Original Paper

# A Type 2 Diabetes Prevention Website for African Americans, Caucasians, and Mexican Americans: Formative Evaluation

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## Abstract

**Background:** The majority of Americans now access the Internet, thereby expanding prospects for Web-based health-related education and intervention. However, there remains a digital divide among those with lower income and education, and among Spanish-speaking populations in the United States. Additional concerns are the low eHealth literacy rate among these populations and their interest in Internet-delivered interventions with these components. Given these factors, combined with the prevalence of type 2 diabetes among low socioeconomic status and Spanish-speaking Americans, strides need to be taken to reach these populations with online tools for diabetes prevention and management that are at once accessible and efficacious.

**Objective:** Using a formative evaluation of an eHealth diabetes prevention and control website, we tested the extent to which African Americans, Caucasians, and Mexican Americans at risk for type 2 diabetes gained knowledge and intended to modify their dietary intake and physical activity subsequent to viewing the website. We also examined their general Internet use patterns related to type 2 diabetes.

**Methods:** A mixed methods approach was undertaken. The diabetes prevention and control website provided educational and behavioral change information in English and Spanish. For this study, eligible participants (1) completed a prequantitative survey, (2) interacted with the website, (3) completed a qualitative interview, and (4) completed a postquantitative survey.

**Results:** After finding a significant differences in posttest diabetes knowledge scores ($P$<.001), a regression analysis controlling for pretest score, health literacy, ethnicity, Transtheoretical Model Stage for exercise and fruit and vegetable consumption, and Internet literacy was conducted. Internet literacy score ($P$=.04) and fruit and vegetable consumption stage ($P$<.001) were significantly associated with posttest scores indicating that those in precontemplation stage and with low Internet literacy scores were less likely to show improved diabetes knowledge scores. We found significant difference in posttest intention to eat a healthy diet each day in the next 2 months after controlling for pretest score, health literacy, ethnicity, Transtheoretical Model Stage for fruit and vegetable consumption and Internet literacy. Those in the Action stage of the Transtheoretical model for exercise were



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significantly less likely (*P*=.023) to improve the posttest score for intention to eat a healthy diet compared to those in the Preparation stage for exercise. We also found that health information is sought commonly across ethnic groups, but that diabetes-related information is less commonly sought even among those at risk. Other specific ethnic usage patterns were identified in the qualitative data including content sought on Web searches and technology used to access the Internet.

**Conclusions:** This study provides in-depth qualitative insight into the seeking, access, and use of Web-based health information across three ethnic groups in two languages. Additionally, it provides evidence from pre-post measures of exposure to Web-based health content and related changes in diabetes knowledge and intention to eat a healthy diet.

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**KEYWORDS**

diabetes; Internet; Mexican-Americans; African Americans; socioeconomic status; dietary intake; physical activity; health literacy; website

## Introduction

The ubiquity of the Internet presents opportunities to equalize access to and usage of diabetes prevention and control information, particularly for health disparate populations including African American and Mexican American populations whose incidence rates of diabetes exceed Caucasians [1]. Obesity resulting from excess calorie intake and physical inactivity over time is associated with diabetes [2]. In the United States, 44.1% of African Americans, 32.4% of Caucasians, and 40.4% of Mexican Americans are classified as obese [3,4]. None of these populations meets federal nutrition [5-7] or activity guidelines consistently. For example, only 11% of the US population met fruit and vegetable consumption guidelines [5] and fewer than 5% met physical activity recommendations [8]. Addressing these behaviors through the Internet to increase healthful nutrition and energy expenditure may contribute to diabetes prevention and control strategies.

Vigilance on issues of unequal access to eHealth [9,10] has now shown that the majority of Americans access the Internet [11]. While there has been and still is a digital divide among those with lower income and education and Spanish-speaking populations in the United States, even these populations are reporting more access to the Internet because of expanded technologies, particularly mobile devices [11].

Today, an additional concern is low eHealth literacy [12,13], which means an individual may have difficulty not only seeking, finding, appraising, and understanding electronic health information, they may also not have the knowledge to apply the information to solve the health problem [13]. The design of diabetes prevention and control websites to accommodate low eHealth literacy abilities with particular attention on learning and usability issues [14] across ethnic populations is an area of growing importance.

There is mounting interest in eHealth/Internet-delivered interventions [15-17], especially studies testing the efficacy of websites singularly or in combination with other intervention components. We conducted a formative evaluation of an eHealth diabetes prevention and control website, including content related to nutrition and physical activity, available in Spanish and English with African Americans, Caucasians, and Mexican Americans at risk for diabetes. A mixed methods approach was taken to examine learning and usability features of the website. We examined the participants' general Internet use patterns related to type 2 diabetes. We hypothesized that our participants would gain knowledge and intend to modify their dietary intake and physical activity subsequent to viewing the website. Here, we report both results describing the Internet-based, health information seeking, access, and use by ethnic group, and pre-post measures of exposure to health content on a website, as well as related changes in knowledge and intention to engage in preventive behaviors.

## Methods

### Website Development

The Pittsburgh Regional Initiative for Diabetes Education (PRIDE) initially created a website with content composed by experts in the fields of diabetes education and prevention at the University of Pittsburgh Diabetes Institute (PrideofPA website) [18]. The website provided educational and behavioral change information for those at risk for or diagnosed with type 2 diabetes. Features of the site include videos on topics such as physical activity and nutrition, medications, social support, and a local map pinpointing nearby Diabetes Self-Management Education locations. In addition, this site has a diabetes risk calculator to help people determine their potential risk for diabetes. The risk calculator is based on risk factors identified by the American Diabetes Association (ADA) and allows individuals to answer a few simple questions to determine their risk for type 2 diabetes. The website directs people to be screened and talk with a medical provider. See Multimedia Appendices 1-3 for examples of website content.

The website content and risk calculator were also translated into Spanish by professional translators specializing in Mexican-origin Spanish and culturally relevant examples were added to content and videos. Feedback from Mexican American end users was obtained through cognitive interviews (TSSC website) [19]. The resulting website available in English or Spanish was then the focus of a formative evaluation process whereby eligible participants (1) completed a prequantitative survey, (2) interacted with the website, (3) completed a qualitative interview, and (4) completed a postquantitative survey.



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## Participants

A total of 71 adults at risk for diabetes because of overweight or obesity status and/or family history of diabetes were recruited across African American, Caucasian, and Mexican American populations to participate in one-on-one interviews, in order to assess whether and in what ways the website and diabetes risk calculator were appropriate for moderate- and high-risk populations. Participants in southwestern Pennsylvania (PA) were asked to review an English language version of the website and risk calculator and were either African American (n=19) or Caucasian (n=27), while the Mexican American participants (n=25) were from Brownsville, Texas (TX), and were asked to review a Spanish-language version of the website.

## Recruitment

Recruitment and data collection were carried out between summer 2011 and spring 2012. In either study site (PA or TX), participants were recruited via local universities, churches, physician offices, school organizations, Internet sites, and community organizations/events. The recruitment process was the same across the three populations. Caucasian, African American, or Mexican American adults aged between 18-54 years, who read and speak English or Spanish, with a body mass index (BMI) greater than 24 and/or who were at risk for diabetes by family history, and had an email address, were considered eligible for participation. Individuals ineligible for the study included women who were pregnant, those currently diagnosed with diabetes, those unwilling to access the Internet for health information, and those who were in the Maintenance stage for fruit and vegetable consumption or exercise according to the Transtheoretical Model [20]. A staff member or project volunteer provided an overview of the project, explained inclusion/exclusion criteria, and concluded with a request for volunteers to participate in the study, including the first step of completing the eligibility screening. Separately, fliers were distributed that summarized key points of the project and included a phone number to reach a study contact.

## Screening Process

Recruited participants were screened for eligibility via an online battery of tools hosted by SurveyMonkey. All participants who completed the eligibility screening tools received a US$10 incentive regardless of their study eligibility.

Participants were asked to answer the following:

1. Would you ever consider using the Internet to search for health information? Participants who answered “no” to this question were disqualified from participation in the study.
2. Do you have a family member who has diabetes (mother, father, or sibling)? Participants who answered “yes” to this question qualified as at risk for diabetes for the purposes of this study.
3. Self-reported height and weight. These data were used to calculate BMI. Participants categorized as overweight or obese and at risk for diabetes were deemed eligible for the study.
4. Internet Literacy Assessment. A literacy tool used to characterize participants as low, moderate, or high Internet users [21] but was not used for eligibility criteria.
5. Transtheoretical Model Staging Algorithm Pretest. This assessed participants’ readiness to meet guidelines for physical activity and fruit/vegetable consumption [20] with those in maintenance being excluded from the study.

Participants who qualified as eligible and were interested in enrolling in the study went on to complete an additional two questionnaires: (1) Diabetes Knowledge Questionnaire Pretest, which was a 25-question, self-administered questionnaire that assessed the participant’s diabetes knowledge [22,23], and (2) Theory of Planned Behavior Questionnaire Pretest, which was a 56-question, self-administered questionnaire designed to assess the participant’s intentions to change or modify their behavior [24].

## Interviews

Participants were contacted via phone by a study representative to schedule an in-person study session, to be conducted at the University of Pittsburgh Medical Center or the University of Texas School of Public Health Brownsville Regional Campus. The sessions consistently lasted approximately 90 minutes and were conducted in the participant’s native language (English or Spanish). First, informed consent was obtained from participants. Second, participants completed the Short Test of Functional Health Literacy in Adults [25].

Next, participants were introduced to the website and instructed that they had 20 minutes alone to explore it. At the conclusion of the 20 minutes, the study representative returned to the room and asked participants to complete three guided tasks on the site about diabetes: (1) to identify two things they learned about being at risk for type 2 diabetes, and (2) to assess in a real-life scenario how they would apply the information. Participants were given 15 minutes to complete these tasks.

Upon completion, trained study staff performed a semistructured interview to assess the participant’s overall thoughts about the website. The audio-recorded interviews ranged from 10-60 minutes in duration, with a mean of 35 minutes. Interview questions inquired about the participant’s diabetes risk test results, past experiences searching for health information online, perceptions of the website, and motivations and barriers to exercising and making healthy food choices.

To conclude the session, participants were asked to complete posttest assessments on the following three surveys: Diabetes Knowledge Questionnaire, Transtheoretical Model Staging Algorithm, and Theory of Planned Behavior Questionnaire.

## Qualitative Analysis

Audio recordings of the semistructured interviews were transcribed verbatim. Qualitative analysis of the transcripts commenced with the full research team identifying an initial list of codes based on the questions included in the interview guide. This list of codes was then expanded upon and refined through four rounds of test coding (13/71 or 18.3% of the transcripts were double coded) using ATLAS.ti 6.0, a computer-assisted qualitative data analysis software program. In the first round of test coding, 2 coders (one from each study site) each analyzed selected participant transcripts. Using EUSEBIUS, a software package developed in-house at the



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Qualitative Data Analysis Program, this first round of coding agreement was adjudicated by the full research team and a Fleiss' kappa was calculated to measure intercoder agreement. The kappa statistics served to guide codebook modifications. The codebook was finalized once it was deemed to effectively capture the key themes emerging from the interviews with relevance to the project's research questions. The 2 initial coders from each site also served as adjudicators and coaches for the 6 other coders to ensure consistency within and across the sites.

Once the coding was completed, members of the research team reviewed the coded data to identify the dominant themes. Further, distinctions were made concerning viewpoints shared by participants from all three ethnic groups and those that differed according to ethnicity. Although the quotes for the Mexican American participants in this study are presented in English, the interviews were conducted in Spanish.

### Quantitative Analysis

A comprehensive dataset was established for each participant including their SurveyMonkey data and the paper-pencil data from posttest. Double data entry was conducted on any paper-pencil collected data to ensure accuracy. For univariate analysis, a *t* test or its nonparametric counterpart, a Wilcoxon rank-sum test, was used. For multivariate analysis, a linear regression was conducted. A significance level of 0.05 was used in the analyses to determine significance.

## Results

### Descriptive and Qualitative Results

The sample for this study included African American, Caucasian, and Mexican American adults, primarily females, with some college education, and making under US$40,000/year (Table 1).

We report on Internet usage for health seeking by ethnic group, related generally to health and specifically to diabetes, and on whether content on a website related to diabetes increased knowledge about and intention to engage in preventive behaviors. We have summarized qualitative and quantitative findings related to these topics.

**Table 1.** Demographics of sample (N=71).

| | Gender | | Education level | | Household income | |
|---|---|---|---|---|---|---|
| | Male | Female | <College | Some college+ | <$40,000 | >$40,000 |
| Ethnic group | % (n) | % (n) | % (n) | % (n) | % (n) | % (n) |
| African American (n=19) | 15.8 (3) | 84.2 (16) | 10.5 (2) | 89.5 (17) | 78.9 (15) | 21.1 (4) |
| Caucasian (n=27) | 14.8 (4) | 85.2 (23) | 0.0 (0) | 100.0 (27) | 13.24 (9) | 25.00[a] (17) |
| Mexican American (n=25) | 16.0 (4) | 84.0 (21) | 24.0 (6) | 76.0 (19) | 87.0 (20) | 13.0 [a] (3) |
| Total (71) | 15.5 (11) | 84.5 (60) | 11.27 (8) | 88.73 (63) | 64.7 (44) | 35.3 [a] (24) |

[a]Participants refused to answer.

#### *Internet Searching Theme: Seeking Internet-Based Health Information Is Normative*

Participants described regular interactions with Web-based health information. Searches for online health information occurred either as a routine part of their life, or as an intermittent targeted search activity, or a combination of both (Table 2):

1. *Habitual Searching*: Participants described regularly seeking online health information as part of a daily or regular pattern. They also indicated that their searches covered a wide variety of health topics. Participants frequently used the term "To Google it" when asked about online searching methods, which reinforces not only their familiarity with searching for information online but the extent to which Google's search engine has permeated our culture.
2. *Intermittent Health Information Searching:* Participants also discussed searching for online health information when particular questions arose or circumstances dictated the need for this information.
3. *Habitual and Intermittent Health Information Searching:* Some participants discussed a combination of patterns for searching for health information. They may regularly be online learning about health topics (eg, a chronic health condition they have), but then intermittently "look into" certain topics.

Studies focused on the digital divide specific to online health-related information seeking indicate that the propensity to search online for health information is linked most strongly with education level and Internet access. That is to say that the higher the education level and the greater the Internet access, the more likely one is to search online for health information. Differences in the rate of electronic health information seeking between ethnic groups do exist but to a lesser extent [26,27]. In our sample, there were no marked differences by ethnic group in the description of the frequency of searches. However, while all participants had indicated a willingness to search for health information as criteria for inclusion in the study, 2 Mexican American participants interviewed commented that they had never searched for health information online, while all African American and Caucasian participants indicated some past history with searching online.



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**Table 2.** Quotes from frequency theme: searching for health information is commonplace.

| Participant ethnicity | Habitual searching | Intermittent searching |
|---|---|---|
| African American | A lot, couple times a week. Not necessarily diabetes, but always about health. Always about eating and exercising, always. | Mmm…couple times a year, just depending on what's going on in the family. |
| Caucasian | Weekly. Yes. Pretty much general definition, you know then that kind of segues into symptoms. You know, not drilling down into management, but, risk factors, symptoms, starting there. | My daughter has a lot of medical problems, so I do use the Internet a lot. Basically I would just go into Google or Yahoo, type in the basic thing that I was looking for. Sometimes it would be a little overwhelming because you have all these links and you don't know exactly where to go...For example, she has asthma, so I would type in things, like…ways to make it more tolerable, or ways to treat, alternative treatment methods, things like that. Just like a general term. On average probably two to four times a month maybe, depending on what I'm going through at the time. If I'm sick or she's sick. |
| Caucasian | Quite a bit, especially lately. You know, a couple times a week at least, you know, at various times through the day, and so it's been frequent lately. | |
| Mexican American | There are times that people tell me "hey, there is a website." Or some time ago, people told me that there was a talk about stem cells, that they may help diabetes. That is when I go in and look…I am not on the computer all day because I am a stay home mom. Whenever I have a chance I sit down and read. Generally it is once a week…and I also get my daughter involved. | I would say like every 2 weeks, when I get a chance I go and…search this and that. |
| Mexican American | Two or three days of the week or more when I feel like working at the computer. | |

### *Content Theme: Searching for a Broad Spectrum of Health Content*

Participants described searching for health information either to increase their general knowledge on a condition or health topic, or in a more targeted manner to understand ailments and symptoms (Table 3). The reasons for these searches were often imbedded in personal, friend, or family need for information.

#### Searches for Health Conditions or General Health Topics

The spectrum of health content searched for by participants ranged widely. Topics such as men's health, cancer, mental health, various chronic conditions (multiple sclerosis, polycystic ovary syndrome, autoimmune conditions), flu symptoms, sexually transmitted diseases, concussions, food allergies, caloric intake, hypoglycemia/hyperglycemia, thyroid disorders, health care provider information, and side effects of medications were examples of health information that had been previously sought. Participants were interested in learning more about health issues they or family/ friends were experiencing or health issues they did not understand.

Participants across all three ethnic groups described searching for online health information for themselves; however, it was less common for African American participants to describe searching for health information for family and friends as compared to Caucasian and Mexican American participants.

#### Searches to Understand Symptoms

Participants searched for health information to understand, diagnose, or treat symptoms either they or someone they cared for was experiencing. Symptoms such as cough, aches/pains, asthma, constipation, and H1N1 symptoms were specifically mentioned as reasons to search.

Also, participants from all three ethnic groups commonly mentioned searching for symptoms, with African Americans discussing this search approach slightly less often than Caucasians and Mexican Americans. However, there were no marked differences by ethnic group in how the searches were conducted or approached.

African American participants discussed looking for health information regarding weight status, desire to lose weight, and finding healthier food choices (Table 4), whereas other ethnic groups did not discuss this content.

## Searching for Diabetes-Related Information Specifically

Participants were asked about how they interacted in the past with health information websites of their own choosing specifically on the topic of diabetes.

### *Diabetes Information Theme: Searching for Diabetes Information Online Is Not Universal*

We found that of the 71 interviews conducted, 47 (66%) of participants indicated they had searched for diabetes information though there was a range of topics discussed and a difference in depth of search (Table 5). Those participants who had family or friends with diabetes discussed more in depth searches. There were no ethnic differences in the discussion of searching for diabetes information online.

Searching the Internet for any type of health information is commonplace across the ethnic groups and for many of our



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participants is a regular part of their daily and weekly routines. Diabetes-related online information had previously been sought by 47 of 71 participants but all were deemed at risk for diabetes based on study screening criteria. The participants indicated that they searched for information for themselves regarding symptoms of diabetes and for loved ones with diabetes regarding their dietary intake and medications.

**Table 3.** Content theme: Searching for a broad spectrum of health content.

| Participant Ethnicity | Searching for health conditions or general health topics | Searching as a reaction to symptoms |
|---|---|---|
| African American | Everything. Literally. But strangely, I didn't do diabetes. Cancer…Everyone—it seems like everyone's dying from cancer, heart disease. I mean, it's kind of like the same thing, and I always thought, food was our trigger, like one of our main triggers, and how we're eating. | I usually will go on Google, and whatever I think the ailment would be, I'll just type that in and see what comes up. I'll go to various websites, but it's hard when you're looking up information online 'cause not a lot of the sites are trustworthy. You have to kind of find a way to filter out the good sites from the bad ones. Find out what information is actually useful and what could be discarded…Even if I'm sniffling and sneezing, I'm like, "Ugh, this might be a cold." I'll type in "common cold" or "swine flu." |
| Caucasian | I would say maybe, maybe once a month. I mean it possibly could be more. Like if I'm on, like MSN website, MSN.com, and you know they're advertising something that has to do with health, I might click on it. Or, if I want to look into something…then it might be more. | Anytime I think I'm sick, since I don't have health insurance, I try to find a website. It will tell me "Well, if you have this and this, it might be this." I can kind of get a feel for if it's the flu or something like that…Recently, my girlfriend has some mental health issues, so I've been looking up those kind of things on WebMD or different websites like that. That's the only one I can think of off-hand now. They've just been really unhelpful. |
| Mexican American | Yes, I have searched for cholesterol because that is what always worries me a little bit more, right? For the same reason, because of family issues. I have a grandfather who had a heart attack, and an aunt who had a stroke. So then you focus on cholesterol. | So, there specifically is what most interests me. Since these two had breast cancer, that's where I focus more to see what risks I have. |

**Table 4.** Content theme: Additional health information sought by African American.

| Participant ethnicity | Searching for health information about weight loss, dietary intake |
|---|---|
| African American | Well, weight, you know. What causes the weight, calories intake. I'm still trying to learn about that, what the calories are, and what would be right for me to have in a day. They say women should have no more than 2000 calories—I think it's 2000, or 1500 to 2000 calories—but what would that consist of, you know? Like what would I have in the morning? Would I have 300 or 400 calories in the morning, and maybe 200 calories for that type of calorie? I'm kind of confused when it comes to how much I should be eating. |
| African American | It's always been easy for me to find information. I'm good with computers and it's just easy. All you have to do is just put in a name and you can just find whatever you want to find…I always look at things about weight. And about food. I always look for weight, food, and exercise. Even in stores I always read labels. |

**Table 5.** Searching for diabetes information online is not universal.

| Participant ethnicity | Previously searched for diabetes-related information | Has never searched |
|---|---|---|
| African American | More so…yeah, my doctor had mentioned something about a drug that she could possibly give me if my blood sugar didn't improve, so I looked that drug up. | No. I never looked. |
| Caucasian | Yes. I actually did look for it a couple other times because I was thinking that I was. I just actually remember this because my friend said that she felt that she was experiencing symptoms of diabetes…being thirsty often. And so I remember I Googled it, I was like, "oh, I'm thirsty a lot, too," and, I was like "I do eat a lot of sugar, so, and it's in my family." I went and just looked up about diabetes. Yeah, I was looking for the symptoms, because I think to be diagnosed you have to go to your doctor and have blood work done. | No. For some reason diabetes is [chuckles] not really one of those. I know of some people with diabetes, and it's not like as serious...like they're living with it, so. |
| Mexican American | It is important that she [daughter] sees how the whole system works and how diabetes affects her as well. Very important for her to know. And I also investigate a lot about carbohydrates, because our doctor talks a lot about the importance of the carbohydrates diabetics need to take. Then there are times when we do not know the portions, the foods, the carbohydrates. | No, to tell you the truth because I was never at risk. I really didn't worry a lot for that. I worried more about triglycerides or something that I'm at risk for. |



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## Environment for Accessing Online Health Information

### *Access Theme: Utilizing Various Locations and Technologies to Access Online Health Information*

Participants also reported conducting online searches in various locations such as their home, place of work, and the library. The most popular location for searching for online health information by all ethnic groups was the home. A range of technology was used including desktops, laptops, tablets, and phones (Table 6).

Ethnic groups differed by location and type of technology used. More Mexican Americans participants accessed Web-based health information on desktop computers, whereas Caucasian participants tended to access Web-based health information more often on phones, laptop computers, or other mobile devices. African American participants also indicated using public facilities such as libraries for Internet searches more often than the other two ethnic groups.

### *Reacting to Risk Score Theme: Features of Website Can Elicit Emotional Reaction*

Participants were asked for their opinions on a diabetes risk calculator that was part of the website. The calculator assessed participants' risk through a series of questions based on the ADA risk factors regarding genetic predisposition to diabetes, levels of physical activity, age, and BMI. Based on their responses, participants received a low, moderate, or high risk score for diabetes.

All but 5 participants received a risk score of either high or moderate. More participants reacted with surprise about a high or moderate score than did those who did not find these scores surprising. Participants who received a low risk score did not express surprise but rather emotions such as relief and happiness. Some of these low-risk participants had made behavioral changes to decrease their risk of diabetes and those behavioral changes were reinforced by the low-risk categorization. Participants reacted differently to the moderate or high risk scores, where some said they would change their behaviors while others did not indicate such changes would be occurring. Ethnic differences among these reactions or indications of intention to change behavior were not found. Quotations representing these themes are presented in Multimedia Appendix 4.

The designers of the website included a risk calculator to provide information about individual risk for diabetes in a manner that would be educational and could create an emotional reaction as a catalyst for actions including being tested, more in-depth information searching, and preventive behavior change. Based on the participants' reactions of surprise or relief, it appears that the risk score calculator does elicit an emotional reaction. However, only some participants expressed motivation to make changes in their behavior, including seeking support from physicians and recommitting to exercise routines. Other participants reacted to the risk score without statements indicating commitment to change behaviors. For many, but not all, the risk score calculator appears to be an appropriate, thought-provoking, and emotion-provoking element on the website. Furthermore, the themes associated with the risk score calculator do not show patterns by ethnic group.

### *Returning to Website Theme: Indication of Return to Website Likely*

In the present study, return use of the website was not tracked over time, but unlike similar studies that only focused on assessing the feasibility/desirability of the website without going forward with full-scale use of the website [28,29], interviewers did inquire about the likelihood of the participants to return to use the website in the future. The overall expected return rate was 81%. We examined the results by ethnic group and found that the predicted return rates for Caucasians were somewhat lower than for other participants: African American 82% (16/19), Caucasian 70% (19/27), and Mexican American 91% (23/25).

## Quantitative Results

Quantitative surveys were administered to participants in this study as a pretest (as part of the enrollment procedure) and as a posttest (after exposure to the website and qualitative interview). We examined whether improvement occurred in participants' diabetes knowledge after using the website. After bivariate analysis indicated significant mean score differences in diabetes knowledge from pre- to posttest ($P \leq .001$), a regression analysis was conducted with diabetes knowledge post score as the dependent variable, controlling for several independent variables (Table 7).

We found significant differences in posttest diabetes knowledge scores after controlling for pre-test score, health literacy, ethnicity, Transtheoretical Model Stage for exercise and fruit and vegetable consumption, and Internet literacy. Internet literacy score, and fruit and vegetable consumption stage were significantly associated with posttest scores indicating that those in pre-contemplation stage and with low Internet literacy scores were less likely to show improved diabetes knowledge scores.

We also examined participants' intention to be physically active or to eat healthy after viewing the website. We examined posttest intention scores after controlling for pretest intention, health literacy, ethnicity, Transtheoretical Model Stage for exercise and fruit and vegetable consumption, and Internet literacy. We found no significant differences in intention to be physically active. We did, however, find in the bivariate analysis a significant difference in intention to eat a healthy diet each day in the next 2 months from pre- to posttest ($P = .002$).

Based on these findings, we conducted a regression model examining the intention to eat a healthy diet as the dependent variable and pretest intention score, health literacy, ethnicity, Transtheoretical Model Stage for exercise and fruit and vegetable consumption, and Internet literacy as independent variables (Table 8).

All participants were exposed to the website between pre- and posttest administration. We found significant difference in posttest intention to eat a healthy diet each day in the next 2 months after controlling for pretest score, health literacy, ethnicity, Transtheoretical Model Stage for fruit and vegetable consumption, and Internet literacy. Those in the Action stage



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of the Transtheoretical model for exercise were significantly less likely to improve the posttest score for intention to eat healthy diet compared to those in the Preparation stage for exercise.

**Table 6.** Accessing online health information.

| Participant ethnicity | Utilizing various locations and technologies to access online health information |
|---|---|
| African American | It could be on a laptop at home, my netbook at home, the desktops in the library, and I've even done searching on my smart-phone. |
| Caucasian | Yeah, I don't do phone. I don't even know what they're called anymore. [laughs] So it's pretty much at home, you know we have the laptop. |
| Mexican American | Yes, a desktop…but my son has an iPad and that is much easier to search. So when I don't have time to sit down at the computer because someone is using it, well I use that. |

**Table 7.** Diabetes knowledge post exposure to website controlling for health literacy, ethnicity, transtheoretical model stage for exercise and fruit and vegetable consumption, and Internet literacy.

| Parameter | Estimate | Standard Error | *P* value |
|---|---|---|---|
| Intercept | 10.78 | 4.77 | .027 |
| Pre-diabetes knowledge score | 0.40 | 0.07 | <.001 |
| Health literacy | 0.13 | 0.14 | .37 |
| African American | -0.84 | 0.85 | .32 |
| Caucasian | 0.81 | 0.77 | .30 |
| Mexican American | 0.00 | . | . |
| Pre-exercise stage | | | .48[b] |
| Pre-exercise stage CONTEMPLATION | -0.29 | 0.85 | .74 |
| Pre-exercise stage PREPARATION (REFERENT) | 0.00 | . | . |
| Pre-exercise stage ACTION | 0.75 | 0.74 | .32 |
| Pre fruit/vegetable stage | | | .010[b] |
| Pre fruit/ vegetable stage PRE-CONTEMPLATION | -3.09 | 0.90 | 001[a] |
| Pre fruit/ vegetable stage CONTEMPLATION | -0.21 | 0.75 | .78 |
| Pre fruit/ vegetable stage PREPARATION | 0.00 | . | . |
| Pre fruit/ vegetable stage ACTION | -1.073 | 1.87 | .57 |
| Internet literacy score | -0.04 | 0.02 | .04[a] |

[a]Significant at $P \leq .05$.

[b]From *F* test



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**Table 8.** Intention to eat a healthy diet post exposure to website controlling for health literacy, ethnicity, transtheoretical model stage for exercise and fruit and vegetable consumption, and Internet literacy.

| Parameter | Estimate | Standard Error | *P* value |
|---|---|---|---|
| Intercept | 3.03 | 1.20 | .01 |
| Pre-intention for healthy diet | 0.51 | 0.09 | <.001 |
| Health literacy | -0.01 | 0.03 | .78 |
| African American | -0.26 | 0.19 | .19 |
| Caucasian | -0.20 | 0.18 | .29 |
| Mexican American | 0.00 | . | . |
| Pre-exercise stage | | | .073[b] |
| Pre-exercise stage CONTEMPLATION | -0.17 | 0.20 | .41 |
| Pre-exercise stage PREPARATION (REFERENT) | 0.00 | . | . |
| Pre-exercise stage ACTION | -0.41 | 0.18 | .023[a] |
| Pre fruit/ vegetable stage | | | .62[b] |
| Pre fruit/ vegetable stage PRE-CONTEMPLATION | 0.05 | 0.22 | .82 |
| Pre fruit/ vegetable stage CONTEMPLATION | -0.12 | 0.18 | .50 |
| Pre fruit/ vegetable stage PREPARATION | 0.00 | . | . |
| Pre fruit/ vegetable stage ACTION | 0.44 | 0.44 | .32 |
| Internet literacy score | -0.01 | 0.01 | .30 |

[a]Significant at $P \leq .05$

[b]From *F* test

# Discussion

## Principal Findings

This study examined health information seeking on the Internet for African Americans, Caucasians, and Mexican Americans as well as learning and intention changes related to exposure to a diabetes prevention/-education website. Qualitative data describe seeking, access, and use of Web-based health information. Quantitative pre-post measures document an association between exposure to health content on a website and changes in diabetes knowledge and intention to eat a healthy diet.

Using a mixed method approach, we provide insight by ethnic group that may be helpful to other developers of Web-based health content. We found that health information is sought commonly across ethnic groups, but that diabetes-related information is less commonly sought even among those at risk. We also found that despite risks, individuals react emotionally to information showing their risk categorization. These emotions ranged from surprise and concern to not surprised and encouraged. Our participants recalled information from the website on physical activity and healthy food choices that could help them prevent diabetes, but not all indicate intention to act on this information. We also showed that in past Internet searches, only African Americans reported seeking nutrition-related information—one part of the energy expenditure equation that if improved could prevent the development of diabetes. This diabetes prevention site shows promise for promoting behavior change. Other eHealth interventions have also shown support for behavior change ranging from the promotion of physical activity and/or proper nutrition among a workforce [30,31], to information about influenza and the common cold [28], to breastfeeding education [32], to education about mammography aimed at Taiwanese women [33], to patients suffering from depression [34] and schizophrenia [27].

This study documents that while all three populations do access the Internet, Caucasians do so more often with mobile devices at this point in time. The Caucasian participants in this study also reported greater education and income than did the African American and Mexican American participants. This is a limitation of this study and seems to corroborates other studies' results indicating that socioeconomic status and Internet access are more strongly linked to online health information seeking behavior than is race or ethnicity alone [11,35,36]. However, we also did have a diverse array of electronic devices reported for accessing the Internet across ethnic groups (tablets, phone, laptops, and desktops). In the future, Web-based health information should be prepared on platforms for mobile devices as people are moving more to cell phones and tablets to access the Internet instead of being bound to desktop computers.

Several features of the site provided useful information to the participants across ethnicity. The diabetes risk calculator based on the qualitative responses from participants provided an emotive reaction, useful in fostering behavior change [37,38]. Additionally, based on quantitative results, exposure to the website was associated with changes in intention to make



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healthier food choices. Also, exposure to the website was associated with increased knowledge about diabetes.

At least two points need to be made about improvements to this website, which may also be informative for other health promotion website sites. The design of diabetes prevention and control websites to accommodate low eHealth literacy with particular attention on learning and usability issues [14] across ethnic populations is an area of growing importance. While there were several features of the site that were designed with low eHealth literacy populations in mind (eg, explanatory videos with lay role models), those with lower eHealth literacy showed less intention to apply the healthful food choice information available on the site. Future research should consider how best to obtain formative feedback through engagement of low eHealth literacy populations and then more effectively pilot test the content and activities designed to meet their needs.

The second point is related to the design of websites for increasing physical activity. Our findings further demonstrate that Web-based information has the potential to reach diverse populations with information and activities that can increase physical activity. However, this study found that exposure to the website was not associated with increased intention for physical activity. Like kinetic video gaming that has advanced to promote physical activity, website developers should explore innovative strategies for going beyond knowledge enhancement to addressing intention and actual energy expenditure among those who visit their site.

We found the overall expected return of 81% was consistent with other studies that did track use [39], or return rates, over an extended period of time, where return rates of between 88% [40] and 77% [31] were reported, and the likelihood of participants to return to the site generally decreasing with time. Returning to a site, particularly when it can support changes in energy expenditure over time is an important feature to explore among those at risk for diabetes.

### Limitations

There are limitations to the study including its small sample size and the lack of a control group not exposed to the website. From the qualitative data collected in the three populations we reached theoretical saturation where no new conceptual ideas were being presented during the interviews. We were able to determine saturation through our simultaneous data collection and analysis process. With a sample size of 71 participants, we discontinued enrollment. From a quantitative perspective, this is a small sample size, and yet we were able to detect several statistically significant findings. Future research should expand the quantitative portion of this research to more fully explore the knowledge, intention for behavior change, and Transtheoretical Model Stage of Change outcomes.

Another limitation of the study was the lack of a control group that completed identical pre- and posttest measures but was not exposed to the website. Budgetary limitations and a prioritization of enrollment of three ethnic groups determined the study design. One way we tried to control for potential biases associated with this design was the immediacy of the posttest measures (directly following website viewing). In this way there was more, although not complete, control of what intervention content could account for any changes in knowledge and behavioral intention.

Future evaluation of the websites should directly address these two limitations. The sample size for Caucasian, African American, and Mexican American adults should be increased to allow for robust statistical analysis with the power to detect statistically significant differences. Additionally, the evaluation should include a control group that is exposed to a comparable website with diabetes information (eg, American Diabetes Association or Centers for Disease Control and Prevention).

### Conclusions

The results of this study advance the field of eHealth diabetes prevention on two fronts. The qualitative results provide insight into the seeking, access, and use of Web-based health information across three ethnic groups in two languages. Additionally, this study provides evidence of an association found between exposure to Web-based health content and related changes in diabetes knowledge and intention to eat a healthy diet.

## Acknowledgments

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The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the Air Force Surgeon General's Office or the US Government.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Diabetes home page in English.



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[JPG File, 246KB - resprot_v2i2e24_app1.jpg ]

### Multimedia Appendix 2

Interactive videos available in Spanish and English.

[JPG File, 273KB - resprot_v2i2e24_app2.jpg ]

### Multimedia Appendix 3

Inyectando insulina.

[3GP File, 4MB - resprot_v2i2e24_app3.3gp ]

### Multimedia Appendix 4

Theme: Reacting emotionally to risk score.

[PDF File (Adobe PDF File), 174KB - resprot_v2i2e24_app4.pdf ]

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## Abbreviations

**ADA:** American Diabetes Association
**BMI:** body mass index
**PRIDE:** Pittsburgh Regional Initiative for Diabetes Education

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Original Paper

# Portal for Families Overcoming Neurodevelopmental Disorders (PFOND): Implementation of a Software Framework for Facilitated Community Website Creation by Nontechnical Volunteers

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## Abstract

**Background:** The Portal for Families Overcoming Neurodevelopmental Disorders (PFOND) provides a structured Internet interface for the sharing of information with individuals struggling with the consequences of rare developmental disorders. Large disease-impacted communities can support fundraising organizations that disseminate Web-based information through elegant websites run by professional staff. Such quality resources for families challenged by rare disorders are infrequently produced and, when available, are often dependent upon the continued efforts of a single individual.

**Objective:** The project endeavors to create an intuitive Web-based software system that allows a volunteer with limited technical computer skills to produce a useful rare disease website in a short time period. Such a system should provide access to emerging news and research findings, facilitate community participation, present summary information about the disorder, and allow for transient management by volunteers who are likely to change periodically.

**Methods:** The prototype portal was implemented using the WordPress software system with both existing and customized supplementary plug-in software modules. Gamification scoring features were implemented in a module, allowing editors to measure progress. The system was installed on a Linux-based computer server, accessible across the Internet through standard Web browsers.

**Results:** A prototype PFOND system was implemented and tested. The prototype system features a structured organization with distinct partitions for background information, recent publications, and community discussions. The software design allows volunteer editors to create a themed website, implement a limited set of topic pages, and connect the software to dynamic RSS feeds providing information about recent news or advances. The prototype was assessed by a fraction of the disease sites developed (8 out of 27), including Aarskog-Scott syndrome, Aniridia, Adams-Oliver syndrome, Cat Eye syndrome, Kabuki syndrome, Leigh syndrome, Peters anomaly, and Rothmund-Thomson syndrome. The editor progress score was used to measure performance for a portion of sites.

**Conclusions:** The PFOND system provides a convenient and structured Internet resource for the facilitated creation of information resources for families confronted by rare disorders. The system empowers volunteers to participate in the creation of quality content, while allowing for the inevitable turnover of contributors over time. The next phase of PFOND development will focus on volunteer participation in system development and community engagement.



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**KEYWORDS**

medical informatics; medical genetics; inborn genetic disease; rare disease; social media; consumer participation

## Introduction

The general public uses the Internet as a primary source to obtain health information, with roughly 4% of all Internet queries being health-related [1]. The majority of Internet users have obtained health information online [2,3]. There are rich sources of online medical information, exemplified by MedlinePlus, WebMD, the Mayo Clinic information portal, and Yahoo! Health [4]. Genetic disorders constitute an important subset of human disease in which DNA sequence variations fully cause or partially contribute to the disease [5]. Information about genetic diseases can be accessed online for many disorders [6-8], with the Online Mendelian Inheritance in Man (OMIM) site being one of the most enduring disease information resources [9]. Wikipedia, one of the most widely read health information resources, contains articles about many disorders [10,11]. For individual disorders, online communities may form to share information and to provide support for families struggling with the arising challenges. The popular Facebook and Twitter platforms host more than 200 breast cancer groups and 500 diabetes groups [12]. Diverse resources have been developed commercially to promote exchange between patients (eg, PatientsLikeMe) [13], while some robust communities participate in discussion boards such as that provided by Yahoo (eg, EyesApart for strabismics) [14].

A subset of genetic disorders benefits from strong support by nonprofit or academic organizations that deliver high-quality content through polished websites. For instance, the Huntington Disease Society of America maintains a website providing extensive information for families afflicted with the disease [15]. Similarly, the Cystic Fibrosis Foundation supports CF families with informative content [16]. Unfortunately, such robust information and resources are not available for many families confronted with rare genetic disorders [10], where rare refers to disorders arising in less than ~5 per 10,000 individuals [17]. While each disorder by definition impacts a small number of families, an estimated 7000 rare disorders impact a substantial population. For example, 25-30 million patients in the United States and 27-36 million patients within 25 European Union countries are impacted. When including a family member or a caregiver, the number of people directly affected by rare disorders approaches 100 million in the United States and the European Union [18]. Resources with broad coverage of rare genetic disorders include OMIM, GeneTests, and OrphaNet. These sites provide information for research professionals but have limited content for the general public [19,20]. The challenge posed to rare disease communities is enormous. It is recognized that such communities may receive less attention for the development of therapeutics [21], expert clinicians are more likely to be geographically inaccessible [18], and they may never encounter another family facing the same challenges [18,22].

Families confronted with rare genetic disorders face the challenge of finding useful information about the characteristics of the disease, guidance for the care of the afflicted family member, and news of emerging research findings [17,23,24]. Periodically a website or Facebook page may be created providing some information or links, but such resources are usually poorly maintained over time [25]. The developers of these sites may not have the technical skills to provide a complete set of features, may lack the communication skills to convey complex topics to a lay audience, and in most cases will have limited endurance for the hard work required to communicate within a small global population of interested individuals, especially if simultaneously struggling to provide care to impacted family members [26,27].

We have developed an Internet-based information portal designed to allow volunteer editors to manage delivery of information about rare disorders. Originally envisioned with a focus on neurodevelopment and subsequently broadened, the Portal for Families Overcoming Neurodevelopmental Disorders (PFOND) is a prototype Internet service that provides a basic set of automated functions and information about selected rare disorders. It delivers news items and summaries of recent scientific articles about a disorder and can support a discussion board when moderators are available. When a member of the public is available to participate in the management of a topic, the system allows for their participation in the editorial process. As a volunteer editor, the individual can compile more extensive information about a disorder, create articles, incorporate links to information resources, and oversee the discussion board. At the conclusion of a volunteer editor's effort, the enriched content is maintained until a new volunteer is engaged to focus on the disorder page. This novel fusion of dynamic and static content within PFOND is intended to provide a basic ongoing functionality, while allowing enriched content when dedicated volunteers are available. As this report focuses on the initial development of PFOND, we assess the fraction of initial sites successfully developed and the first phase development of a gamification-based scoring procedure to encourage editor participation. In addition to providing information for and promoting the sharing of experience between families struggling with rare genetic disorders, PFOND is intended to draw clinical research and social attention to rare genetic disease as a whole.

## Methods

### Content Management Software

To facilitate the long-term maintenance of PFOND, the websites must be readily modified and moderated by individuals with limited technical expertise. Highly customized disease information pages are difficult to maintain without a dedicated administrator or Web developer. Depending on available resources, and acknowledging the dedicated and long-term efforts of some developers, such sites may stagnate with little new content and outdated styling. The use of Content



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Management Systems (CMS) reduces the upkeep cost by providing graphical interfaces through which volunteer editors can efficiently manage a site [28].

WordPress is an open-source blog tool and publishing platform implemented with PHP scripting language and MySQL database software. It is best known for its free hosting service, which is streamlined for blogging [29]. The software provides many additional features that make it a suitable CMS for this project [28]. It has been used to build successful sites for businesses, education, media, and others. This popularity has resulted in a broad community of users worldwide familiar with the software interface and a strong pool of online and published user guides and training manuals [28].

WordPress was chosen over other potential systems (eg, Drupal, Joomla!) for the following reasons:

- Its popularity means there are a variety of available "plugins" (software that can be installed into the system to provide additional functionality), many of which are suitable for inclusion in PFOND.
- It is maintained by hundreds of developers and contributors who provide ongoing support, additions, plugins, and fixes, thus minimizing the risk of the system becoming obsolete.
- The administrative interface (used by editors to manage content on the site) is preferred over other systems as it is easier to learn and navigate.
- As an open-source project, the software is freely available for this unfunded, community service project.

## Website Customization

To minimize development costs, WordPress plugins were used extensively to implement system functionality, including discussion board and newsfeed features. Table 1 lists the plugins that are used in the PFOND system. Additional plugin information can be found on the WordPress website [30].

Specific features not available from existing plugins had to be implemented *de novo*. By default, WordPress allows only two types of content to be created: *posts*, which hold dynamic, blog-like entries; and *pages*, which are meant to hold static content such as site or contact information. To provide support for customized sections of the site, new *post types* (types of content) and *page templates* (PHP scripts that control how a page displays information) were added. These custom features facilitate or allow editors to add and manage a list of information about a disease, research experts, and external sites related to the disease; the About, Experts, and Links pages to automatically sort and display information and provide options for visitors to navigate through them; and the News Page to properly display items generated using the automatic feed syndicator.

In addition, custom widgets allow editors to configure content in their site's one or more sidebars. For example, widgets can show Google results for any search term, a list of new members, and recent forum posts.

**Table 1.** Utilized WordPress plugin modules.

| Plugin | Author | Description |
|---|---|---|
| Achievements | Paul Gibbs | Allows for the gamification of certain Wordpress actions |
| Adminize | Frank Bültge | Fine-tune user access to backend functions by hiding unnecessary items from WordPress administration menu |
| BuddyPress | Open source | Provides social networking functions such as user profiles and forums |
| FeedWordPress | Charles Johnson | Provides Atom/RSS syndication to collect articles for the News Page |
| Multisite Global Search | Alicia García Holgado | Adds the ability to search the content of the individual disorder websites |
| Multisite User Management | Brent Shepherd | Assigns default roles for new users that join the site |
| Site Creation Wizard | Jon Gaulding, Ioannis Yessios | Allow users to create a site using predefined templates |
| Widget Context | Kaspars Dambis | Controls which widgets are displayed on which pages |

## Site Theme

The typical visitor will never see the back-end system. Unless they volunteer to participate in the editorial process, users will engage the system through the graphical front-end. Hence, the website's design plays a significant factor in attracting and serving its target community. The fonts, colors, and layouts of WordPress sites are controlled by "themes"—many of which are available for download online. For the pilot project, a customized PFOND theme was created to establish a look and feel for future PFOND sites. The following factors were taken into consideration:

- Navigation: The site should be easy to navigate, allowing new visitors to quickly find the information they seek. This has been accomplished, in part, by keeping a relatively "flat" menu hierarchy.
- Simplicity: A cleaner design is preferred to minimize loading times and allow nontechnical users to more easily navigate the site.
- Customizability: Colors, fonts, banners, and other elements can be changed without disrupting the design.

## Multisite and Site Templates

Two important aspects of PFOND are the ability to generate new disease sites in a simple manner, and the capacity to share selected forum posts, news, and disease information across sites. It is expected that a network of sites can have a greater impact on disease communities through the exchange of ideas and information. These goals were achieved using the WordPress multisite feature, which allows multiple, independent sites to



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operate under a common WordPress installation. Using plugins and custom scripting, the multisite feature can be adapted to include global search results and discussion boards.

The site creation process was designed with simplicity as the primary consideration. Administrators generate a new site by filling in a form to specify the desired URL, disease name, and site title. New sites are created using a default standard template, and each site allows for independent but limited customizations. The standard template contains a set of predetermined widgets, sample pages, and posts, and other visual settings, which enable editors to set up the site with few steps and therefore maintain a focus on site content.

### Additional Software Technologies and Download Information

A dedicated virtual server running CentOS was established to host the system. The following technologies were used in the development of the PFOND prototype: HTML, CSS, JavaScript, PHP, MySQL, and Apache Web Server. The software components introduced in this manuscript can be downloaded from the GitHub software repository [31].

### Motivation Mechanisms Within the Pilot Project

Two phases of testing were performed to assess system stability and usability. We recruited 8 volunteers in the alpha phase and an additional 74 volunteers in the beta phase. Two motivation mechanisms were introduced: communication and gamification-based feedback scoring. Personal email communications and small group meetings were conducted, informing volunteers about the project and encouraging their engaged interest. As the project scale increased, we implemented an achievement scoring system and other gamification features to guide the editors through the website construction and allow them to assess their performance relative to that of other editors.

## Results

### Overview of the PFOND Content

The PFOND system was implemented as described above in the Methods section. The resulting website will be described as a walk-through of the key pages encountered by the users of the system. For each disorder, four sections are generated, including a home page, a disease information page, a news page, and a discussion board. The pages are illustrated in Figures 1 and 2. The editor interface is described in a subsequent section.

The PFOND homepage for a disorder provides a summary of recent information. The editor can supply a front-page feature article, while the remaining sections are automatically extracted from online sources or internal pages of the system. In addition to the feature article, the page displays recent news articles about the disorder (obtained from Google News), recent internal posts from the “Community” or online resource links (from system users), and notifications about changes to the PFOND system.

There are four key subsections for each disorder. The “About” page contains information about the disorder, including a sidebar that facilitates navigation. The “Overview” section describes the characteristics of the disorder and the frequency in different populations. The “Diagnosis and Treatment” section provides information about available tests and treatments. The “Research” section provides an academic perspective of the disease, including an introduction of the underlying mechanisms when known. While the creation of the material displayed on this page represents the greatest contribution of volunteer editors, it is static and therefore the last modification date is clearly presented to inform readers of its currency.

The “Experts” page contains information about researchers active in areas related to the disease, and summaries about their work convey how the disease is currently studied. In addition to the informative summaries of research interests, a link to a website of each identified expert is provided to facilitate access to emerging findings (if available). The information on this page is particularly helpful to a new volunteer editor attempting to build upon the foundation of a departed volunteer. In the testing phase of the project, concerns were raised about providing clinical expert contact information without authorization or in-depth knowledge. As volunteer editors are not qualified to judge the quality of practitioners, the focus of this page is restricted to active researchers in the field and information presented is obtained from each researcher’s website. A warning is provided to readers to indicate that the list does not represent an endorsement or recommendation of the listed individuals.

The “News” pages present articles related to the disorder, from both lay and scientific sources. When a volunteer editor is engaged, the editor can select articles to feature on the system, providing a brief summary of the content and a link to its original source. The content of this page is predominantly produced by automated methods set-up and refined by a volunteer editor. Two key sources are displayed. A news feed is presented using the Google Alerts service, which is constrained by a set of search terms specified by the editor. Scientific articles reported in the Medline database are obtained from the PubMed RSS Feed service in a similar manner. This automation allows the user community to find recent information despite the transient attention of volunteer editors.

While editors are active, readers can use the discussion board under the “Community” page to share their understanding, questions, and stories with other members. Discussion boards provide a record of past issues for future readers to draw upon. Furthermore, the social networking on discussion boards can provide peer support for families. However, discussion boards are the most challenging aspect of PFOND. Maintaining high-quality content and minimizing “spam” and inappropriate text requires editorial review of the board contents. Given the necessity of timely posting and the focus on volunteer editors as moderators, manual review of these posts may not be possible. Blogs with large and active readership have found community-based methods to “vote down” bad content, but the nature of a rare disorders system means the readership may be strikingly small and therefore unable to support such participatory filtering. While the PFOND system has been implemented with discussion board features, the board is activated only when a volunteer indicates a commitment to facilitate the discussion on a regular basis. In the discussion section, we raise the challenging issue of how nonexpert editors should handle difficult questions or situations arising in a discussion board.



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## Editor Interface

The operating interface (Dashboard) used by volunteer editors is structured in a simple format to serve two purposes (Figure 3). First, we seek to minimize the time required for volunteers to learn the system. Many of the options presented by default in the Wordpress Dashboard were removed, leaving the volunteers with less distraction. Second, the removal of or limited user access reduces the chance for unintended disruptions to the PFOND service.

Editors can modify their user name, email address, and other meta information in the Profile tab in the dashboard. In addition, they can replace the homepage picture, adjust the color scheme, and add links and RSS feeds to the site through options in the Appearance tab. The average volunteer will spend the greatest portion of his or her time editing content that appears in the Disease Info tab, rather than having to address technical matters.

**Figure 1.** Introducing PFOND. Screenshots of the PFOND system homepage surrounded by images of selected disorder home pages, including aniridia, Cat Eye Syndrome, and Rothmund-Thomson syndrome.

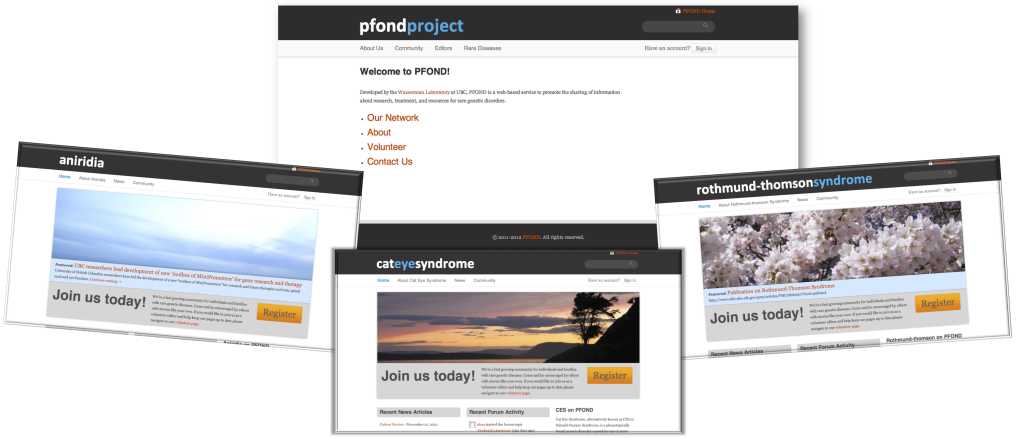


**Figure 2.** Selected components of a PFOND site for Kabuki Syndrome (Home page, About page, News page).

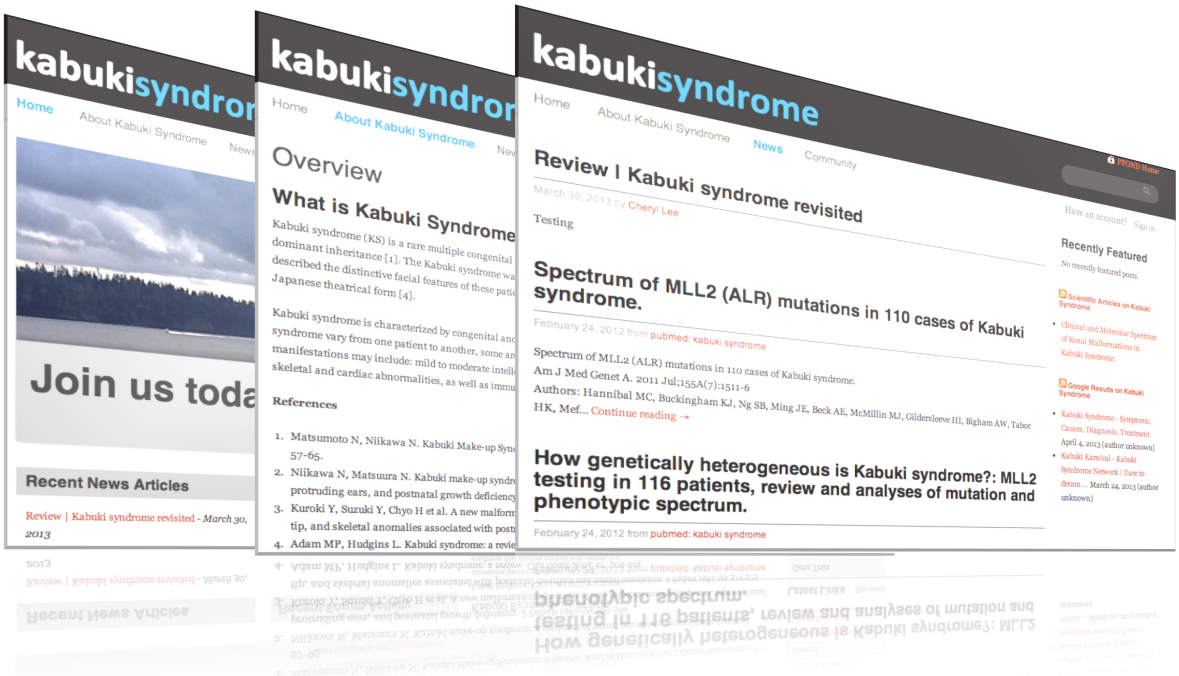




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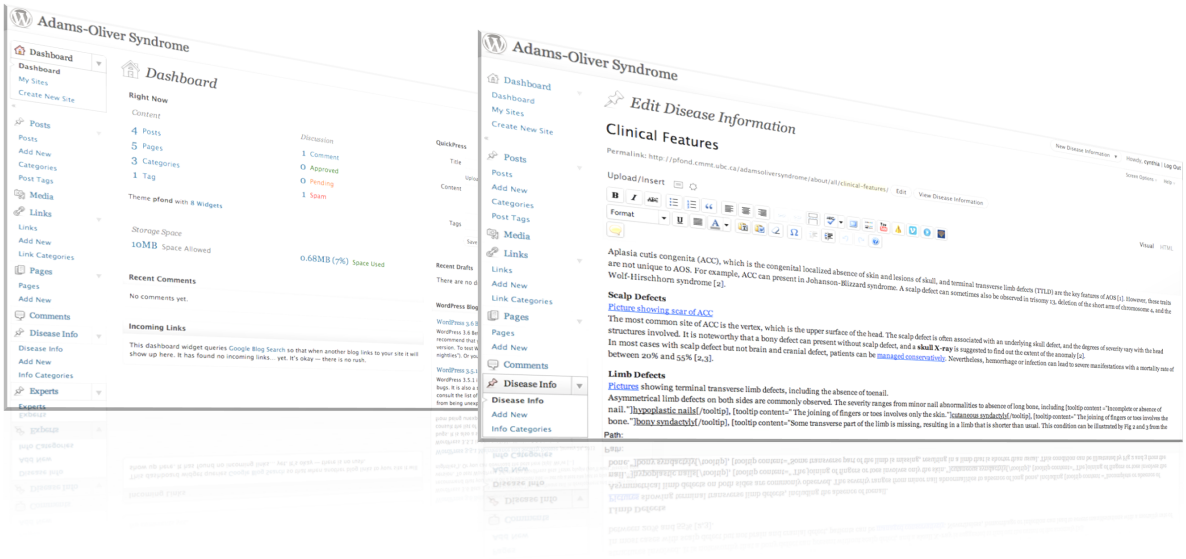
**Figure 3.** Selected views of the PFOND editor interface.




## Pilot Project

To validate the software and confirm the utility of the interface for efficient volunteer utilization, a two-phase pilot project was performed.

### *Volunteer Recruitment*

The model for PFOND is dependent upon the recruitment of volunteer editors to provide content and facilitate creation of new disease sites. In order to test the system, two stages of volunteer recruitment were conducted. In the first alpha-phase, volunteer requests were distributed within the University of British Columbia (UBC) Department of Medical Genetics and the Centre for Molecular Medicine and Therapeutics, seeking referrals to potential volunteers. A set of 8 individuals responded and registered on the system. An introductory in-person session was conducted. Four disease sites were initiated. In the beta phase, we recruited an additional 74 volunteers through announcements on UBC Career Services volunteer board, all physically based in the surrounding community (in order to offer an initial face-to-face introduction to the project, attended by 20 volunteers). A total of 27 disease sites were launched, of which five were topics specifically requested by volunteers.

### *Testing the PFOND Software*

The testing of the system was performed by the recruited volunteer editors, following the process depicted in Multimedia Appendix 1. The goal of the initial study with 8 volunteers was twofold: to test the stability of the system and to test the usability of the editor interface. The identified system problems (10 in total were recorded) were addressed immediately by the website programmer, and the suggestions on design were compiled and discussed for potential future incorporation. In the second phase, we sought to further test the stability of the online system and gather feedback about new features. Moreover, we shifted from a combined training and communication method (online and face-to-face) to an online-only approach. The beta phase of testing was intended to allow transition from local volunteers to a global community. The prototype testing was limited to a set of basic aspects, including ease of use, customizability, community access, and automated news aggregation. For ease of use, the beta-testing process confirmed that the volunteer editors could use and maintain their sites without advanced technical knowledge. A subset of editors elected to customize fonts, colors, headers, and menus, confirming the capacity of the system to facilitate customization. Each volunteer editor established an automatic news aggregation feed by establishing and managing subscriptions to news and scientific articles. With 8 “published” PFOND sites online, the process confirmed that new disease sites could be created with relative ease.

### *Feedback Mechanisms*

Multiple approaches were tested for providing feedback to volunteers about their progress. Each volunteer editor had the opportunity to file a monthly report indicating his or her work



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on the system, to which directed responses were provided. Such reports were used as a means for tracking the engagement of the volunteers and to identify disease sites to which additional editors could be assigned. Volunteers could request a review of their work and an assessment of the work remaining to bring the quality of their disease site content to a level suitable for release of the site to the public, which occurred for 4 out of 23 volunteer teams.

Based on previous experience with development of the Transcription Factor Encyclopedia [32], the developers recognized that editors benefit from measureable goals. Thus, a scoring procedure was implemented in which editors were automatically assigned points for specific tasks to guide and motivate editors throughout the development process (Figure 4). Information about some rewards was provided on the system, while other rewards were surprises intended to encourage volunteers to surpass the minimal goals specified (Table 1). The achievement system was part of a broader gamification strategy to engage participants (Table 2). Gamification is not limited to digital technology [33,34], and meaningful gamification requires user-centered design [35]. The use of external rewards to control behavior risks the nongame context being perceived negatively [35]. Adopted from Deci and Ryan's "self-determination theory", three innate needs for intrinsic motivation have been identified and described in the context of gamification [34,36]. Within our initial framework, PFOND meets some of these criteria. Since users can integrate the activity with their personal goals and needs, the activity is likely to be perceived as positive [35]. Table 2 lists the point values assigned to specific achievements by editors. The contributions of volunteers can be assessed in part by the points earned. Table 3 shows the coverage of gamification mechanisms within the current implementation.

### *Released PFOND Sites*

A total of 8 PFOND sites have been released (ie, "published") on the system, of which 4 were created entirely by volunteer editors and 4 were created with participation of the development team. The initial pre-alpha testing of the site focused on aniridia, for which the Aniridia Foundation International (AFI) allowed us to incorporate information from their outreach website. An automated message indicates the source and encourages readers to go to the AFI site for the most current information. The published volunteer contributions address Aarskog-Scott Syndrome (ASS), Cat Eye Syndrome, Kabuki Syndrome, and Rothmund-Thomson Syndrome. Three were assigned topics and one (ASS) was a volunteer-requested topic. The volunteers with published websites are included as authors on this report, consistent with their important contributions to the project.

**Table 2.** PFOND feedback scoring.

| Entry | Score | Expected |
|---|---|---|
| New editor status | 2500 | 2500 |
| Monthly report | 1000/month | 3000 |
| Image | 2500/image | 2500 |
| Forum activities (PFOND-wide activities) | 2500 for the 1st time, 5th time, 10th time; 1000 for the 20th, 30th, 40th, etc, up to 90th | 7500 |
| Profile update (hidden) | 500 for the 1st, 3rd, 5th | 1000 |
| Tooltip activation | 1000 for the 1st, 5th, 10th; 5000 for the 25th | 3000 |
| RSS feeds | 2500/each | 5000 |
| News | For the 1st post: 2500; from the 2nd to the 10th post: 1000/each; 2500 for the 20th, 30th, 40th, etc | 15,500 |
| Research expert | 1000/each, up to 3000 points | 3000 |
| Submission for site review | 1000/each | 2000 |
| Approval for site | 20,000 | 20,000 |
| Disease information | 1st: 2500; 5th, 10th, 25th, 50th: 1000/each; 100th: 5000 | 5500 |
| Total | | 70,500 |
| Maximum | | 100,000 |



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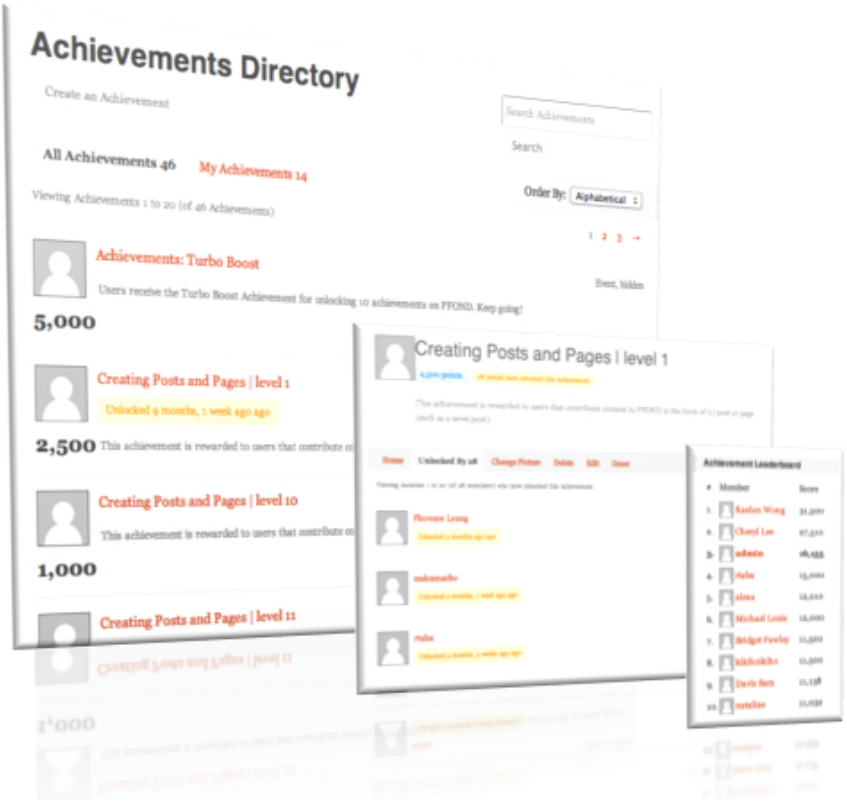
**Table 3.** Relationship between PFOND and the three innate needs for successful motivation by gamification as proposed by Deci and Ryan [33,35].

| Intrinsic motivation | Principle | Applications in PFOND |
|---|---|---|
| Relatedness | Personal goals | Editors registered in the system share a common goal: to serve the rare disorder community. |
| | Connect to a meaningful community of interest | The editors are connected by their common goals and interact with users with the same interest. Within each group, editors can discuss how to finish the goal together. |
| | The meaningful story and the social context meaning | Volunteers are aware of the needs of or have connections to the rare disorder community. |
| Competence | Provide interesting challenges | There are two independent challenges being a PFOND editor: one, master the system; two, create content for the website. |
| | Provide clear, visual, varying, and well-structured goals | See Figure 4 and Table 2. |
| | Provide juicy feedback | Editors get feedback from other volunteers and users. |
| | Beware of unintended behaviors | The points are tuned to specific actions aligned with the editor motivation, decreasing the likelihood of alternatives. |
| Autonomy | Play is voluntary | All editors in PFOND are volunteers, and there is no requirement to monitor the scores provided. |
| | Beware of losing autonomy | We focus on individual accomplishment. The structure encourages tasks to be completed, allowing the editors to shape the content at each step in the manner that they determine. |
| | Beware of devaluating activity | Working on rare disorders gives a strong value to the activities of the editor. We build on this key motivation in each step of the project, from recruitment to completion of a functional site. |

**Figure 4.** Achievements scoring system.



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## Discussion

### Principal Findings

The PFOND project provides an intuitive Web-based software system to enable the creation and maintenance of websites for rare genetic diseases. It is intended to allow nontechnical editors to participate in the creation and delivery of disease information informed by scientific research. Grouping services for diverse disorders within one framework offers several potential advantages: (1) greater public awareness of available resources, (2) shared technical challenges to allow volunteers to focus on quality content rather than system management, (3) the capability to share information across communities where appropriate, and (4) the opportunity for transitioning between volunteer editors over the long-term to accommodate the transient nature of volunteer editor service. Most importantly, PFOND aims to provide a cyber home for patients and their families.

The development of PFOND addresses an information gap for rare diseases. Key resources can be identified for each disorder and presented in an easily accessible format. Although the information in no way diminishes the necessity for professional advice and counselling, families provided with improved online information about emerging clinical research may develop a deeper understanding and therefore be better equipped to discuss matters and concerns with their health care providers [37-39]. Ideally, the information presented would accelerate the dissemination of information about identification of beneficial approaches to the disorder, such as available treatments, dietary changes, or useful devices [39,40].

Online resources such as PFOND promote awareness that there are other families facing similar challenges, which may help alleviate any sense of isolation [18,24]. For sites with an actively moderated discussion forum, users will have the opportunity to directly engage with peers to gain insights from their experience and diverse information sources [41,42]. While there are risks of inaccurate information, some studies suggest such problems may be infrequent [43,44]. Nevertheless, the risk remains that users may present claims and suggestions that may be inaccurate or inappropriate. While moderation can reduce the potential problem, the fact that PFOND is maintained by volunteers with no requisite training results in two choices: (1) exclude the benefits of forum interactions from the site or (2) include a clear warning to users that information presented in forums may not be reliable. Recent online services may help alleviate the challenges. Broader access to qualified medical professionals, such as provided by HealthTAP [45], may alleviate the tendency of users to seek medical advice from forums [45,46].

The online community is dynamic and growing. Increasingly individuals are turning to the Internet for volunteering and opportunities to participate collectively in projects with positive social impacts. The most novel aspect of PFOND is the focus on the volunteer for the creation and dynamic development of websites focused on communities impacted by rare disorders. An enduring volunteer-powered resource allows for an online community to form and to continually benefit from new information and insights into the challenges faced at different life stages by those impacted by a disorder.

### Future Directions

Three areas of activity are expected in the next iteration of PFOND development. First, the existing system can be extended to better support users with accessibility challenges, such as limited vision. Second, the system can be made available to a broader range of volunteer editors who can contribute to building and improving the site. Third, the framework of PFOND will allow for structured, quantitative research of both user and volunteer editor engagement/satisfaction and editor performance when provided with distinct gamification features or innovative design elements. In the longer term, there may be opportunities to promote exchange between related PFOND communities. Each of the future directions brings challenges.

Users of PFOND are more likely to be challenged by impairments than the average Internet user. Thus, the further development of PFOND will require greater attention to the issue of website accessibility, which can be addressed by increasing the flexibility of the design. The pilot version has been designed to be easily navigated, but additional work will be required to make it accessible, particularly for users with low vision [47]. While the use of WordPress as the underlying system will allow assistive software to be applied [48], there are additional steps that can be taken in the next iteration of PFOND. Users can be empowered to change display settings to use larger font sizes, increase line spacing, and apply more contrasting colors. Site editors will need structured training to configure these options to suit their target audience (for example, the aniridia site could use more readable fonts by default). The introduction of the assistive features is a key step moving forward.

The ultimate goal for PFOND is the engaged participation of volunteer editors from around the globe. The current prototype was tested within the geographic confines of one university, with extensive oversight of the initial cadre of participants. In the second phase, the system can be modified to minimize supervisory time, allowing senior volunteer editors to take on additional supervisory activities, while empowering the development team to maintain an overview of the material being posted each day. In the second phase, we will disseminate calls for participation across volunteer recruitment boards, both in global posting boards (eg, VolunteerMatch) and in directed fashion to volunteer boards serving specific communities such as university students [49].

Appropriate gamification mechanisms are especially important for the system to succeed on a large scale. Inappropriately implemented gamification could decrease editor engagement, creating a perception of decreased social value if such extrinsic motivation mechanisms are required [35]. An irrelevant and enforced scoring system relying on points, leaderboards, and badges can do more harm than good. The current PFOND system has emphasized intrinsic motivation (as seen in Table 3), in addition to points and leaderboards. When users are able to connect their goals to values they hold, a better outcome might be expected. However, there is limited published research on the effectiveness of game-like elements to promote patterns



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of activity within Internet-based community service systems. We will implement additional gamification features, including badges, and measure how effective they are in motivating editors to finish a website, using the PFOND framework to compare and contrast distinct approaches on the successful completion of PFOND sites and on user satisfaction and perception.

For such measurements, one potential user survey is WAMMI (Website Analysis and Measurement Inventory), a 60-item questionnaire, but an average user may be unlikely to complete such a long instrument [50]. A shorter survey developed by van Schaik and Ling (2009) assesses user perceptions of ease of use, utility disorientation, flow, and aesthetics [51]. The reliability and validity of the scales have been confirmed. The experience of editors can be measured with a different survey, as they use a different interface with less Web-like design. The Software Usability Measurement Inventory (SUMI) is intended for such non-Web user interfaces [52] but conveniently shares similarities with WAMMI [51].

The PFOND site incorporates some innovative design features, but in the next phase it will be possible to measure the impact of a series of features. The first phase emphasis on content building limited, but did not preclude, innovation. For instance, the PFOND site includes dynamically updating elements and static summaries in partnership to better address the transient nature of editor participation. In the next wave of the project, flexibility for innovation will be added to the system. In addition to the accessibility features addressed above, we will encourage volunteer editors to review the IDEO Methods Cards App in order to inspire potential features [53]. Through this community participation, we will identify a subset of innovative features to test within the system, providing a subset of editors with the design feature and measuring their perception using validated surveys.

The solid computational foundation introduced in this report lays the groundwork for a broader international volunteer effort for creating online resources for families struggling with rare disorders.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Steps to establish a new PFOND site. (a) In the first step, volunteers submit an application to serve as an editor. (b) Accepted editors use an intuitive admin interface to create a PFOND site. (c) Editors collect and update their site with disease information, relevant news items, pertinent links, and field experts. (d) When ready, editors publish a PFOND site making it accessible to all readers. (e) The new site is added to the PFOND homepage and is indexed by search engines for increased exposure.

[PNG File, 2MB - resprot_v2i2e25_app1.png ]

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## Abbreviations

**AFI:** Aniridia Foundation International
**ASS:** Aarskog-Scott Syndrome
**CF:** cystic fibrosis
**CMS:** Content Management System
**OMIM:** Online Mendelian Inheritance in Man
**PFOND:** Portal for Families Overcoming Neurodevelopmental Disorders
**SUMI:** Software Usability Measurement Inventory
**WAMMI:** Web Site Analysis and Measurement Inventory



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Original Paper

# Mamma Mia: A Feasibility Study of a Web-Based Intervention to Reduce the Risk of Postpartum Depression and Enhance Subjective Well-Being

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## Abstract

**Background:** Currently, 10-15% of women giving birth suffer from symptoms of postpartum depression. Due to a lack of knowledge of this condition and the stigma associated with it, as well as few treatment options, a large proportion of postpartum women with depression remain untreated. Internet-based interventions have been found effective in treating depression, anxiety, phobias, and addictions. Hence, we developed such program ("Mamma Mia") with the aim of reducing the risk for postpartum depression and enhance subjective well-being. Mamma Mia is based on positive psychology, metacognitive therapy, and couples therapy. It starts in gestational week 22, and lasts until 6 months after birth. During pregnancy, Mamma Mia is delivered weekly (every Monday). After birth, Mamma Mia is delivered three times per week for six weeks. The remaining weeks, the program is delivered more sporadically. In total, Mamma Mia consists of 44 sessions. The program is individualized, interactive, and tunneled (ie, the user is guided through the program in a pre-determined manner).

**Objective:** The purpose of the present study was to pilot test the intervention in order to assess the feasibility and acceptance among program users.

**Methods:** The present paper reports a feasibility study that combined quantitative survey data with semi-structured interviews. Participants (N=103) were recruited via hospitals, well-baby clinics, and Facebook. Due to time constraint in completing the current study, our results were based on participation in one of the two phases: pregnancy or maternity. Participants in the pregnancy phase were surveyed 4 and 8 weeks after intervention enrollment, and participants in the postnatal phase were surveyed 2 and 4 weeks after intervention enrollment. The survey assessed perceived usefulness, ease-of-use, credibility, and unobtrusiveness. All measures were filled in by participants at both measurement occasions. Data were analyzed by running descriptives and frequencies with corresponding percentages. Binomial tests were carried out to investigate whether demographics differed significantly from a 50/50 distribution. Paired sample t tests were used to examine differences between time 1 and 2. Four participants were interviewed in the qualitative follow-up study, where they were given the opportunity to address and elaborate on similar aspects as assessed in the survey.

**Results:** More than two-thirds of users found Mamma Mia to be of high quality and would recommend Mamma Mia to others. By far, most also found the amount of information and frequency of the intervention schedule to be appropriate. Mamma Mia was perceived as a user-friendly and credible intervention.

**Conclusions:** Overall, the user acceptance of Mamma Mia was good and our findings add to the feasibility of the program. The effect of Mamma Mia on depression and subjective well-being will be evaluated in a large randomized controlled trial, and if found to be effective, Mamma Mia could serve as a low-threshold prevention program.



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**KEYWORDS**

pilot project; Internet; early intervention; depression postpartum; health promotion; well-being; eHealth

## Introduction

### Postpartum Depression: Prevalence, Risk Factors, and Treatment

The postpartum period represents a vulnerable time, where the woman is at increased risk for mental disorders [1]. Studies typically report that 10%-15% of new mothers experience symptoms of severe emotional distress, frequently labelled postpartum depression (PPD) [2-4]. Postpartum depressive disorders vary in severity; ranging from the mildest kind seen in postpartum blues to moderate or major depression, to the most severe cases known as postpartum psychosis [3]. While only 0.2% of new mothers experience postpartum psychosis, postpartum blues affect as many as 50%-80% of postpartum women and it is thus considered to be a fairly "normal" phenomenon. Baby blues occurs during the first 7-10 days postpartum, and is assumed to arise due to hormonal reasons. Eventually, it wanes without treatment, especially with the support of family and friends and with the reassurance of health personnel that this reaction is quite normal [2]. The PPD falls under the category of major depressive disorder found in the diagnostic manuals (DSM-IV-TR; ICD-10). According to the manuals [4,5], description, symptoms, course, and outcomes of PPD are similar to major depressive disorder. The only difference is the time of its occurrence. The depression strikes in a woman's life when she is expected to be as happy as can be, which obviously makes the experience of the depression particularly arduous. In order to fulfill a diagnosis of PPD, one must experience a period of at least 2 weeks of depressed mood or loss of interest in almost all activities, as well as experiencing at least four of the following symptoms: change in appetite and weight, sleep, and psychomotor activity; decreased energy; feelings of worthlessness or guilt; difficulty thinking, concentrating, or making decisions; and recurrent thoughts of death or suicidal ideation, plans, or attempts [4].

Factors that put women at elevated risk for PPD include a personal history of depression, family history of depression, negative life events, partner conflicts or low relationship satisfaction, low levels of social support, and certain baby characteristics [6,7]. The most common symptoms of PPD are tearfulness, feelings of hopelessness, inadequacy, guilt, inability to cope with and feel joy over the arrival of new baby, agitation and anxiety, loss of appetite, poor concentration and memory, sleep disturbances, fatigue, social isolation, and suicidal ideation [8]. Women who suffer from PPD are less capable of carrying out maternal duties, such as engaging in important developmental activities with the baby, like playing and talking, which may influence the child's cognitive, and socioemotional development [9], as well as the infant's attachment style [10]. Men have an increased risk of depression when their partner is depressed [11], and children of depressed fathers are at increased risk of behavior problems [12]. Finally, many women risk experiencing less severe on-going symptoms long after the depression is considered over, and they are at risk for recurring depression [13]. The personal cost as well as the cost to society caused by PPD is large; thus, illustrating the pressing need for effective prevention and early intervention.

According to the National Institute for Health and Clinical Excellence (NICE) guidelines [14], effective treatment of depression is to provide immediate support and information, problem-solving, and self-help. Several studies have also found cognitive-behavioral therapy [15], cognitive treatments [16], and metacognitive therapy [17] to be effective. However, a large proportion of those who suffer from PPD do not receive treatment, in part due to the stigma associated with the disorder as well as limited access to effective treatments [18]. Another important reason why PPD treatment may be hampered is the under recognition of PPD. The under recognition is not only due to the brief consultations with the medical health professionals, but is also due to the difficulty in distinguishing PPD symptoms from normal symptoms seen in new mothers, such as tiredness, change in eating habits, difficulty with concentration and sleeping. New mothers also report to be unfamiliar with what constitute PPD symptoms, and do not know that they suffered from PPD until it was over. All these factors combined cause many people to suffer "in silence''. In sum, barriers to effective treatment including lack of resources and trained providers and social stigma associated with PPD [19] suggest a need for innovative approaches to public health prevention and promotion.

Many Web-based interventions have been designed and documented to be effective in treating various mental problems including depression [20], anxiety [21], and stress [22]. Studies document that people with these mental disorders greatly benefit from Web-based interventions [23,24] and that Web-based interventions represent a low threshold service with a high reach [25]. More recently, two studies found support for the feasibility and usability of Web-based interventions targeting PPD [26,27], but there exist no randomized trials testing the efficacy of PPD interventions. Web-based interventions have been found successful in reaching women of lower socio-economic status, a group typically found to be harder to reach [28]. It is also noteworthy that young women (ie, women in childbearing age) are the ones who use Internet most frequently when it comes to acquiring health-related information [29]. A Web-based intervention can thus both prevent the development of depressive symptoms as well as reach out to the many people that suffer "in silence'', and it seems promising considering that many people prefer first line services (ie, local- and home-based services) rather than regional or specialist health care services.

### The Web-Based Intervention: Mamma Mia

#### *Overview*

Mamma Mia is an automated/unguided Web-based self-help intervention. The aim of Mamma Mia is threefold: (1) to prevent PPD, (2) to treat pregnant women/new mothers with



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mild-to-moderate symptoms of depression, and (3) enhance subjective well-being. Overall, Mamma Mia consists of 3 phases (see Table 1). The pregnancy phase starts in gestational week 22 and ends in week 40 (estimated due date). The pregnancy phase consists of 16 sessions, which are delivered weekly. The maternity phase starts when the infant is 1-2 weeks old and lasts for 6 weeks. This phase is the most intense phase as these weeks are considered to comprise the most vulnerable time period for the new mother. Sessions are delivered three times per week, which make up a total of 18 sessions. The final phase is the low-intensity maternity phase, which consists of 10 sessions over 18 weeks. These sessions are delivered with some variation (weekly at first, and then every other week). In total, Mamma Mia consists of 44 sessions over a period of 11 months. For each session, the user receives an email with a hyperlink. By activating the link, the user gains access to Mamma Mia and proceeds in a predetermined/tunneled sequence of Web pages (ie, the tunnel information architecture) [30]. In terms of delivery methods and information architecture, Mamma Mia is similar to previous eHealth programs, and thus represents a well-tested approach to treatment [31-34].

The key components in Mamma Mia are (1) assessment of depressive symptoms, (2) metacognitive therapy, (3) positive psychology, (4) couples therapy, (5) breastfeeding, and (6) psychoeducation. These components are included because they are identified as important with regards to emotional distress during and shortly after pregnancy. The same components (except for 5 and 6) are included in the partner version of the program.

### *Assessing Depressive Symptoms*

The most common screening-tool for PPD is the Edinburgh Postnatal Depression Scale (EPDS), which assesses depressive symptoms during the last 7 days [35]. The program will monitor the participants' level of depressive symptoms over time (as measured by the EPDS). Depressive symptoms will be assessed on three occasions during pregnancy and four times after birth. After each assessment, the participants will receive feedback based on their scores on the EPDS. The feedback is divided into three categories: (1) when there are no depressive symptoms, (2) when there are some depressive symptoms, and (3) when the score is indicative of severe depression. If the participant's score suggest the presence of some/many depressive symptoms, the program will recommend the user to speak to someone they trust about how they are feeling, and if necessary, seek professional help (the program suggests where one can seek professional help). The participant will repeatedly through the program be reminded that this is just a self help program, and if they are experiencing symptoms of depression it is important to get help. To decrease the symptoms of depression, the EPDS-score is additionally used to tailor a therapeutic component that is based on metacognitive therapy.

### *Metacognitive Therapy*

Metacognitive therapy [17] is a recent development in understanding and treating mental health problems, which has been proven effective in treating depression [36]. The approach is based on a specific theory proposed by Wells and Matthews [37]. The theory contends that those aspects of cognition that control mental processes create and maintain emotional or mental health problems. This mechanism leads to patterns of worry, rumination, threat monitoring, high conceptual activity, and counterproductive coping behaviors, and it is referred to as the cognitive attentional syndrome. In contrast to cognitive therapy, metacognitive therapy does not deal with the content of specific negative thoughts, feelings, or beliefs (eg, "I am worthless and incompetent"). Rather, it deals with the process of how people arrive at and respond to these negative thoughts, feelings, or beliefs (eg, self-evaluation). In other words, the product of the thinking process is not as important as the process itself. It is an inflexible and recurrent thinking style in response to negative thoughts, feelings, or beliefs that causes problems and needs to be treated. In consequence, a key aspect in metacognitive therapy is therefore to help people experience detached mindfulness, which is a disengaged and objective form of awareness in response to thoughts, feelings, and beliefs. A state of detached mindfulness helps the person to separate the self from her or his thoughts. Thus, the present program educates users about mindfulness exercises to reduce the functions of thoughts [38]. One such exercise is turning negative thoughts track, which is based on the acceptance and commitment therapy [39], and uses a combination of acceptance and mindfulness to help people distinguish themselves from thoughts, feelings, sensations, and memories. Other concrete tasks that aim to enhance mindfulness include "the body scanning" exercise and "the gong" exercise. Both tasks are based on audiotapes that instruct the person to try to visualize and focus on either a sound (the gong) or a marble travelling up and down on one's spine. Thoughts can come and go, one is only to register that they are there, not evaluate them.

**Table 1.** Overview of the online-sessions of Mamma Mia across program phase.

| | Pregnancy phase | Maternity phase (high intensity) | Maternity phase (low intensity) |
|---|---|---|---|
| Time period | Gestational week 22-40 | 2-8 weeks postpartum | 9-26 weeks postpartum |
| Frequency | 1 session per week | 3 sessions per week | Variation[a] |
| Number of sessions[b] | 16 | 18 | 10 |

[a]From 9-14 weeks postpartum, there is 1 session per week. From week 14-18, there is 1 session every other week. Then there is one session 22 weeks postpartum, and the final session is 26 weeks postpartum.

[b]Total number of sessions is 44.



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### *Positive Psychology*

Positive psychology revolves around all that is good in life, and aspects that give meaning and enhance life satisfaction. Concrete tasks aimed at enhancing positive emotions, engagement, and a sense of meaning/purpose has been developed [40]. The basic idea for the different tasks is the assumption that the effect of positive emotions extends beyond the immediate moment. Peterson and Seligman [41] argue that engaging in the tasks may enhance well-being, a sense of skill, efficiency, mastery, mental hygiene, as well as a person's social network. That is, a person's fundamental needs may be strengthened, which in turn may lower the risk of mental disorders. Indeed, several studies have demonstrated that various "happiness-tasks" have not only enhanced a person's sense of life satisfaction, but also reduced the prevalence of depression [42,43]. Seligman et al [44] argue that these studies suggest efforts aimed at preventing/treating depression would benefit from including components based on positive psychology. One of the crucial ingredients in the present program is exactly that. Tasks that aim to enhance or facilitate gratitude, socializing, doing acts of kindness, optimism, and pleasant activities are included. The different tasks are described in some detail below.

The gratitude component involves assignments such as counting one's blessings, writing down 3 good things that happened during the day, writing a letter of gratitude, and saying "thank you" more often than usual. In order to increase socialization and thus strengthen the social network, which in turn facilitates social support, one is encouraged to initiate social interaction with friends and relatives. Assignments include calling a friend and inviting him/her out and mapping one's social network. One is also advised on how to get new friends, and strengthening existing relationships (eg, find out about a friend's plan and follow-up the next week by asking how it went, or give compliments to a partner or friend). In terms of acts of kindness, one is encouraged to do acts of kindness to others, keeping track of such acts, and plan them ahead of time. Examples of kind acts are provided, while one is also encouraged to figure out such acts for oneself. The "best possible self" exercise is intended to increase optimism [45,46]. Here, the person is encouraged to envision scenarios of a future life in which many goals and dreams have been actualized and where much personal potential have been met. Assignments in the coming week will ask the person to elaborate on the scenarios, to recognize what one has already achieved that is in line with the best possible life scenario, challenge and turn around obstructive thoughts, and break major goals down into achievable sub-goals and milestones. The final positive psychology task is based on cognitive behavioral therapy [47], and is intended to facilitate the engagement in pleasant activities. The program starts by prompting the person to compile a list of activities that make her/him feel good. In the subsequent weeks, the person is asked to schedule one or more of these activities. She or he is also asked to determine a goal for one of the activities. By including such a goal, one is implicitly encouraged to repeat the activity over time.

### *Couple's Therapy*

A recent study suggests relationship dissatisfaction to be the strongest predictor of maternal emotional distress during pregnancy [48,49]. Hence, a unique component of the program is dedicated to enhancing communication between partners and facilitating healthy conflict resolution, which in turn is expected to improve relationship satisfaction. The couple's therapy is mainly based on a course that has been evaluated as an online program [50]. The course is based on cognitive behavior therapy. Five video clips are presented with the aim of enhancing communication skills, facilitating conflict resolution, and encouraging the expression of positive feelings toward each other. Following each video clip, one is encouraged to make use of the techniques that have been introduced. An example of a task is to let one's partner know when he or she made you feel appreciated; this task is intended to facilitate the expression of positive emotions between partners. Another task that targets healthy conflict resolution is "the active listening" task. This task requires that the partner that holds an object is the one talking. The other partner listens. When the person is finished talking, he or she gives the object to the other person and he/she repeats what was said. This task is intended to encourage listening and to raise awareness in terms of how one typically and ideally communicates in a relationship.

### *Breastfeeding*

Research suggests a relation between breastfeeding and depressive symptoms [51-55]. Formative research done prior to the development of Mamma Mia aimed to discover the topics that were most important with regards to well-being and depressive symptoms [56,57]. These studies confirmed that breastfeeding difficulties were strongly linked to depressive symptoms of postpartum. Hence, a component in the program focuses on breastfeeding, both normalizing difficulties associated with it, providing useful advice and assistance, as well as informing of the optional use of substitute.

### *Psychoeducation*

Every session in the program includes information regarding topics such as emotional lability in pregnancy, changes and challenges in the partner relationship, the importance of social support, the fetus and the infant's development, birth etc. Short video clips are available to demonstrate and explain the infant's state regulation system (sleep-wake cycles), and this information is integrated with issues related to the infant's capacity to sleep and rest, soothability, interaction/communication etc. The intention is that the program will provide the woman with relevant information adjusted to her own progress through pregnancy and after the child is born.

## The Present Study

Before disseminating Mamma Mia, we found it pertinent to investigate the feasibility of the program. Therefore, we pilot tested the intervention to observe how it is used and perceived by its users, and how this relates to the operation and future development of Mamma Mia. Consequently, the objectives with the present study were to (1) examine user acceptance of Mamma Mia, (2) examine how it was perceived among end-users, and (3) identify potential issues with use, acceptance,



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and program-specific needs that might provide added value to Mamma Mia and its operation and future development.

## Methods

### Survey Design and Data Collection

#### *Overview*

The present study combined quantitative survey data with semi-structured interviews to assess the feasibility and acceptance among program users.

Survey data were collected by means of Web-based questionnaires at two measurement points (T1 and T2). Due to time constraint in completing the current study, our results were based on participation in one of the two phases: pregnancy or maternity. Participants in the pregnancy phase were surveyed 4 and 8 weeks after intervention enrollment, and participants in the postnatal phase were surveyed 2 and 4 weeks after intervention enrollment. Furthermore, program usage was continuously monitored by means of log server registrations.

#### *Measures*

##### Perceived Usefulness

Six items were rated on a scale from 1-7 in order to assess a person's belief that using Mamma Mia is useful and helps increasing well-being [58].

##### Perceived Ease-of-Use

Four items were rated on a scale from 1-7 to measure a person's belief that using Mamma Mia is free of effort [58].

##### Perceived Credibility

Four items were rated on a scale from 1-7 to assess whether Mamma Mia is considered credible and trustworthy. User Satisfaction is measured in terms of how users rate the overall quality and satisfaction of the program, and whether they would recommend it to others. Four items were rated on a 1-7 scale [59].

##### Unobtrusiveness

Four items were rated on a 1-7 scale to assess whether users have the opportunity to use Mamma Mia seamlessly as part of their daily routines. Estimated means of all the measures were reported in Table 4 [60].

Technical problems were measured using a single yes/no option ("Have you experienced any technological problems in using Mamma Mia?"). Participants that responded "yes", were provided an additional open-ended question, "Please describe the technological problems you have been experiencing?"

Improvements were assessed using a single open-ended question, "If you could improve anything in Mamma Mia, what would that be?"

### Recruitment and Participants

Participants were recruited at 5 health care clinics and 2 hospitals. Here, midwives/public health nurses handed out a brochure and offered to try Mamma Mia. We recruited primarily women, and their partners through the women. The reason why we did it this way is because women often go to the follow-ups at the well-baby clinics and hospitals by themselves. Potential participants had to take home the brochure and send an email to the administrator of the program to register for participation. Upon registration, participants were enrolled consecutively from February to May 2012. Participants were also recruited on Facebook (30% of the total sample). In order to be included in the study, one had to be in gestational week 22 or 2-3 weeks after birth, or one had to be the partner of a women in gestational week 22 or who had given birth within the last two weeks. The two inclusion criteria we applied were that all participants had to be 18 years or older, and they had to be able to read and understand Norwegian.

A total of 103 users were recruited from February to May in 2012. By far, most participants were female (82%) and the mean age was 31.4 years (SD 4.3; range 20-41 years). Female participants were on average slightly younger (mean 31.1, SD 4.4) than male participants (mean 33.4, SD 4.0). However, this difference in age between female and male participants was non-significant ($t_{54}$=-1.1, $P$=.28). Furthermore, binomial tests of 50/50 proportions (all $P$ values, $P$<.02) confirm that most participants were ethnically Norwegian, had 4-5 years of college or university education, currently employed, and had no previous children ($P$≤.02). Most participants who were recruited were in their pregnancy and multinomial tests of equal categories show further that most participants were currently in a relationship ($P$≤.01). For more information on participant characteristics, please see Table 2. Missing data ranged from 4% (41/103)-32% (33/103).

### Interview Design and Data Collection

A total of 103 participants were recruited to test the usage of Mamma Mia, among which a random subset of 10 was invited to take part in an interview. Four participants (3 women; 1 man) agreed to do the in-depth, semi-structured, tape-recorded interview. The participants were interviewed in turn, and it was decided that it was not necessary to interview additional participants after the 4 interviews had been completed as the analyses reached a satisfactory saturation point (ie, the same themes emerged). An interview schedule was developed with open-ended questions with prompts and follow-up questions employed to elicit a breadth and depth in responses [61]. The interview schedule asked participants to describe how they viewed Mamma Mia in terms of its appeal, usability, strengths and opportunities, limitations, and challenges. The interview schedule also addressed the participants' fidelity to the program, and why there had been a high/low degree of fidelity. Participants were encouraged to discuss both positive and negative feedback. Participants were also encouraged to think aloud in terms of how to best market the program, and the final question was an open question, where participants could raise issues that had not been addressed in the interview. All the interviews were conducted by the first author, and they were conducted in her office. They lasted approximately 1 hour. The data were transcribed verbatim.

### Participants

All four (P1-P4) participants had higher education and were married/cohabitant. Three participants had previous children.



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Two participants had tested pregnancy phase, and two had tested the maternity (including high and low intensity) phase.

**Table 2.** Participant characteristics (N=103).

| Variable | | Frequency | Percentage |
|---|---|---|---|
| **Gender** | | | |
| | Female | 85 | 82.5 |
| | Male | 14 | 13.6 |
| **Marital status** | | | |
| | Single | 6 | 5.8 |
| | Co-habitant | 31 | 30.1 |
| | Married | 34 | 33.0 |
| **Education** | | | |
| | ≤ 1-3 years college or university degree | 22 | 21.4 |
| | ≥ 4-5 years college or university degree | 48 | 46.6 |
| **Occupational status** | | | |
| | Employed | 61 | 59.2 |
| | Unemployed or student | 10 | 9.7 |
| **Children** | | | |
| | No children | 46 | 44.7 |
| | 1 or more children | 25 | 24.3 |
| **What part of Mamma Mia was accessed** | | | |
| | Pregnancy | 75 | 72.8 |
| | Maternity | 23 | 22.3 |
| **Parental role by program version** | | | |
| | Mother, pregnancy | 64 | 62.1 |
| | Mother, maternity | 20 | 19.4 |
| | Father, pregnancy | 10 | 9.7 |
| | Father, paternity | 4 | 3.9 |

# Results

## The Survey

### *Program Usage*

In total, 78.6% (81/103) participants were engaged with Mamma Mia, while 21.4% (22/103) participants did not initiate the use of Mamma Mia. In the pregnancy phase, the average number of completed program days was 7.4 (SD 6.9). Median number of completed program days was 6. In the maternity phase, the average number of completed program days was 11.5 (SD 11.8). The median number of completed program days was 5. The program lasted for 11 months. Due to time constraint in completing the current study, however, we chose to study adherence within a limited time frame. Consequently, users have not been given the chance to complete the program. Thus, usage data may not accurately reflect adherence.

### *Survey Response Rates*

The response rates varied from 25% (6/24)-58.6% (44/75) (see Table 3 for details). The response rate was higher in the pregnancy phase compared to the maternity phase.

### *User Acceptance*

Overall, 65% (67/103) of responders rated Mamma Mia to be of high quality. Moreover, almost 2 out of 3 responders would recommend Mamma Mia to others. A total of 43% (44/103) reported that the information presented in Mamma Mia was relevant to them. In terms of the quantity of information in each session (ie, program day), users reported that the amount of information was appropriate. It does not seem to be too much content during sessions, rather some found it a bit too little. In the pregnancy phase of Mamma Mia, 78% (58/75) reported that one session per week was appropriate, while the rest found one session per week to be too rare. In the maternity phase, 67% (16/24) found three sessions per week to be appropriate, while 33% (8/24) found it a bit too much.

Table 4 illustrates how participants rated Mamma Mia in terms of usefulness, ease-of-use, credibility, unobtrusiveness, and



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satisfaction. The theoretical range goes from 1 through 7 for all five scales. Generally, ratings were high, indicating good user acceptance. Paired sample *t* tests were performed to compare ratings across time (T1 and T2), and results suggested that the ratings were stable over time. Therefore, Table 4 reports the figures from T1 only.

### *Improvements*

A total of 47 improvements were suggested by the participants. Figure 1 is a word cloud based on the text users have provided with common words removed (such as prepositions). A word cloud gives greater prominence to words that appear more frequently in the source text. As can be seen, words like “information”, “adjustment”, “platform”, “independence”, and “multiparous” were the most prominent. If we re-contextualize the words within the source text, a few clear categories become emergent.

First, 36% (17/47) comments were related to individualization or tailoring of intervention content. Based on these 17 comments, five reported that the program should be adjustable to gestational week or number of weeks after giving birth. Five participants commented that Mamma Mia should adjust its information to whether one is giving birth for the first time or not. Finally, 6 participants also noted that Mamma Mia should adjust the couples’ therapy so that (1) users without partners can skip the couple’s therapy and (2) that the couples’ therapy can be repeated so partners more easily can manage to follow it together. Regarding (1), one participant actually reported feeling “down” when faced with the couples’ therapy as it merely acted as a reminder about a recent sensitive event (ie, most likely a breakup). Although such cases may not occur very frequently, they pose a real threat to the well-being of the individual and act counterproductive to the objective of Mamma Mia. Regarding (2), it is not exactly clear, based on participants’ comments, what actions can be taken to help couples follow the couples’ therapy together. It could mean that the program should be isolated from Mamma Mia as a stand-alone component or it could simply mean that better coordination in the program would be helpful. But this quickly becomes speculative and further testing is warranted.

Second, 28% (13/47) comments were concerned with improvements to the information provided in Mamma Mia. It seems that users have a two-fold opinion. On the one hand, some users request more information, especially about the baby in utero and about mothers’ emotional and physical development during pregnancy. On the other hand, some information seems redundant or familiar, especially for women who already have children. The latter may be an important cue for increasing adherence. In a recent study by Tonkin-Crine and colleagues [62], they interviewed participants to identify reasons for not engaging with a Web-based intervention for chronic illness. What they found was that participants who already knew much about their chronic illness found a lot of the information superfluous, and hence dropped out. Participants suggested that more information should be optional or adjusted according to the level of knowledge of the participant, which inevitably leads to some form of individualization or tailoring.

The third emergent category is related to technological development. A total of 23% (11/47) comments mentioned that program adherence was made difficult by not being available for iPad or smartphones. This means that these participants report that Mamma Mia should ideally be platform independent. Platform independence ensures the accessibility and ubiquity of Mamma Mia as participants can take the program on-the-go or wherever they are. In conclusion, we have identified three main categories of suggested improvements which account for 87% of the variation in participants’ responses. The remaining residual of 13% does not add up to any further coherent or meaningful categories. Typically, the residual consists of individual responses such as “discovered typos” or “option for chatting with health personnel”.

**Table 3.** The response rate across program phase and assessments.

| | Pregnancy phase (n=75) | Maternity phase (n=24) |
|---|---|---|
| T1 | 44 (58.6%) | 8 (33.3%) |
| T2 | 31 (41.3%) | 6 (25%) |

**Table 4.** User acceptance of Mamma Mia.

| Variable | Mean | SD |
|---|---|---|
| Perceived usefulness | 4.2 | 1.3 |
| Perceived ease-of-use | 6.1 | 1.0 |
| Perceived credibility | 5.8 | 0.9 |
| Unobtrusiveness | 5.1 | 1.4 |
| User satisfaction | 4.6 | 1.5 |



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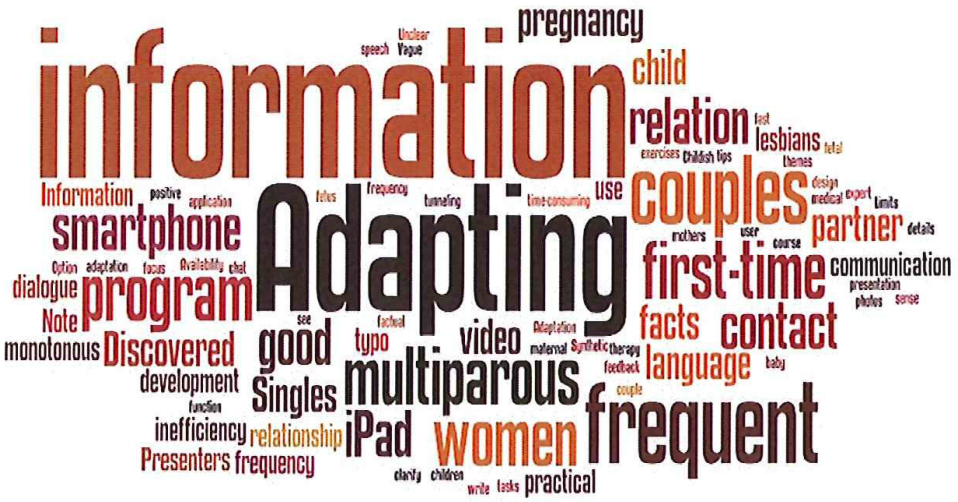
**Figure 1.** De-contextualized word cloud analysis of suggested improvements.




## Reflective Practice and Participant Feedback

The first lesson from the present study is that not all participants seem to read information about Mamma Mia very carefully during recruitment. It is estimated that roughly 10% of the participants that were recruited, had passed the gestational week 22 or were more than 2-3 weeks passed giving birth. Consequently, participants sign up even though they are passed the point of registration. This results in "confusion", "misunderstandings", and questions about "where can I adjust the program to my gestational week?" At least two participants also had to be re-registered from the prenatal phase to the postnatal phase of Mamma Mia, because they signed up late in their final trimester.

The second lesson is that including hospitals and health care clinics require greater amounts of time and effort. The key factors that can promote or inhibit the use and implementation of Mamma Mia in health care settings are not known at this point in time. However, the overall impression during recruitment was that hospitals and health care clinics experienced difficulties recruiting the numbers expected and needed. Only 61.2% (63/103) participants were recruited at hospitals and health care clinics despite the fact that 925 brochures were handed out and 9 meetings were held about Mamma Mia, at the very same hospitals and health care clinics. Consequently, RBUP (Centre for Child and Adolescent Mental Health) started recruiting participants online after the recruitment had started at hospitals and health care clinics, and with less time and less effort they managed to recruit 35% (36/103) participants. Also, due to the slow recruitment, the question "Where were you recruited for the user survey of Mamma Mia?" was included late into the recruitment period. Out of 7 responses, only 1 reported being recruited at a health care clinic. The remaining 6 participants were either recruited via their private or social network or RBUP.

## Data Analysis and Results

### *The Interviews*

#### Overview

We were interested in the women's qualitative experience of Mamma Mia, and in the issues they themselves raised in relation to it. The analyses relied upon organizing sections of the data into recurrent themes [61]. In accordance with Braun & Clarke [63], our approach is based on a thematic analysis, as opposed to a theoretical analysis; our themes were identified in an inductive manner, making the themes strongly linked to the data; and we took a semantic approach in that we did not look for a deeper meaning beyond what the participant said. Furthermore, we followed Kissling's recommendation [64] to let the data itself suggest names for the themes, and took direct quotes from the transcripts to illustrate the kind of data classified by each theme. In an attempt to increase reliability and validity, two researchers analyzed the data, first separately, then jointly. Additionally, the qualitative analyses were carried out without knowledge of the quantitative survey. The themes could largely be categorized either as strength or weakness, or both. Thus, the findings are presented below in terms of strengths and weaknesses for each theme.

#### Strengths

##### *Accessibility*

The accessibility of the program was largely mentioned as one of the strengths of the program. The opportunity to complete the sessions at home or at work, depending on when one had the time was greatly appreciated. This is in line with previous research [65].

##### *Information: Amount and Frequency*

Participants appreciated that the information was concise and brief, and it was easy to understand. Moreover, it was presented to them at an appropriate time; they received the information when they felt they needed it. The women enjoyed that the



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program was organized according to a tunneled sequence; that is, they were guided through the program and had to complete one module before proceeding to the next. As one participant said "to me, the program felt like a safe guidance that contained the information I needed when I needed it" (P1). The frequency of the sessions was found to be appropriate, although it was suggested that the preparation phase of the program could ideally have had more frequent sessions.

#### *Psychoeducation*

The interviewees expressed enthusiasm with regards to the information and exercises that targeted the relationship with partner and sensitivity with regards to the infant's signals. As one participant said: "With Mamma Mia, you get the knowledge you won't get anywhere else" (P2). Moreover, they enjoyed how the program was not a mere channel for information that provides general advice, but it "raised" questions that stimulated to self-reflection and it provided helpful exercises in an interactive manner. These aspects made learning fun, and stimulated to change.

#### *Confidence and Credibility*

Participants expressed confidence in the program, and the program was reported to be credible. Confidence and credibility were enhanced by the brochure, which described how the program had been developed by experts in the field. It was emphasized in two of the interviews how it was of great importance that health personnel whom they trusted were the ones who conveyed information regarding the program. One participant (P1) expressed how she felt "that the program was developed and provided as part of the public health care system", and thus she felt that the program was a good thing for her.

#### *Fidelity*

The major reason for high fidelity was the participants' curiosity in terms of what was to come in the program. Another reason why participants completed the program was that completing the sessions proved to be break and a "time-out" for multiparous women in a hectic everyday life. As one woman said "the program provided an opportunity to take the time to connect with the baby in my tummy" (P3). Ordinarily they would not have taken the time to focus inward on the fetus, and so the program facilitated contact and attachment with the unborn baby. A final reason for completing the program was the desire to be confirmed; confirmed that she was "doing the right thing" for her baby (P1).

### Weaknesses

#### *Inflexibility*

A major limitation had to do with a lack of flexibility. As one participant said, "my main complaint is the inflexibility in terms of when you can start with the program, you should be able to start up regardless of where you are in your pregnancy" (P2). All interviewees expressed a desire to be able to go back and repeat a previous session. The inability to use the program on tablets and smart phones was also mentioned as a major limitation. Finally, because of its emphasis on the relationship with the partner, the program was viewed as targeting the nuclear family, and other family constellations (such as single mothers) would likely not find the program to be adjusted to their needs. As one participant said, "a friend of mine, who is about to become a single mom…she sort of chose to have this baby on her own. She went to Denmark and had a donor. I thought many of the themes in the program would be good for her, but then I thought, no, no, it wouldn't work, cause the program is really custom-made for the "standard person" for the nuclear family" (P1).

#### *Information*

Although the information provided throughout the program was largely emphasized as one of the strengths in the program, it was mentioned that the follow-up phase (10 weeks postpartum and onward) could have contained more information regarding the baby's development and attachment etc.

### Recommendations for Improvement

#### *Accessibility and Fidelity*

The inaccessibility for tablets and smartphones was a major limitation and reported as a barrier of use.

#### *Expectations*

The interviewees were encouraged to describe how the program could be further improved, and expectations emerged as a common topic. Specifically, they wanted the program to focus more on expectations with regards to breastfeeding. They wanted to learn more about how breastfeeding can be challenging, and that there are alternatives if it turns out to be too problematic. Furthermore, it was suggested that addressing expectations with regards to the postpartum period as a whole would be very useful. Many new mothers plan to do too many things after having a baby, and Mamma Mia could therefore serve as a useful reminder that having a baby is both unpredictable and inherently hectic in and of itself.

## Discussion

### Principal Findings

The purpose of the present study was to assess the feasibility and acceptance among program users with regards to the Web-based intervention Mamma Mia, as well as to identify potential issues that could be improved. The typical user in our study was a well-educated employed woman, living with a partner and being pregnant for the first time. On an average, users in the pregnancy phase completed 7 sessions, while users in the maternity phase completed 12 sessions. The user-survey and interviews identified critical internal and external success factors for initiation and continued use of Mamma Mia (ie, factors that promote or inhibit intervention adoption) [66]. Internal factors refer to the strengths and weaknesses internal to the intervention such as its information quality, while external factors refer to the opportunities and threats presented by the external environment to the intervention such as technological changes or lack thereof. Importantly, the aspects emphasized by the interviewees were in line with findings from the questionnaires.

### Program Strengths and Weaknesses

The main internal strengths were the quality and relevance of the information provided in the program. More than two-thirds



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of users found Mamma Mia to be of high quality and would recommend Mamma Mia to others. By far, most also found the amount of information and frequency of the intervention schedule to be appropriate. Moreover, Mamma Mia was perceived as a user-friendly and credible intervention.

In terms of internal weaknesses, it was mentioned that the program sessions could be more frequent during the pregnancy phase, and in the maternity phase there could be more information regarding the baby's development and attachment.

### Opportunities and Threats for Real Implementation

Mamma Mia is operated on a stable platform and there were few reports of technical problems. In line with previous research [63], the accessibility of the program in terms of allowing users to complete the sessions at home or at work emerged as an important advantage of the program. Health care workers that conveyed the information regarding Mamma Mia emerged as both an external threat and potential strength. They constituted strength in terms of enhancing the credibility of the program, which in turn made the participants more eager to try the program. However, as described earlier, many health care workers failed to inform potential participants about the program, which posed a fundamental barrier to initiation of the program. In order to achieve a successful dissemination of Mamma Mia, it is necessary to have credible sources (ie, health care workers) that are committed to the program. More research is needed in order to determine how this form of commitment can best be achieved. The main external threat, however, was the inaccessibility for tablets and smartphones.

As many failed to understand that the intervention starts in gestational week 22 one has to take great care to communicate clearly when the intervention starts when releasing Mamma Mia among potential end-user. Communication and marketing plans have to ensure that users are registered at the right time according to gestational week, and one has to carefully plan how to implement Mamma Mia during point of care in health care settings.

### Improvements

Findings suggest a need for improvements in mainly three domains: (1) making Mamma Mia available for iPads and smartphones to increase accessibility, (2) provide more information, and (3) individualization to gestational week, couples versus singles, first-time parents versus second-time parents.

The most common barrier of use was the inaccessibility for *tablets and smartphones.* In turn, improvements were made such that the final version of Mamma Mia is available for iPads and smartphones.

More frequent program sessions during the pregnancy phase as well as more *information* regarding breastfeeding, sleep, child development, and attachment were requested, and all of these requests were taken into account and incorporated in the final revision of the program. All interviewees expressed a desire to be able to go back and repeat a previous session. Thus, the final version of Mamma Mia includes a "personal" home page, which gives an overview of all the sessions one has completed, and all the sessions that are to come. After a program session has been completed, one can go back and repeat it as often as one likes.

In terms of *individualization*, there is a definite long-term goal to adjust Mamma Mia to the needs of single parents, parents who have premature infants, parents with previous children, as well as non-Norwegian speakers. Participants in the present study also requested an improved flexibility in terms of program initiation. Participants wanted the program to be adjusted to their respective gestational week. This request has not been accommodated, however. Mamma Mia starts in mid-pregnancy because it is considered optimal to promote relationship satisfaction and prenatal attachment early (but not too early when the risk of miscarriage is still high) when the goals are to prevent depression and enhance well-being. In consequence, the program initiation continues to be limited to gestational week 22.

### Limitations

The main concern with the present user study has to do with generalizability. Due to the use of a convenience sample the findings may not be representative for all mothers (eg, ethnically diverse users, fathers or partners, and users with lower socio-economic status). There was a substantial dropout from the treatment program in this study. However, treatment dropout is common to most Internet-based programs [67]. Particularly, for comprehensive multi-session interventions, like Mamma Mia (ie, for each session added), an opportunity for dropout is also added [33]. Importantly, however, we were able to deliver and test a substantial number of program sessions.

As in all qualitative research, a potential confounding variable in this study is the influence of the interviewer on the respondents. As the interviewees were aware that the interviewer had a professional interest in Mamma Mia, it may have influenced the responses in different ways. For instance, the participants may have wished to come across in a socially desirable manner, and hence were likely to give positive feedback. On the other hand, they may have felt that the interview was the perfect opportunity to communicate directly what could be improved to the developers of the program. As the interviewees all gave nuanced feedback, it is likely that they felt comfortable being honest in the interview setting. It is important to note that while additional nuances would probably be captured with a larger sample; the main themes described herein would remain [61]. Moreover, the themes from the interviews were in line with the findings from the quantitative data, which adds to the reliability of the findings.

It is of essence that participants are invited to use Mamma Mia when they are in gestational week 22, which is why follow-ups in hospitals and well-baby clinics are thought to be the best settings to recruit women. That way midwives and doctors can inform women of the program when they are close to gestational week 22. In the present study, the primary setting for recruitment was the hospital and well-baby clinics, and yet only 60% (62/103) of participants were recruited there. Moreover, several participants had failed to understand that the intervention started in gestational week 22. It is not clear what inhibited successful/efficient promotion of Mamma Mia in hospitals and



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well-baby clinics; nevertheless, it is clear that one has to find an efficient way to organize and deliver Mamma Mia which is unobtrusive to health care personnel. A more comprehensive monitoring of the recruitment process may have revealed the sticking points and thus been informative for further evaluation studies as well as real world implementation of Mamma Mia.

## Conclusions

We were able to deliver a substantial number of sessions, and the high scores on measures of usefulness, ease-of-use, credibility, unobtrusiveness, and user satisfaction suggest a high level of acceptance. Findings from the user survey and interviews were consistent, which add to the reliability of the results. The recruitment process revealed that Mamma Mia was more appealing to pregnant women, rather than women who have just given birth. This is advantageous and not surprising as the program is designed to follow women through both the pregnancy and postpartum months. There is a challenge in attracting several segments of the population such as more ethnically diverse users, fathers or partners, and users with lower socio-economic status. In order to further increase user acceptance of this and similar programs, making such programs more adaptable to individual needs and preferences seems to be a key factor. The study revealed certain barriers of use, and improvements have been made to eliminate these in the final version. Overall, the user acceptance of Mamma Mia was fairly good and our findings add to the feasibility of the program. We find it appropriate to proceed to the next step of evaluation: a randomized controlled trial to test the effect of Mamma Mia on well-being and postpartum depressive symptoms.

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## Conflicts of Interest

None declared.

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## Abbreviations

**EPDS:** Edinburgh Postnatal Depression Scale
**PPD:** postpartum depression
**RBUP:** Centre for Child and Adolescent Mental Health

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Original Paper

# Development, Implementation, and Evaluation of a Structured Reporting Web Tool for Abdominal Aortic Aneurysms

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## Abstract

**Background:** The majority of radiological reports are lacking a standard structure. Even within a specialized area of radiology, each report has its individual structure with regards to details and order, often containing too much of non-relevant information the referring physician is not interested in. For gathering relevant clinical key parameters in an efficient way or to support long-term therapy monitoring, structured reporting might be advantageous.

**Objective:** Despite of new technologies in medical information systems, medical reporting is still not dynamic. To improve the quality of communication in radiology reports, a new structured reporting system was developed for abdominal aortic aneurysms (AAA), intended to enhance professional communication by providing the pertinent clinical information in a predefined standard.

**Methods:** Actual state analysis was performed within the departments of radiology and vascular surgery by developing a Technology Acceptance Model. The SWOT (strengths, weaknesses, opportunities, and threats) analysis focused on optimization of the radiology reporting of patients with AAA. Definition of clinical parameters was achieved by interviewing experienced clinicians in radiology and vascular surgery. For evaluation, a focus group (4 radiologists) looked at the reports of 16 patients. The usability and reliability of the method was validated in a real-world test environment in the field of radiology.

**Results:** A Web-based application for radiological "structured reporting" (SR) was successfully standardized for AAA. Its organization comprises three main categories: characteristics of pathology and adjacent anatomy, measurements, and additional findings. Using different graphical widgets (eg, drop-down menus) in each category facilitate predefined data entries. Measurement parameters shown in a diagram can be defined for clinical monitoring and be adducted for quick adjudications. Figures for optional use to guide and standardize the reporting are embedded. Analysis of variance shows decreased average time required with SR to obtain a radiological report compared to free-text reporting ($P$=.0001). Questionnaire responses confirm a high acceptance rate by the user.

**Conclusions:** The new SR system may support efficient radiological reporting for initial diagnosis and follow-up for AAA. Perceived advantages of our SR platform are ease of use, which may lead to more accurate decision support. The new system is open to communicate not only with clinical partners but also with Radiology Information and Hospital Information Systems.

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**KEYWORDS**

radiology; structured reporting; vascular surgery; abdominal aortic aneurysms

## Introduction

The report is one of the most essential components of the daily work for a radiologist. It is the way that the radiologist communicates with referring clinicians and includes diagnostic findings, conclusions, and sometimes recommendations. The written radiology report serves as the primary mode of communication for physicians in the diagnostic everyday work and is an invariably part in the health record of a patient. In the last decade, radiological reports consisted of typed, dictated, or even handwritten text [1].

While there have been some advances in the development of reporting software systems, radiology reports generally are lacking in structure, clarity, conciseness, consistency, and readability [2]. Follow-up reporting of similar radiology exams are frequently different from the baseline studies and are often confusing due to the lack of similar structure. In spite of the critical importance of radiology reports, they consist mostly of one large text module, they are non standardized, maybe incomplete, and unclear [3,4]. The use of free-text, conventional dictation allows radiologists to dictate in narrative style and in any level of detail. Frequently, if two radiologists are reporting the same imaging data, the final report may look very different; even there is an equal understanding about all of the radiologic findings and conclusions. Thus, it is almost a challenge for physicians to interpret and analyze radiological findings accurately and efficiently. Some improvement was made by introducing structured text modules which are reached in consensus within an individual radiology department or even suggestions of international Radiological Societies, (eg, the RSNA). These text modules are especially helpful for reports without pathological findings or simple reports. By reducing the possibility of variability in other areas within medicine, quality management has been improved [5]. Likely, there may be an improvement in quality in radiological reports by less variability [6].

To improve clinical acceptance of our radiology reports, the involved departments decided to analyze the need for more structure and, particularly, standardization.

This pilot study embraces creation and implementation of a software application for Structured Reporting (SR) for abdominal aortic aneurysm (AAA). The objective of the development of a SR application was to gain an efficient comprehensive reporting standard for AAA. An additional aim is to introduce a novel method that provides efficient medical reporting with less possibility for error among expert and non-expert readers.

## Methods

### Participants

To understand the key data of this implementation, we conducted interviews of hospital staff within the departments of vascular surgery (senior physicians, n=2–at least five years work experience; residents, n=2–at least two years work experience) and radiology (senior physicians, n=2–at least five years work experience; residents, n=2 at least one year work experience), supplemented by a review of project documentation. We analyzed qualitative data from field observations and formal interviews. Interviews took place during a 1-year period following system implementation and were performed by the same interviewer. The investigator recorded notes during the consultation hours. Interview notes were iteratively reviewed to identify the most common and essential elements for the chosen local clinical environment. Subsequently, the usability of the introduced method is assessed by evaluating its acceptability by the users based on questionnaire responses.

### Actual State Analysis

Process orientation is one of the most vital elements of quality management. To optimize and devise workflow processes more efficiently, it is necessary to reflect the whole cycle of interactions and different issues within an organization [7]. To increase shared knowledge and improve the processes related to radiological reporting, we proposed a pilot study using the Business Process Modeling Notation, a user-oriented language for a model of the specifying business processes [8]. The objective of this process was to analyze decision making within the departments of vascular surgery and radiology of a multidisciplinary working group. Previous experiences using this notation in process modeling within exactly those departments are not known.

A hospital workflow consists of a sequence of connected steps, a sequence of operations, declared as the work of a person [9]. In terms of treatment of an AAA vascular surgeons request computed tomography (CT) images to have reliable measures of selected positions of the aorta. As a result of the increasing life expectancy, AAA is one of the most common atherosclerotic arterial diseases involving the aorta [10]. Diagnostic investigation, quick therapy plans, post-operative control, and follow-up management are common time points of interaction between the involved clinical departments. The related processes can be seen in Figure 1.



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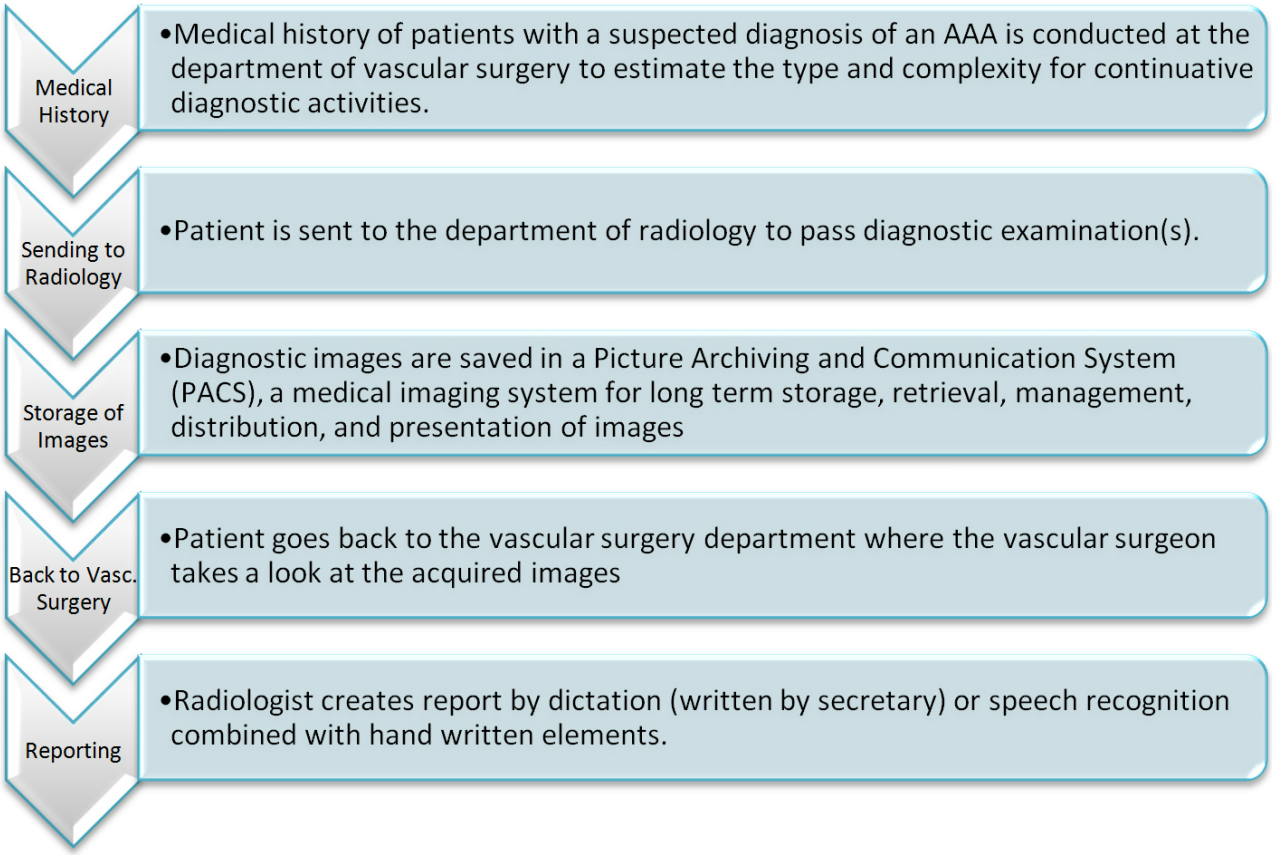
**Figure 1.** Related processes between departments of radiology and vascular surgery.




## SWOT Analysis

### *Overview*

The SWOT analysis is a strategic planning method. It aims to identify the strengths, weaknesses, opportunities, and threats of a project [11]. Table 1 is a SWOT analysis of the pre situation within the departments of radiology and vascular surgery. The analysis was performed to evaluate the use of free-text reports approach to develop a new concept of reporting. Attributes of the departments that were helpful to achieve the objective were defined as strengths; attributes considered detrimental for our purpose were defined as weaknesses. Additionally, external conditions considered as helpful to achieve the objective were defined as opportunities. External conditions that could be detrimental to the objective were defined as threats [12].

### *Strengths*

The most relevant strength found was that the department of radiology has a good technical infrastructure and a well coordinated IT management with an optimal support for user and workflow. All clinical information can be fetched at any time and from every workstation.

### *Weaknesses*

The current free-text reports do not fulfill the daily expectations of the in-house clinical partners. The reports were individually unstructured containing a monolithic text module. A quick overview of defined medical parameters was not ensured (eg, a direct comparison to former reporting results). The clinician was missing a structured form and essential information in one view. There was no trust that measurements were taken correctly by radiologists.

### *Opportunities*

The adoption of a structured, standardized reporting provides the potential for a greater chance of acceptance by referring clinicians. For clarity: the readers know where they can expect the description of a certain detail or aspect within the report. By gaining acceptance by all users in the conception of a new method of reporting, individual user requirements can be considered. According to the collaboration of both departments, the essential medical parameters can be discussed and implemented. The quality of a diagnosis of a clinician could be ameliorated by a second opinion by radiologists. Hereby, the communication could be enhanced between the clinical departments and an optimization of the processes can be achieved. Another advantage of structured reports is that clinical data and measures can be used for scientific and statistical needs.

### *Threats*

A risk of the implementation of such a system is that radiologists may feel that they were forced to use a system which they do not agree with and will refuse to use it clinically. It may take longer to fill in a standardized report at first use compared to the creation of individual text. Another risk is that it might be inadequate for individualized disease conditions or differential diagnosis. Standardized reporting tools could also be regarded as detrimental to “personalized medicine”.



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**Table 1.** SWOT analysis performed between departments of radiology and vascular surgery.

| | Descriptions | Strengths | Weaknesses |
|---|---|---|---|
| **Opportunities** | | | |
| | Optimization of clinical workflow | Technical infrastructure (HIS[a], RIS[b], and PACS[c], modalities) | Communication to vascular surgery |
| | Quality improvement by second opinion, professional expertise (two medical specialists) | High standardization of routine workflow | Involvement of specialized requests of vascular surgeons in radiological reports |
| | | Specialization within team | Time requirement |
| | | High quality mangement | Unstructured format of radiological reports (free text) |
| **Threats** | | | |
| | Radiological reports do not fulfill formal expectations | Interface between radiology and vascular surgery | Improvement of quality of internal processes |
| | Not in due time availability of radiological reports | Specification of required topics | Development of structured radiological reports |
| | | | Bundling of expertise |

[a]hospital information system.

[b]radiological information system.

[c]picture archiving and communication system.

## Technology Acceptance Model

Davis et al [13] first introduced the Technology Acceptance Model, which consists of four primary factors: external variables, perceived usefulness, perceived ease of use, and intention to use. Within this pilot study, we examined the actual acceptance of free-text reports by vascular surgeons at our medical center.

The structure of the report as well as its acceptance by the users, were the criteria we took as a basis [14]. Examining the external variables, the acceptance of free-text reports by our clinicians was assessed. Clinicians can be seen as customers and radiologists as suppliers in the value chain (ie, they are the primary stakeholders in data extraction). In our case, customer needs are important in the internal sense.

Since the radiologist defines the content of the report, there might be a mismatch regarding parameters expected by the surgeon (eg, in case of therapy planning or monitoring). A report usually starts by mentioning if prior exams (in-house or external) are present for comparison with date and modality. In general, a radiologist reports all pathological findings. Some reports strictly follow a topographical order, while others report relevant findings first than the less relevant ones depending on the "individual style" of the radiologist. A summary usually points out the relevant findings often in a hierarchical order and should contain a clinical interpretation.

A type of "visual clarity" of reports is usually missing since reports contain only one text module with all aspects and a short summary. The time needed to create a report varies with experience of the radiologist, his eagerness to describe every detail, and the reporting system including the technical skills of the radiologist to navigate the system. Finally, a report may need to be reviewed by a second colleague depending on the departmental rules and the experience of the first reader. Therefore, availability of a radiological report after the patient is coming back to the referring physician from a diagnostic examination is not guaranteed.

Perceived usefulness within state-of-the-art reporting is not given because clinicians might not read them due to their unstructured und unclear text modules as well as low quality in their constitution. Perceived ease of use cannot be declared as simplicity. The current reports are not always available in time and a quick overview about certain measures is not possible. Clinicians deduce their handling like individuals from their own expertise, knowledge, experiences, and perceptions without regarding the reports of radiologists.

The intent to use radiological reports is to obtain a second opinion of another qualified person, in this case from radiologists. On this note, clinicians are able to make an accurate diagnosis by consulting a radiologist. In this case, the best possible medical care could be assured.

## Determination of Medical Parameters

Prior to implementing a Web-based application for structured standardized reporting, we defined our internal medical reporting parameters of AAA by analyzing the existing workflow and requested report features based on interviews. To create a basis for efficient communication exchange between departments, it is necessary to agree on the most relevant medical parameters of AAA.

We reviewed existing literature about the classification and reporting standards of AAA [15]. The structured report conveys the relevant medical parameters in a logical manner to make it easy for clinicians to find the necessary data quickly.



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### Usability Test: Statistical Analysis

Usability and reliability of the method is validated within a real test environment in the department of radiology. The prototype was used by a special focus group of radiologists. Real patient data (pseudonymised) related to AAA were first read using the traditional way of reporting, and then using the new implemented Web-based software tool. To avoid a bias, time between the two reporting methods was at least one week. For a comparison between both ways of reporting, analysis of variance (ANOVA) was used to show difference of time effort. A *P* value of less than .05 is considered to be statistically significant.

By evaluating its acceptability by the users, questionnaire responses were gathered to conduct a controlled comparison of the performance of the new software in relation to the medical transcriptionist way of reporting.

## Results

### System Design

The highly adaptive design of SR led to a variety of methods of its use. Our application consists of four layers; Layer I: as a database, we used the relational database management system MySQL (Oracle corporation, Redwood Shores, California, USA). Layer II: the entire database connection is encapsulated in the data access layer using Hibernate (Red Hat, Raleigh, North Carolina, USA). Layer III: the business logic layer is implemented with Spring (SpringSource/VMWare, Palo Alto, California, USA). Layer IV: the graphical user interface (GUI) is written in Extended Google Web Toolkit (GWT), an open source set of tools for implementing Web applications. By using the combination of Spring and Hibernate, the GUI and database can be easily replaced by other possibilities. The GWT (Google, Menlo Park, California, USA) was chosen because of the high graphical attractiveness for the user [16].

### Graphical User Interface

The SR offers several of the following advantageous features: the parameters included standardized point-and-click menu topics, including anatomy, measures, and additional diagnostic findings, listed by organ and dedicated pathologies. The whole application is structured into three tabs: Tab A: characteristics of pathology and adjacent anatomy, Tab B: measurements, and Tab C: additional findings including a free-text option for personal judgment. Clicking on one of these tabs presents predefined standardized options that can be chosen. The selection of the medical parameters is effected dynamically. In relation to referred clicks, the relevant parameters are automatically displayed to minimize the depth of the graphical interface. The use of free-text is restricted to a minimum, as the most relevant information is entered through user-friendly tab menus. Radiologists are also allowed to interrupt their report. All registered parameters can be saved. Furthermore, SR offers the functionality of generating a PDF file for a medical report. An export function for statistic reasons is also available.

### Characteristics of Aortic Pathology

#### *Scope*

The scope of "characteristics of pathology" shown in Figure 2 constitutes of four items: (1) kind of pathology, (2) examination, (3) details about aortic pathology, and (4) details about surgery and potential complications. The options for the first item are: AAA, thoracic aortic aneurysm, and thoracic-abdominal aortic aneurysm. In the future it is planned to standardize radiological reporting for other aneurysms so that the template would change dynamically by clicking the required kind. The definition of the pathology requires defining the type of aneurysm (eg, Type I according to jointly used classification).

The options of "kind of examination" are: (1) first examination, (2) progress control, (3) Pre-OP: internal images, or external images, and (4) Post-OP: control, before discharge, 3 months, 6 months, 12 months, and 24 months. The radiologist continues with entering the measurement of the maximum diameter of the aneurysm sac. At this point, there is a possibility for clinical monitoring: all previously entered measurements in further radiological reports according to one patient are represented automatically in a progress diagram to have an overview about the whole development of the clinical history (Figure 3): automated monitoring for disease becomes possible through data mining. Dates of surgeries and complications, like an endoleak, are also embedded. Subsequently, the existence of a rupture or inflammation of the aortic wall can be noted. If post-surgery and Endograft for "kind of examination" certain additional information are needed: An Endograft can be migrated, broken, infectious, or have an intraluminal or extraluminal thrombosis. Furthermore, the occurrence of an endoleak with date as well as type (type 1-5) is necessary.

#### *Measurement*

The most relevant anatomic measurements of vessels along the aorta and its branches can be entered in the SR template (Figure 4). The position of each measurement is highlighted in a graphic as a sort of a guideline with the background to support slightly uncertain radiologists, for example residents (this input process also has a learning effect). Detailed information about the relevance of arteriosclerosis, thrombosis, or stenosis can be provided. The whole table is structured into (1) thoracic branches, (2) visceral branches, (3) iliac run-offs, and (4) miscellaneous. Regarding the required parameters, not every item requires a value or detailed information. Point-and-click choices were chosen to be inclusive of all commonly used parameters to describe aortic anatomy in detail.

#### *Additional Findings*

There is an option for radiologists to use free-text in the last tab of the report to have the opportunity to give additional relevant information if necessary. The free-text function allows writing individual medical advices or investigations that are not listed in the standard reporting.

The necessity of findings may need clarification with other clinicians, which can be checked at the beginning of tab 3 (Figure 5). Further, an alphabetically sorted list of additional findings is proposed which offers the main affected organs and



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their dedicated pathologies. The choices from the drop-down menus of an organ would result in complete, standard pathologies being created automatically. For example, the user could choose “lung,” and the pathology “embolism” would consistently appear in the report. Not all information can be captured in a structured report. A radiologist will need a narrative option to express unusual elements or to describe image parts that should also be documented. Such a function for more information of additional findings and a general conclusion can be entered in each free-text field in form of keyboard entry or speech recognition. Finally, a radiological conclusion should be entered.

**Figure 2.** Characteristics of aortic pathology, including kind of pathology, kind of examination, details about the pathology, and surgery details with potential complications.

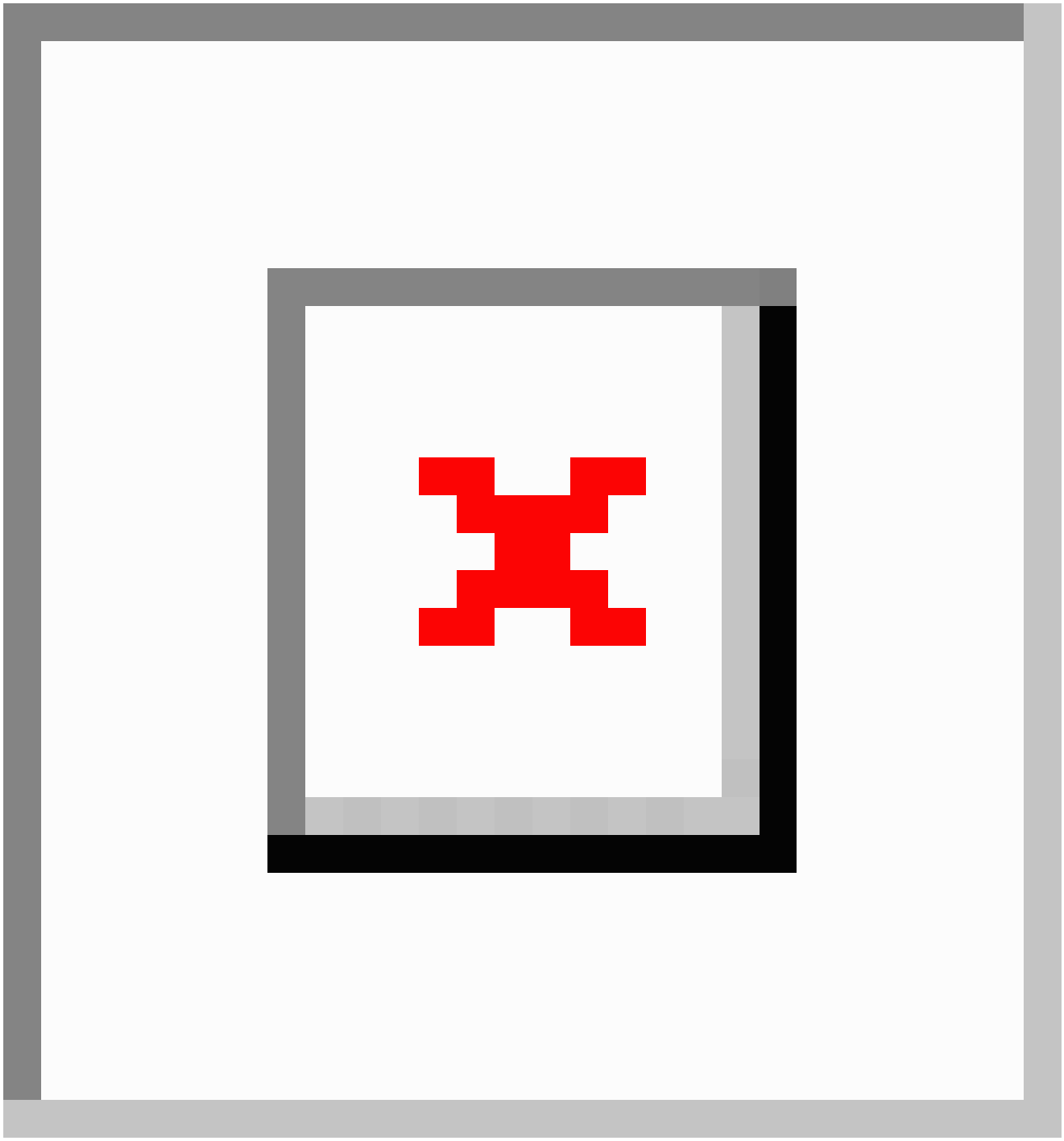



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**Figure 3.** Example of a graph for progress-monitoring for an AAA, including the respective dates of the certain aortic diameter, surgeries, and endoleaks.

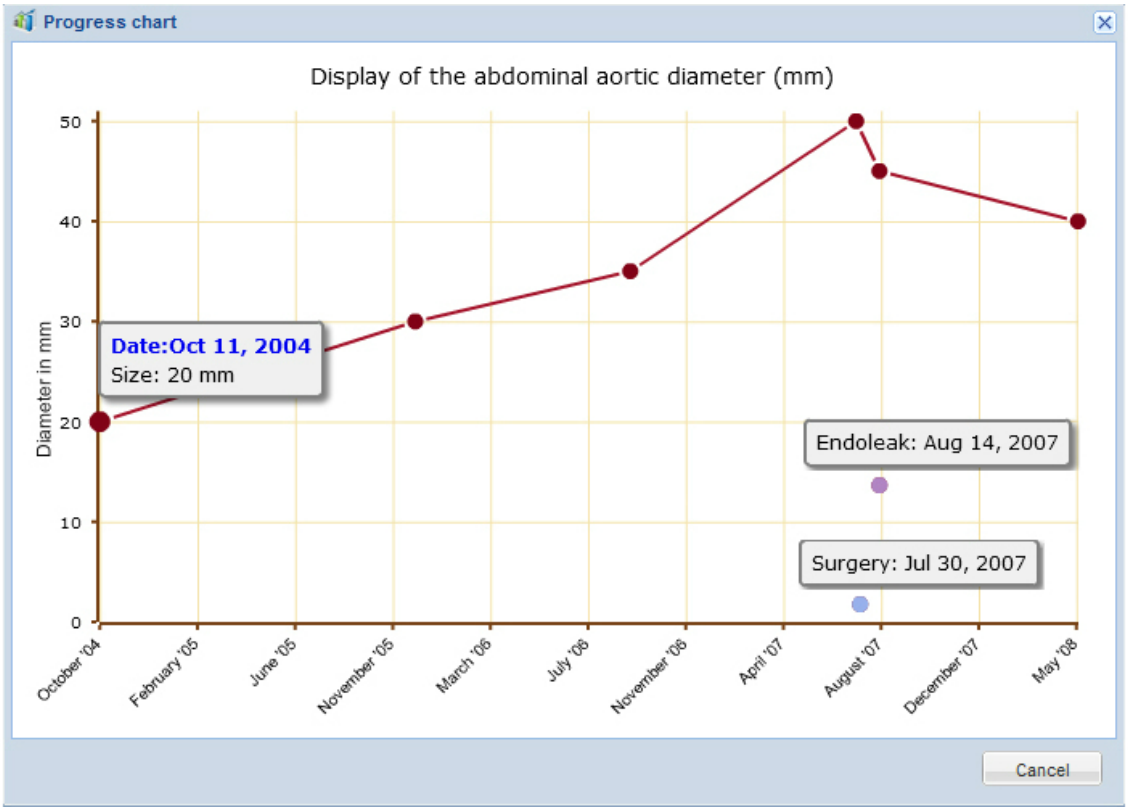


**Figure 4.** A1-A7 measurement positions depend on individual pathology. A8-A10 request the minimum diameter in case of stenosis or maximum in case of aneurysma.

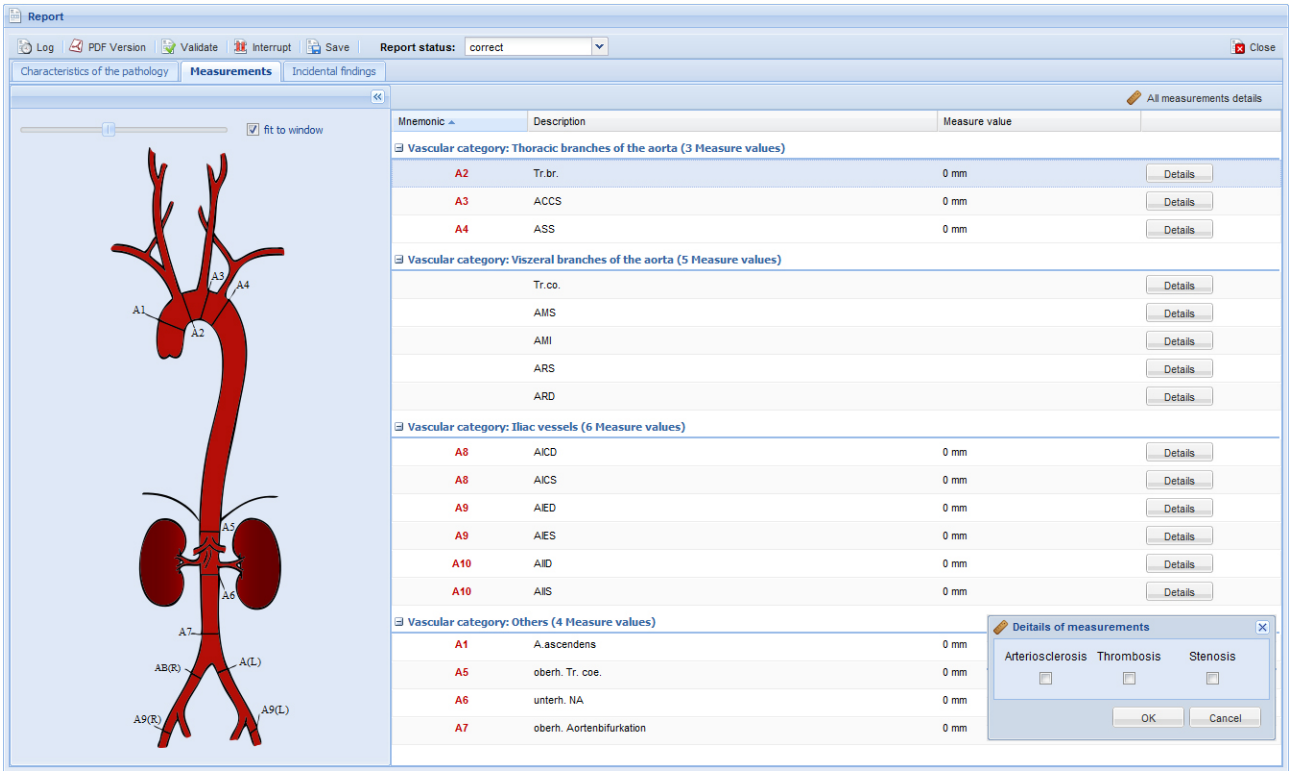




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**Figure 5.** Additional findings and free-text options, including a list of standard incidental findings and free-text options for additional information of incidental findings, notes, and a concluding personal review.

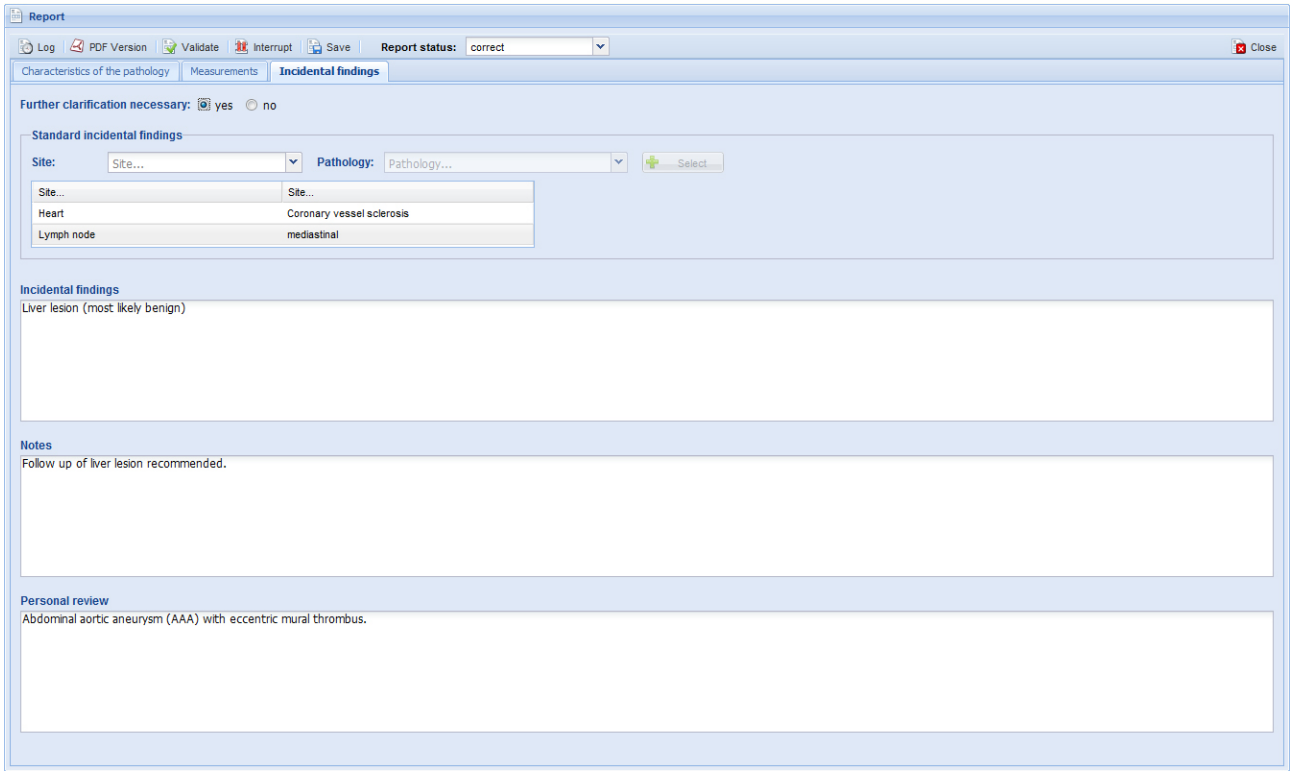
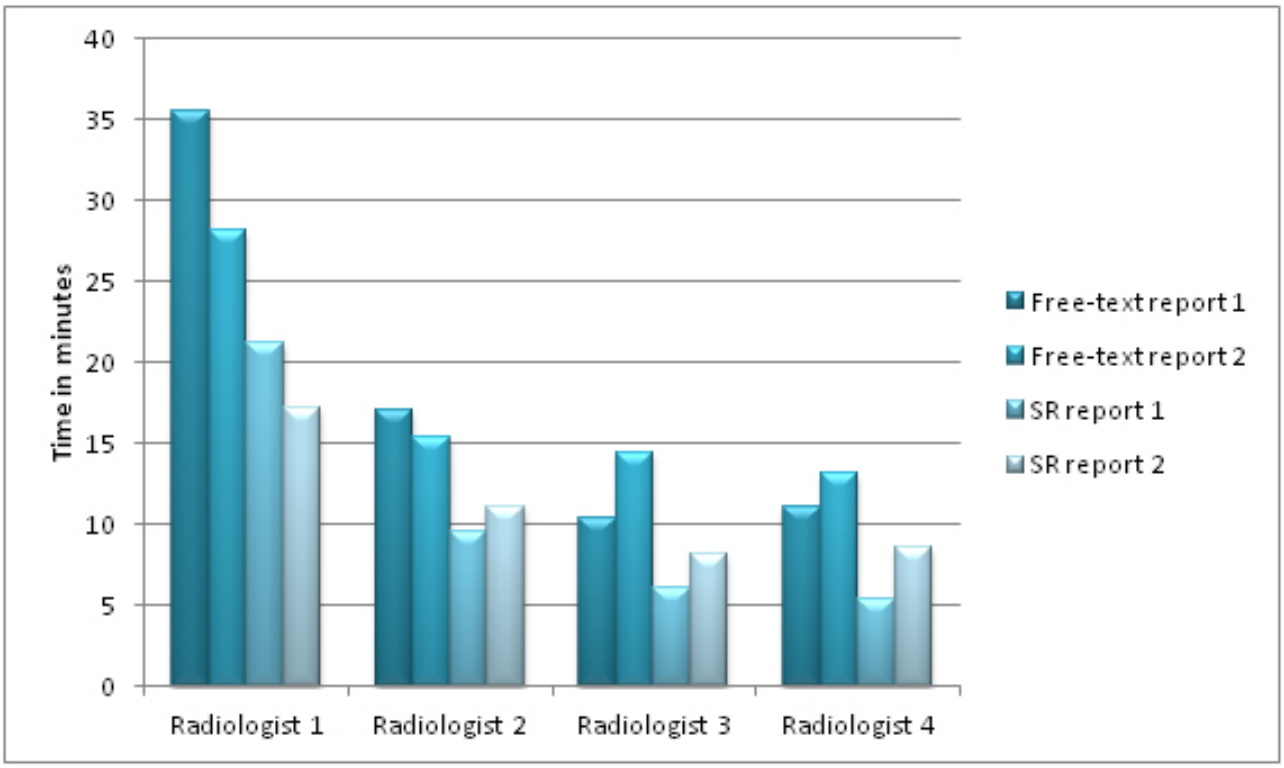



**Figure 6.** Comparison of time used for conventional versus Web-based reporting.




## Evaluation for Usability

The 16 CT images of patients with suspected as well as with confirmed diagnosis of AAA were reported twice by each reader (n=4). In this case, we ensured that reports were written with a one week time difference to avoid reader bias. Perceived advantages of SR are facilitation of workflows and ergonomics of the radiologist. The process of the usability test spread out in 2 scenarios:

1. Phase 1: Observation of radiologists during conventional reporting.
2. Phase 2: Observation of radiologists during SR.



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In a routine clinical environment, a SR template can be used to generate uniform and consistent reports. Basic medical parameters of pathology should be entered, but it is also exempted to radiologists to report in a free-text area, especially for additional findings. The performance of structured reporting within the usability test is measured against the measured reporting times. By this way we can ensure objectively if there is an improvement versus the conventional way of reporting.

The free-text report is not dictated but rather typed in manually not to show a bias between the two reporting methods. The results for averaged reading time are summarized in Table 2.

To obtain a radiological report, ANOVA shows a reduced reporting time with SR compared to free-text reporting ($P$=.0001).

After several interviews, in-house referring clinicians and radiologists stated that structured reports had better content and greater clarity than conventional reports.

The evaluation procedure was based on DIN EN ISO 9241 software ergonomics in information technology and software product evaluation. The objective was to validate the usability and ergonomics of our new tool for SR. To evaluate the system's effectiveness and efficiency, radiologists (2 senior physicians and 2 residents) were asked to complete a questionnaire using a scale from 1 (not useful) to 7 (excellent). The questions included 7 ergonomic principles, which are listed in Table 3 including mean values.

The results show that radiologists characterized the SR system as an innovative concept providing added value to the current reporting workflow (average rating=6.4/7.0).

**Table 2.** The time utilized for structured reporting and free-text option.

| Radiologist | Free-text reporting [min : s] | | Structured Reporting [min : s] | | Mean Difference |
|---|---|---|---|---|---|
| | Read 1 | Read 2 | Read 1 | Read 2 | |
| 1 | 36:51 | 28:22 | 21:15 | 17:23 | 13:18 |
| 2 | 17:07 | 15:33 | 9:57 | 11:09 | 05:47 |
| 3 | 10:37 | 14:46 | 6:06 | 8:11 | 05:33 |
| 4 | 11:03 | 13:14 | 5:41 | 8:58 | 04:49 |

**Table 3.** Ergonomic principles for software evaluation.

| Principle | Mean |
|---|---|
| Adequacy of tasks | 6.60 |
| Self-descriptiveness | 6.35 |
| Expectation compliance | 6.85 |
| Controllability | 7.00 |
| Individualizing options | 4.05 |
| Learnability | 7.00 |
| Fault tolerance | 6.85 |

# Discussion

## Summary

The current clinical workflow of radiological reporting and reading the report by the referring clinician offers room for improvement, and has been criticized by many groups [17,18,19]. We focused this workflow analysis and improvement on clinical communication between the departments of radiology and vascular surgery, and selected a common diagnosis: AAA. Besides time needed for the reporting processes, the reader experience during the reporting process plays important part. The quality of the reporting may be improved but it also may worsen as shown by various groups [20]. As we have seen in the evaluation, a standardized reporting scheme of suspicious findings on AAA leads to shorter reporting time rates than the standard random reporting.

## Application for Stuctured Reporting

Our Web-based SR application focuses on minimizing production time and improving the content of radiological reports for AAA. Clinicians can easily and quickly identify required data from radiological standardized reports. The SR can provide clinicians with a visual attractive interface showing the necessary measures to assist in quick decision making.

An important advantage for radiologists, especially for residents, is the new guided reporting method. Additionally, there is an opportunity to compare directly initial reports with follow-up reports, which is attractive for radiologists as well as for clinicians, respectively.

The system is flexible enough to incorporate various medical parameters which can be implemented easily. For a successful communication, it is vital to have a consensus concerning the content, meaning, technical expression, and medical terminology. By involving the users in the design process, we



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prevented the use of nonessential parameters. Our Web-application improves the availability of clinical information in the system (eg, provided by the requesting clinician during their request for radiological examination). By observing and interviewing the referring clinicians in the Vascular Surgery department, we found that SR in clinical practice may facilitate the professional workflow in several ways. First, it is possible to gain a more optimal understanding about relevant medical features in consideration of specific pathologic states. The clinicians know where they can find the requested information in a standard template. An inconvenient search in unstructured and unclear free-text is prevented. Particularly standardization through structuring of reports is a worthy goal at the temporal efficiency level. Emergency department encounter forms with a structured format have been shown to improve documentation and decrease test use compared with free-text recording [21].

Standardization of the reporting process is also beneficial for radiologists and enables (1) clarity of radiological reports, (2) quick creation of a radiological report, (3) temporal efficiency by radiological reports in time, and (4) capture of information for retrieval and reuses. The effort for a radiologist at the beginning of using a new reporting system is higher since they must first get used to the new type of radiological reporting. Our findings are auxiliary of the validity of recently proposed objections to SR in radiology [22]. Other groups have shown solutions for SR, especially in gastrointestinal endoscopy. Such applications have been developed, used, and also associated with accurate and complete data entry. The improvement and completeness of structured reports compared with free-text reporting are proved [23,24]. For pelvic ultrasound, a structured data entry system named UltraSTAR has been implemented to reach a high satisfaction among radiologists and gain slightly more complete but certainly more structured data than free-text reports [25].

In our introduced SR system, SR additional lab values can be implemented easily. It is a new era of smart reporting radiological findings with clinical information and the capability to add more clinical parameters if necessary. The goal to minimize the number of conscious steps which are necessary for report creation is achieved. The classification we have proposed in our implementation has the advantage that we reduced the medical parameters for AAA to a minimum in order to have a quick overview. Standardized reports also facilitate the use of real-time diagnosis and decision-making. Within radiology, SR has been most successful in mammography, where Breast Imaging Recording and Data System have been developed by the American College of Radiology [26]. Structured reporting has also been pursued in abdominal ultrasonography and was found to be a viable alternative to free-text dictation in terms of completeness, time efficiency, and user acceptance [27].

The presented SR platform can serve as a communication basis with hospital information systems (HIS), gathering all the necessary information (eg, the surgery date can be retrieved directly). In the initial pilot project, this functionality is integrated to demonstrate this relevant added value. In fact, the evaluated SR platform is a stand-alone version, but with wide-open interfaces, it can be easily adopted to several other systems. It enables context-specific clinical information retrieval from an integrated HIS and the related medical record. Since the presented SR platform is able to communicate via its open interface with other information systems, we embedded our tool as an external program into the existing RIS of our hospital to conduct the evaluation.

The Aspect of An Open Interface Is Essential for Further Developments of Sr Systems to Build a Basis of Efficient Communication Using All Available Electronic Patient Records.

## Comparison to Free-Text Reporting

Compared with structured standardized reporting, free-text reporting implicates the following issues:

1. It is not ensured that all relevant clinical parameters are completely listed in a free-text report.
2. If values are missing within the report, the reader does not know if the measurement was not conducted.
3. Free-text-reports cannot be evaluated automatically in a systematic way.
4. Two radiologists produce two different reports that look very different in their order as well as in their number of details; even if there is an agreement of all findings and the conclusion. Thus, a direct comparison of two reports is nearly impossible.

The inherent disadvantages of free-text-reporting may be due to workflow differences, selection bias, and lack of uniform reporting standards as well as inaccurate reporting. For this reason, existing data of AAA reports are difficult to interpret in a systematic way for statistical purposes. Additionally, the terminology used to describe the findings is not universally agreed and often inconsistent. A conflicting consensus on the definition of a clinically stable patient is also prevalent [28,29].

Recent publications show that regarding the content of the reports, a SR system may also inherent disadvantages like causing a lack of curiosity of unexpected findings [30]. However, during this pilot study, the focus was not on the quality of content of the produced reporting.

## Conclusion

One important goal of using a new standard is to reduce the overall reporting time for radiologists as well as to achieve a faster and easier interpretation for referring clinicians. The presented new pilot application for AAA reporting facilitates the workflow for the radiologist and the referring physician. Clinical research may also benefit from SR since data can be extracted more easily for statistical analysis. Further studies are warranted to evaluate the quality of content using SR.

Structured standardized reporting has the potential to improve the patient care process and expand in other clinical realms within vascular imaging and other diseases. Current reports lack the structure to monitor disease in long-term follow-up patients having AAA. On this account, referring physicians prefer standardized reports because specific medical parameters can be extracted more easily than in a free-text report.



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## Conflicts of Interest

None declared.

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## Abbreviations

**AAA:** abdominal aortic aneurysm
**ANOVA:** analysis of variance
**CT:** computed tomography
**GUI:** graphical user interface
**GWT:** Google Web Toolkit
**HIS:** hospital information systems
**RIS:** radiological information systems
**SR:** structured reporting
**SWOT:** strengths, weaknesses, opportunities, and threats


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Original Paper

# Assessment of Diet and Physical Activity of Brazilian Schoolchildren: Usability Testing of a Web-Based Questionnaire

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## Abstract

**Background:** Information and communication technology (ICT) has been used with increasing frequency for the assessment of diet and physical activity in health surveys. A number of Web-based questionnaires have been developed for children and adolescents. However, their usability characteristics have scarcely been reported, despite their potential importance for improving the feasibility and validity of ICT-based methods.

**Objective:** The objective of this study was to describe the usability evaluation of the Consumo Alimentar e Atividade Física de Escolares (CAAFE) questionnaire (Food Consumption and Physical Activity Questionnaire for schoolchildren), a new Web-based survey tool for the self-assessment of diet and physical activity by schoolchildren.

**Methods:** A total of 114 schoolchildren aged 6 to 12 years took part in questionnaire usability testing carried out in computer classrooms at five elementary schools in the city of Florianopolis, Brazil. Schoolchildren used a personal computer (PC) equipped with software for recording what is on the computer screen and the children's speech during usability testing. Quantitative and qualitative analyses took into account objective usability metrics such as error counts and time to complete a task. Data on the main difficulties in accomplishing the task and the level of satisfaction expressed by the children were assessed by the observers using a standardized form and interviews with the children. Descriptive statistics and content analysis were used to summarize both the quantitative and the qualitative aspects of the data obtained.

**Results:** The mean time for completing the questionnaire was 13.7 minutes (SD 3.68). Compared to the children in 2nd or 3rd grades, those in 4th or 5th grades spent less time completing the questionnaire (median 12.4 vs 13.3 minutes, $P$=.022), asked for help less frequently (median 0 vs 1.0 count, $P$=.005), had a lower error count (median 2.0 vs 8.0 count, $P$<.001), and obtained a higher overall performance score (median 73.0 vs 68.0, $P$=.005). Children with a PC at home spent less time completing the questionnaire (median 12.3 vs 14.9 minutes, $P$<.001), had a lower overall error count (median 2.0 vs 9.0 count, $P$=.03), and had a higher performance score (median 72.0 vs 64.0, $P$=.005) compared to the children without a PC at home. The most common difficulty in completing the questionnaire was in using the scroll bar. The majority of children reported a positive evaluation (liked a lot or liked) for the four design elements, which were evaluated.

**Conclusions:** The results of the present study provided feedback to improve the final version of the CAAFE questionnaire. Quantitative data showed minor errors and system failures, while qualitative data indicated that, overall, the children enjoyed the CAAFE questionnaire. Grade levels and PC use must be taken into account in Web-based tools designed for children.



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**KEYWORDS**

usability testing; questionnaire; physical activity; diet; children

## Introduction

Obesity is a major public health problem worldwide, affecting people of all ages. In past decades, developed countries have experienced a rapid growth in childhood obesity, as have developing countries such as Brazil [1]. According to a survey performed on 9,018 Brazilian children in 2008-2009, one-third of them (~3006 children) aged 5 to 9 years were found to be overweight and 1497 (16.60%) were obese. These figures are worrying compared to those of 1970s, when less than 10% of the children were overweight and 3% were obese [2]. Although obesity epidemics have complex causes, physical activity and diet are the two main determinants of energy balance, and are therefore directly related to the worldwide increase in obesity. To tackle the pediatric obesity epidemic, monitoring tools for nutritional status, physical activity, and diet can be very helpful in determining the effectiveness of policies and health promotion programs.

Due to their importance and strategic role in promoting the health of young people, several survey systems have been specially designed to monitor the physical activity, diet, and nutritional status of schoolchildren [3-5]. All these systems rely on self-reported assessment, as this is the most practical and cost-effective way of collecting data for survey purposes. However, children's self-reported assessments are often prone to bias, as they rely on their cognitive ability to recall details of both physical activities (eg, type, frequency, duration, intensity) [6] and dietary habits (eg, the types and amount of food consumed) [7]. Therefore, the data collection instruments designed for children must be adapted in terms of language and cognitive demand to provide reliable and valid data.

In 2002 and 2007, two surveys using similar methods to investigate nutritional status in schoolchildren and its association with behavioral and sociodemographic factors were conducted in the city of Florianopolis in Southern Brazil [8-10]. A paper-and-pencil questionnaire was used to assess the food consumption and physical activity of schoolchildren aged 7 to 10 years [11]. The validated paper-and-pencil version of the questionnaire titled "Previous Day Food Questionnaire (PDFQ)" was subjected to reliability and validity studies. The results of the reliability study indicated that agreement level between answers from the questionnaire and the observations of school meals was moderate or high for all food categories [11]. In the validity study of the third version of the PDFQ, mean values for sensitivity and specificity were 70.5% and 87.1%, respectively, for 12 food items in three combined school meals [12]. Based on this experience, we developed the CAAFE questionnaire: Consumo Alimentar e Atividade Física de Escolares (Schoolchildren Food Consumption and Physical Activity), a new tool for monitoring the physical activity and diet of young children in Web-based surveys.

The access of Brazilian students to new information and communication technologies (ICTs) has increased as a result of national policies to equip public schools with computers and Internet (eg, Programa Nacional de Tecnologia Educacional—ProInfo and Programa Um Computador por Aluno) [13]. In Florianopolis, the city where the software CAAFE has been tested, all public and private schools are equipped with computer labs and Internet. Taking into account the infrastructure presented in the school setting, the increasing familiarity of children with ICT, and the scarcity of data on the diet and physical activity of Brazilian schoolchildren, it is expected that an online self-reported assessment like the CAAFE questionnaire will be a feasible and cost-effective tool capable of providing data for the planning of health policies.

Web-based health surveys are a promising and attractive alternative to traditional data collection methods. They have several advantages over paper-and-pencil surveys such as standardized questionnaire administration, the elimination of interviewer-associated bias, reduced survey costs, and improved data quality due to automated data checking and storage [14,15]. The past decade has seen the rapid development of several ICT-based tools for assessing diet and physical activity [16-19]. A number of these tools were developed specifically for young people and seem to be feasible for survey purposes [18-29]. Despite their advantages, Web- and technology-based tools are prone to producing measurement bias in addition to that produced by traditional methods. Simple errors such as not scrolling down to see an entire webpage or difficulties in understanding how to correct an erroneous response may lead to invalid data [30]. Some of these errors may occur as a result of poor usability [31].

As far as we are aware, there are few Web-based physical activity and food consumption assessment tools that have presented the results of usability testing [32,33], particularly among schoolchildren [32]. Since usability is an instrument attribute of utmost importance in providing more reliable and valid data, a detailed description of usability testing can promote its use for the development of tools, and provide more quantitative and qualitative data for study comparisons. To that end, usability evaluation of the CAAFE questionnaire is the first step in establishing its feasibility as a tool for Web-based health surveys. The aim of this paper is to describe the general attributes of the CAAFE questionnaire as well as to give a detailed description of its usability characteristics.

## Methods

### Description of the CAAFE Questionnaire

The CAAFE questionnaire was programmed according to international quality standards (CMMI level II) in Brazil by a Web-based system/mobile application company. The questionnaire is a cross-platform (Win/Linux/Mac OS) and browser-based software written using PHP5, HTML5, CSS3,



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and JavaScript. Two-dimensional images integrated into a larger scene (sprites) were used, along with CSS programming and JavaScript language management to animate an avatar that helps children to complete the questionnaire. The application runs successfully on browsers such as Internet Explorer, Firefox, Chrome, and Safari. It requires Internet access and speakers (or headphones), and displays best with the current standard screen resolution (1024 × 768 pixels).

The CAAFE questionnaire was developed for school-based surveys of 7 to 10-year-old children. Schoolchildren can access the CAAFE questionnaire by logging on with a password automatically created by the system and specific for each survey, school, and time of day (morning or afternoon), to prevent the same respondent from answering the questionnaire more than once in a day.

In the formative research to develop the CAAFE questionnaire, several data sources were taken into account including: (1) our experience with the validation studies conducted with the paper-and-pencil versions of the PDFQ [11,12] and Previous Day Physical Activity Questionnaire (PDPAQ) [34], (2) food consumption and physical activity data reported by schoolchildren participating in school surveys using the PDFQ and PDPAQ [9,10], (3) previous Web-based instruments designed for schoolchildren [18-20,22-24,35], (4) data from focus groups conducted with physical education (PE) teachers of schoolchildren [36] and nutritionists working with the school meals program, (5) 7-day food and activity diaries completed by 180 schoolchildren from three schools, and (6) research team discussions with a specialist in child psychology and education to choose the questions and the Web layout according to the children's cognitive abilities. The main lessons learned in the formative research process indicated that the instrument must: (1) be as simple as possible both in the quantity and quality of information required from the children, (2) be attractive and interactive, and (3) include only relevant items to be marked by the children. A more complete description of the formative process of the CAAFE questionnaire will be provided in an upcoming publication.

The CAAFE questionnaire is a single-day recall procedure divided into three sections: (1) registration form, (2) diet, and (3) physical activity. The registration section refers to information about respondents, such as their name, mother's name, sex, weight, height, age, date of birth, and study period. These are simple questions with each screen presenting only one question. The option "I don't know" is offered for almost all the questions, to avoid frustration when the respondent is unsure about the answer. Four questions require the answers to be typed (ie, the name, mother's name, weight and height of the respondent), whereas all the other questions could be answered only by clicking on large icons. In the CAAFE survey system, it is planned that all participants will have their weight and height measured 2 weeks before completing the questionnaire, and will keep these measurements to assist them in answering the survey. The name of the school, city, and state are automatically entered on the database, based on a previously compiled list linked to the password entered. In case of response interruption (eg, Internet disconnected), children can continue the questionnaire at a later time on the same day. Otherwise, children would have to start the questionnaire all over again.

The food consumption section of the questionnaire was divided into six parts (breakfast, morning snack, lunch, afternoon snack, dinner, and evening snack), to help children recall foods and beverages consumed during the previous day. This approach has been frequently used in questionnaires for young children, as it facilitates the recall process [11,18,19]. The foods and food groups, including healthy and unhealthy items, were chosen taking into account the food patterns of children in this age group (reported by schoolchildren in the 7-day food diaries), foods offered in school meals, and foods recommended in the Brazilian Food Guidelines. Upon choosing the food items from a screen with 32 food icons (see Figure 1), schoolchildren can check all six meals to add or exclude specific items. After completing the six-meal events, four questions are asked on different screens: (1) "Did you have a school meal yesterday?" (yes/no); (2) If yes, "Which of these foods did you eat during the school meal?"; (3) "How many times per week do you have school meals?" (none, 1, 2, 3, 4, every school day); and (4) "How do you like the food served in the school meal?" (five options illustrated by a hedonic scale). The meals listed in question 2 are those likely to be offered in the school setting (the first four meals of the day), and include only the foods/beverages previously marked by the children.

The physical activity section is divided into the three parts of the day (morning, afternoon, and evening). Other ICT-based questionnaires have used this strategy to help children recall the physical activities performed [22,23,35]. A closed list of leisure activities, sports, home chores, and sedentary activities was compiled based on the results from focal groups, previous instruments for this age range, and the 7-day recall completed by 180 schoolchildren. Children can choose sedentary and physical activity icons from among 32 options (see Figure 2). When a physical activity is chosen, a modal window opens and the avatar asks the children about its intensity, "How tired did you get during this activity?" and three illustrated icons depicting different degrees of physical exertion are presented. As in the food section, children can check their answers and make changes if necessary in this section also. Next, the avatar asks five questions on separate screens: (1) "Click on the activities you did yesterday when the teacher was present."; (2) "Did you have a PE class yesterday?" (yes/no); (3) "How many days per week do you have PE classes?" (none, 1, 2, 3, 4, every day of the week); (4) "How do you like PE classes?" (five options on a hedonic scale); and (5) finally, children are asked about the mode of transport they use to travel to school (car, school bus, regular bus, motorcycle, on foot, bike, skateboard, or boat).

The final CAAFE questionnaire flow can be accessed in Multimedia Appendix 1. The total number of screens can vary according to the responses chosen (eg, omitting questions regarding the previous school day if the child did not go to school that day). Figure 3 presents the major functionality of the CAAFE survey system as well as the interaction between researchers, children, professionals, and policy makers.



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**Figure 1.** The CAAFE questionnaire food options.

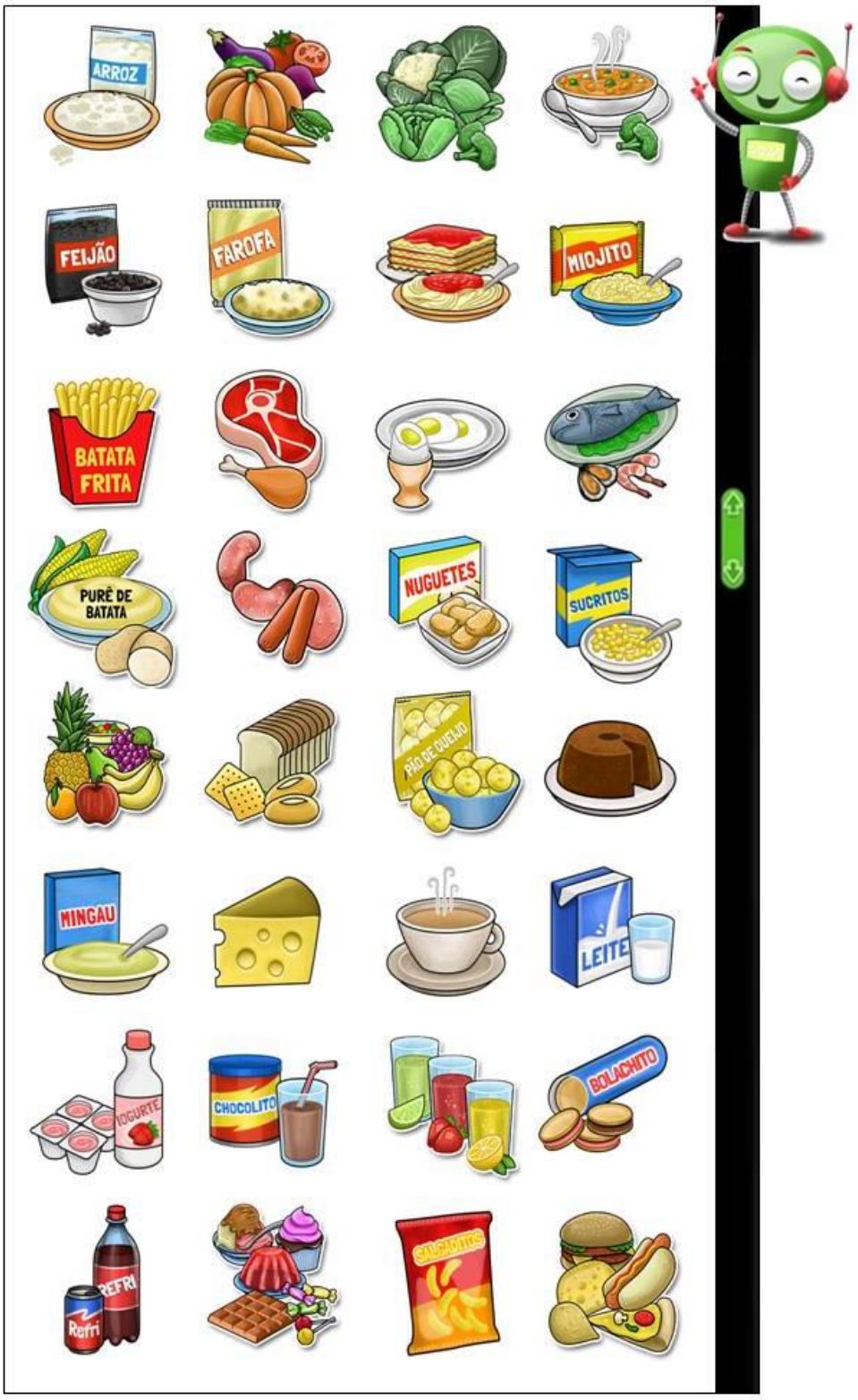




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**Figure 2.** The CAAFE questionnaire activity options.

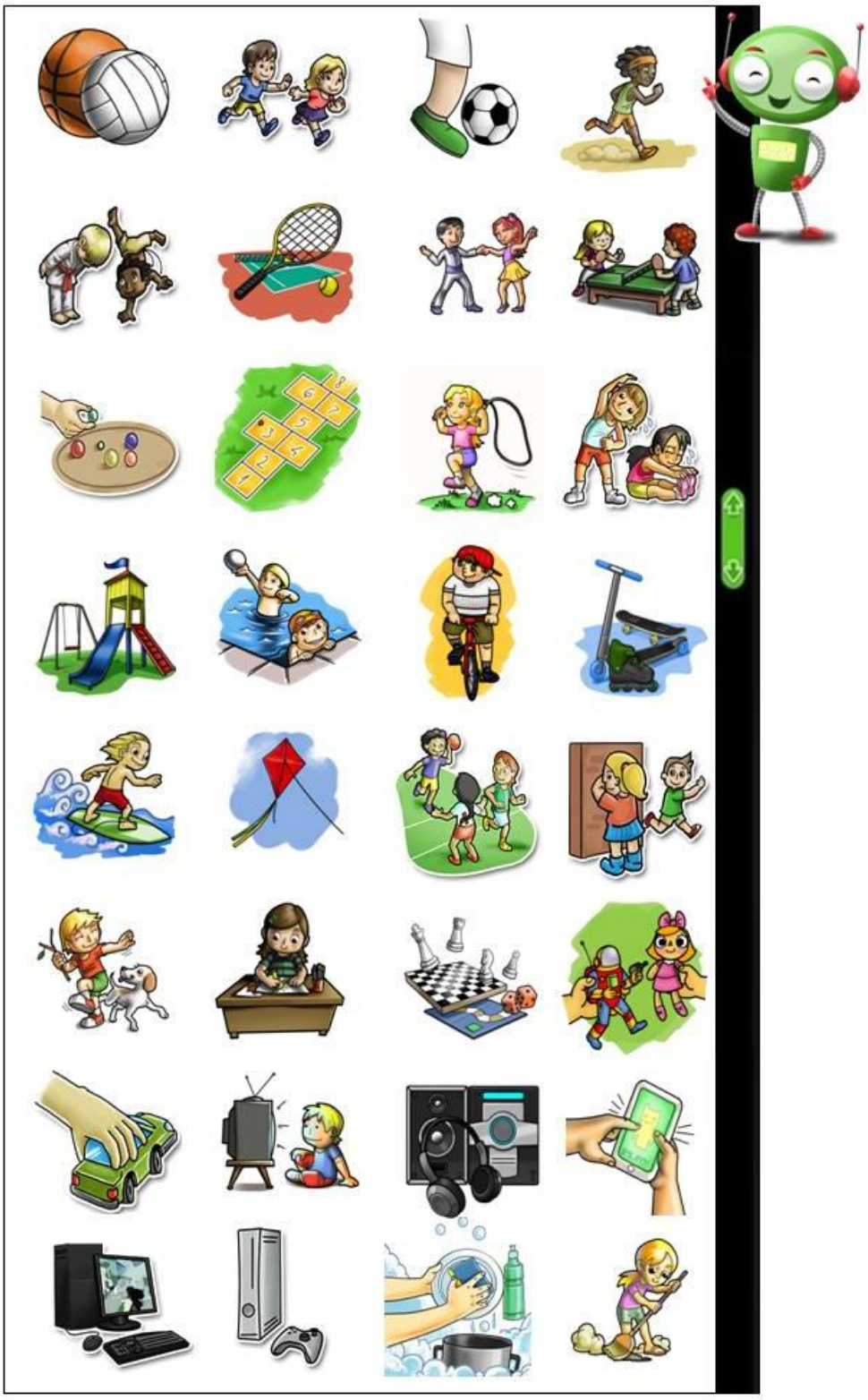



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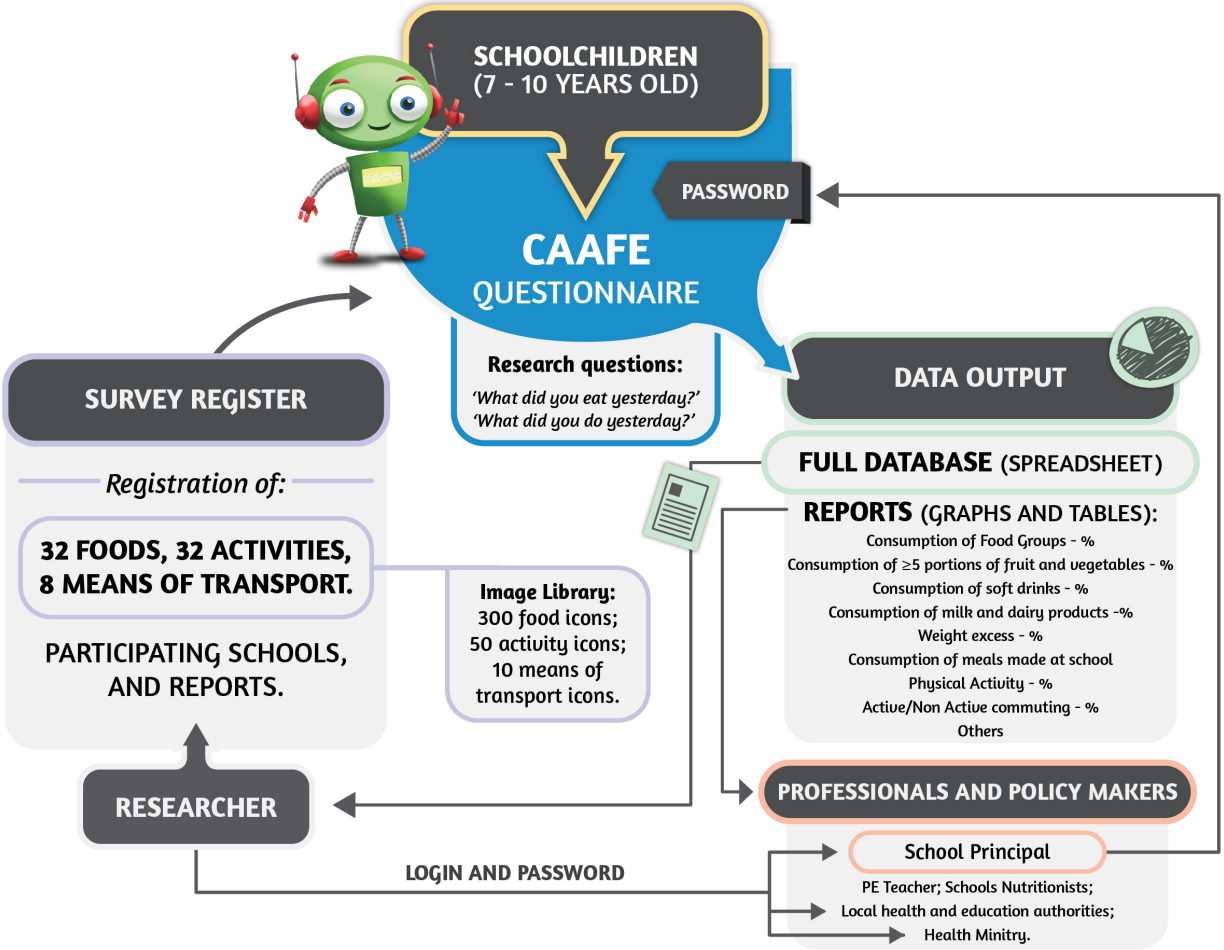
**Figure 3.** Functionality of the CAAFE survey system: survey register, children's responses, and data output.




## Usability Testing

### *Overview*

The most basic and useful method for improving the website usability is user testing that contains three components: (1) selecting representative users, (2) asking them to perform representative tasks with the Web-based interface, and (3) observing where they succeed and where they have difficulties with the user interface [31]. Several methodologies are available for usability testing, depending on the study objectives and on limitations such as time, money, management backing, development team support, and ability to recruit participants [37]. In the present study, we opted to adapt the multiple testing product version method described by Rubin and Chisnell [37]. Our strategy differs from the original method in that each software version was tested by different children.

### *Pilot Test*

A pilot test of usability for the first version of the CAAFE questionnaire was conducted with 110 children (85% of the eligible subjects from five selected classes) aged 7 to 13 years (59 girls/110 children, 53.6%), from two elementary public schools in the city of Florianopolis, the capital of the Santa Catarina, Brazil. This first version had a different questionnaire flow compared to the final version previously described. The metaphor of a diary was used to help children record what they ate/did over the course of the previous day. Both physical activities and food consumption were assessed in the same screen.

The same usability test procedures were used for the pilot test. Several design elements caused disruptions in the flow (eg, hidden buttons, poor quality of drawings), and the children were unable to complete the questionnaire without assistance. In addition, almost all the children (109/110, 99.1%) enjoyed answering the questionnaire, and only a few children reported they had any difficulty completing the task. The mean time to complete the first version was 29 minutes. The low usability performance of this version led to the redesign of the software layout. The main improvements to the final version of the software were the presentation of diet and physical activity sections in separate screens. Improvements were also made in the Web design.

### *Participants*

Six other classes were invited to test the second version of the software. To represent schoolchildren from different socioeconomic backgrounds, four public schools from different regions of the city (central, north, east, and south) were selected. A total of 114 (114/152, 75.0% of the eligible subjects) schoolchildren aged 6 to 12 years (58 girls/114 children, 50.8%) took part in this phase. In order to assess child computer use, all parents answered a questionnaire on the number of computers at home (none, 1, 2, 3, 4, or more), child access to computers at home (yes, no, or sometimes), a computer in the child's



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bedroom (yes/no), main use of the computer by the child (Internet search, games, social network sites, and/or schoolwork), frequency of computer use in a typical week (none to every day), and average time spent on the computer per day (less than one hour to more than five hours).

Both studies were approved by the Human Research Ethics Committee of the Universidade Federal de Santa Catarina (protocol 2250/11). All children gave their oral consent, and parents or guardians were asked to authorize their participation by signing an informed consent form.

### *Location, Equipment, and Schedule*

The location of the test sessions is closely linked to the study design and users [37]. In the present study, all sessions were carried out in the computer labs of the participating schools. There were two main reasons for this: (1) children were familiar with the school computer labs because several academic and nonacademic assignments had been completed there, and (2) school computer labs will be the primary setting for the CAAFE survey system in the near future.

In order to record screen logs and user audio during usability sessions, team laptops were equipped with Morae Recorder. Along with Morae Manager, this software kept a record of the children's navigation process through the CAAFE questionnaire, compiling these data for a subsequent review. A personal computer (PC) monitor, keyboard, and mouse were attached to the research team laptops (equipped with a Morae Recorder) once the children became familiar with the computers. Sessions were arranged in advance with school staff and carried out in November and December 2012.

### *Test Session Protocol*

At the start of the session with children, the moderator introduced the task to the entire class. The children were told that we were testing software and would like to improve it with their help. Small groups of children (n=3-6) were taken to the computer lab according to observer availability. Upon arrival at the computer lab, the children were again introduced to the task and a few questions were asked in order to put them at ease (eg, What is your name? How old are you? Do you have a computer at home? What do you enjoy doing on your computer?). The next step was to introduce each child to one of the observers (one observer per child), who told them that an avatar would explain the task. Each child answered the questionnaire as independently as possible while the observer took notes about their performance. The observers were instructed to position themselves at a desk outside the child's line of sight and to give minimal feedback when asked for help. They were also instructed to encourage the child to try again.

The observer protocol included a four-level performance scale (0, 1, 2, 3) for the 25 screens in the CAAFE questionnaire, providing a total score ranging from 0 to 75 (25 × 3=75). Children's requests for help and any other relevant observations were recorded in the appropriate fields. The scoring on the performance scale is interpreted as follows. Performance scale for level 0 signifies that the child is unable to fill out the questionnaire and continue the Web flow alone. It also interprets that child does not know what has to be done. Level 1 on performance scale tells that child has difficulty with typing, navigates and chooses icons slowly and/or with many unnecessary clicks on the screen, and gives long periods of inactivity on the same screen. Level 2 states that child types efficiently but with a few errors. Child may find difficulty in navigating and selecting icons/items. Score 3 on performance level demonstrates that child types efficiently without errors, and can navigate and choose the options quickly and efficiently. Child showing score 3 on the scale is said to be self-assured.

The children's primary task was to complete the entire questionnaire. Immediately after the task, the observers were instructed to record their observations according to four predefined categories: (1) usability issues: child's difficulties in moving forward and answering the questionnaire due to the Web design; (2) audio and visual elements: any specific comments regarding the icons, screens, or avatar speech; (3) system errors: any programming failure displayed by the system or interrupted Internet access; and (4) child performance, comments on computer skills (eg, using the mouse and scroll bar, typing), cognitive and emotional aspects: understanding the speech, reading and writing levels, and the behavior exhibited (eg, calm, agitated, anxious).

After the children completed the CAAFE questionnaire, an interviewer asked them about their satisfaction with the task performed and what they liked or disliked about the questionnaire. We used a standard form created by the research team. A five-level hedonic pictorial scale was used to evaluate specific aspects of the software layout, such as colors/screens, food and activity icons, and avatars. In addition, children were asked to describe their difficulties during the task and to suggest possible changes for improving the software.

## Analysis

### *Quantitative Analysis*

For quantitative analysis, all recorded screen logs were reviewed and analyzed by the first two authors. The primary task was divided into three parts (registration form, diet, and activities) to describe usability issues in specific sections of the CAAFE questionnaire. Time to accomplish the task (average and range) was set from the first click on the "Start" button.

Each recorded screen was carefully reviewed to divide the main usability issues into four broad categories: Web design usability issues, response inconsistencies, requests for help, and system or Internet failure. Information on the response to the question "Have you already done this task before?", name and date of birth, the time of day the children attend school (morning, afternoon, or both), and the number of PE classes were checked using information from the school staff, and served as the basis for assessing response inconsistencies. Height and weight were not measured in the usability study; therefore, the validity of this information could not be checked. Instead, we looked for "unlikely" data on height (eg, 2.5 m) and weight (eg, 10 kg) and categorized this as "response inconsistencies." Height and weight will be measured in the validation study; we will therefore be able to detect mistakes in data entered by the children and to compare the mistakes with the measures previously collected. All registered occurrences were graphically



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presented. The three main errors, namely Web design usability issues, response inconsistencies, and request for help, system bugs, and Internet failure were identified for types II, III, and IV, while type I presented only a single error, that is Web design usability issues.

Usability attributes were compared according to gender, grade (2nd/3rd vs 4th/5th), and access to a computer at home (yes/no). The Wilcoxon-Mann-Whitney test was used in these comparisons because the distributions were either positively (time to accomplish the task, help request, or mean error count) or negatively (total performance score) skewed. We considered differences to be significant at the $P<.05$ level, and used SPSS version 21 for statistical analysis.

### *Qualitative Analysis*

Qualitative Analysis Was Based on Observers' Notes Made After the Children Completed the Caafe Questionnaire and on the Children's Interviews. for the Former, the Most Relevant Usability Issues Were Highlighted Based on Four Prespecified Topics: (1) Children's Difficulties in the Navigation Process (eg, to Move Forward After Answering a Question), (2) Audio and Visual Elements That Would Cause Doubts, or Any Comments Made by the Children, (3) System Errors That Occurred During Completion, and (4) Difficulties and Behaviors Displayed by the Children. the Children's Impressions of the Software Were Described Based on Content Analysis Along With Frequency Distribution of Their Evaluation of the Key Elements of Software Design.

## Results

### Participant Characteristics

The characteristics of the 114 schoolchildren who participated in the study are presented in Table 1. It was found that 3 out of 4 children had a computer at home, while 16 of the 114 students (14.0%) had no access to computers outside the school environment. The average time spent on the computer was almost 10 hours/week, ranging from no use to 49 hours/week of computer use. The most common use of computers by children, as reported by their parents, was schoolwork and social networking, followed by Internet searches. This result partially contrasted with the data reported by the children in the pretest interview, in which games were cited as the most common computer use, followed by social networks (data not shown).

### Quantitative Results

The usability test sessions with 95 of the 114 participants were recorded, providing data for quantitative analysis (19 individual test sessions could not be recorded due to technical problems). The mean time to complete the registration form, diet, and activity sections was 3.5 min (SD 1.9), 5.7 min (SD 1.5), and 3.9 min (SD 1.1), respectively. The mean time to complete the entire questionnaire was 13.7 minutes (SD 3.7) (Task 4). Figure 4 shows the mean error count for each specific task. The mean error count for the entire questionnaire (Task 4) was 7.2 (median 4; range 0-22; interquartile range 11).

The most frequent difficulty encountered in the Task 1 was the request for help in typing in the respondent's name (17/95, 18%). In addition, about 16 of the 95 children (17%) reported they had already answered the questionnaire when in fact they had not. In the diet and activity sections (Task 2 and 3), the most common error was related to Web design usability issues. In the physical activity section, 48% (46/95) of participants saw the "Continue" button before clicking in a response option. Moreover, about 36% (34/95) of children did not report the correct frequency of PE classes per week. Overall, the most common error in completing the questionnaire was difficulty in using the scroll bar (50/95, 52%). The top three error types are presented in Table 2.

Table 3 shows four usability performance indicators according to gender, grade, and the presence of a PC at home. No difference was found between genders. The children attending 4th and 5th grades spent less time completing the questionnaire, asked for help less frequently, had a lower error count, and had a higher overall performance score compared to those attending 2nd and 3rd grades. Children with a PC at home spent less time completing the questionnaire, had a lower overall error count, and obtained a higher performance score compared to those without a computer at home.



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**Table 1.** Characteristics of study participants (N=114).

| Characteristics | | n (%) or mean (SD) |
|---|---|---|
| **Gender** | | |
| | Boys | 56 (49.1) |
| | Girls | 58 (50.8) |
| Age (years) | | 9.2 (1.27) |
| **Grade** | | |
| | 2nd and 3rd | 53 (46.4) |
| | 4th and 5th | 61 (53.5) |
| **Exposure to computer** | | |
| | Computer at home (yes) | 86 (75.4) |
| | No access to computer at home | 28 (24.5) |
| **Access to a computer at home** | | |
| | All the time | 71 (62.2) |
| | Sometimes | 27 (23.6) |
| | No access | 16 (14.0) |
| Computer in the bedroom | | 26 (22.8) |
| Average time of computer use (hours/week) | | 9.8 (8.8) |
| **Computer use** | | |
| | Internet search | 43 (37.7) |
| | Games | 38 (33.3) |
| | Social networking | 54 (47.3) |
| | Schoolwork | 54 (47.3) |

**Table 2.** Top three errors by type in the usability test session.

| Error type | Errors | Options |
|---|---|---|
| Error type I | Web design usability issues[a] | Poor scroll bar visibility in diet and activity sections |
| Error type II | Response inconsistencies | Number of physical education classes per week |
| | | Children reporting they had already completed the task when in fact they had not |
| | | Name misspelled |
| Error type III | Requests for help | To choose an option |
| | | To type in own name |
| | | To select date of birth |
| Error type IV | System bugs and Internet failure | "Continue" button visible before response options appeared on the screen |
| | | Old version of the intensity scale for physical activities used in the questionnaire |
| | | Need to click twice or more to continue the questionnaire |

[a]There was only one error of type I.



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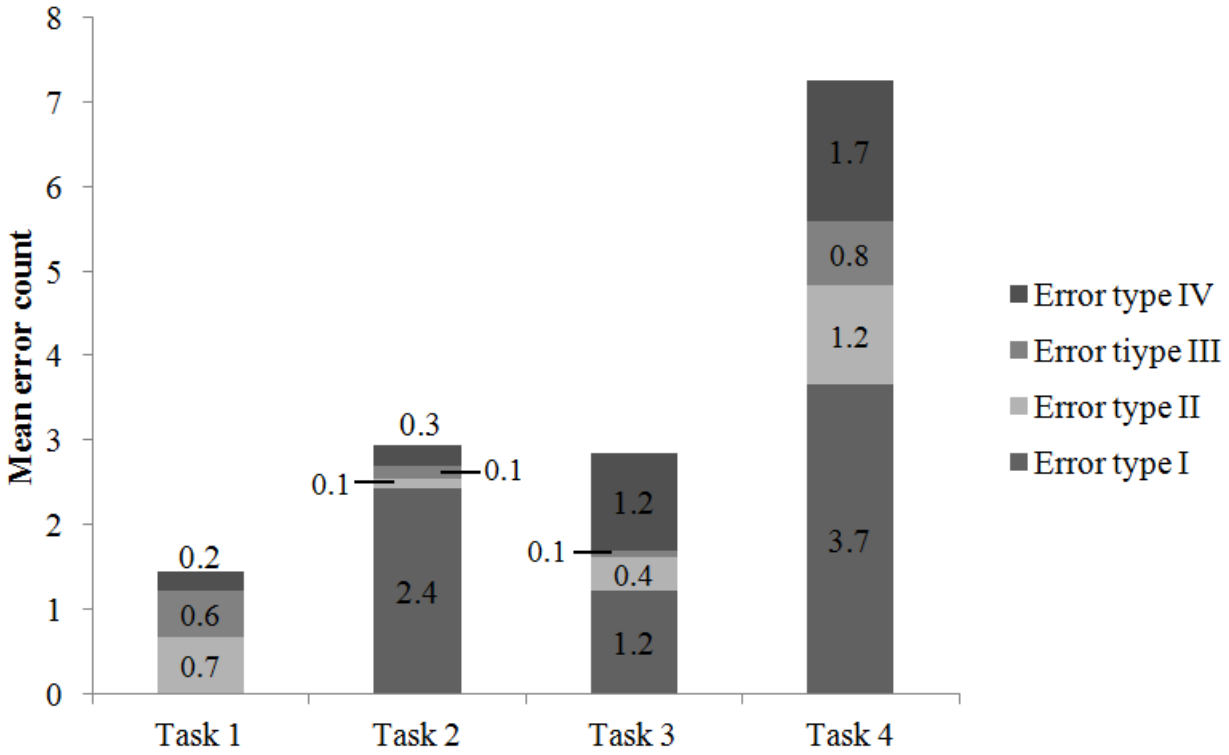
**Table 3.** Usability performance according to gender, grade, and PC at home (N=95). All values are medians.

| | Gender | | | Grade | | | PC at home | | |
|---|---|---|---|---|---|---|---|---|---|
| Usability attributes | Boys | Girls | *P* value[b] | 2nd/3rd | 4th/5th | *P* value[b] | Yes | No | *P* value[b] |
| Time to complete (minutes) | 12.9 | 12.8 | .85 | 13.3 | 12.4 | .030 | 12.3 | 14.9 | <.001 |
| Help request (count) | 0.0 | 0.0 | .50 | 1.0 | 0.0 | .005 | 0.0 | 0.0 | .174 |
| Mean error count[a] | 3.0 | 2.5 | .93 | 8.0 | 2.0 | <.001 | 2.0 | 9.0 | .030 |
| Performance score (0-75) | 70.0 | 72.0 | .63 | 68.0 | 73.0 | <.001 | 72.0 | 64.0 | .002 |

[a]Excluding system errors (type IV).

[b]*P* values for the Wilcoxon-Mann-Whitney test.

**Figure 4.** Mean error count by type according to usability test task. Error type I: Web design usability issues, Error type II: response inconsistencies, Error type III: requests for help, and Error type IV: system bugs and Internet failure.




## Qualitative Results

Table 4 shows the results obtained from the children's interviews regarding satisfaction with the design elements of the CAAFE questionnaire. The majority of children reported a positive evaluation (liked a lot or liked) for the four design elements.

When children were asked about what they disliked about the CAAFE questionnaire, the majority reported liking everything. Two children disliked having to report their height. Two others considered the food section repetitive and the physical activity section boring. One child disliked the avatar's voice, one complained about the sound volume, and another about the need to type in the full name.

When asked about the most difficult part of the CAAFE questionnaire, a majority of children answered that the task was easy to perform. The most common difficulty reported by the children was to recall what they had done the previous day (20/114, 17.5%). Some children (6/114, 5.2%) reported difficulty in remembering their height and weight. Less frequent difficulties cited by the children included typing their own name and that of their mother (4/114, 3.5%), indicating activities organized by an adult (1/114, 0.8%), finding a specific food item (n=1), and reporting the frequency of PE classes (1/114, 0.8%). Only a few children reported something they would like to change in the questionnaire. Some children (12/114, 10.5%) said that additional food/activity/transport options should be included. Some children (8/114, 7.0%) asked to include games related to food and physical activity.



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**Table 4.** Frequency distribution (%) of the children's qualitative evaluation of the design elements (N=114).

| Satisfaction level | Design elements | | | |
|---|---|---|---|---|
| | Colors/Screens (%) | Food icons (%) | Activity icons (%) | Avatar (%) |
| Liked a lot | 103 (90.0) | 78 (68.4) | 85 (74.6) | 103 (90.3) |
| Liked | 8 (7.3) | 29 (25.4) | 20 (17.5) | 10 (8.7) |
| Neutral | 3 (2.7) | 4 (3.5) | 9 (7.9) | 1 (0.9) |
| Disliked | 0 (0.0) | 3 (2.6) | 0 (0.0) | 0 (0.0) |
| Disliked a lot | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |

# Discussion

## Overview

The present study describes an interactive Web-based tool to assess the food consumption and physical activity of schoolchildren in a school-based survey, as well as the results of usability testing, which provided feedback and improved the final version of the CAAFE questionnaire. Quantitative data showed some minor errors and system failures, while qualitative data indicated that children enjoyed the CAAFE questionnaire. Subgroup comparisons demonstrated that children enrolled in higher grades and those who have a PC at home exhibited higher usability performance compared to children in lower grades and those who do not have a PC at home.

## Subgroup Usability Performance Comparisons

Markopoulos and Bekker [38] reported that several characteristics of children such as their capacity and inclination to verbalize, ability to concentrate, and motivation to perform the task may have an impact on usability testing. Gender, knowledge of language and general concepts, and prior experience with a PC are known to affect usability test results and were therefore included in the present study.

No gender differences were observed in usability performance. Gender differences in computer attitudes were reported in the early 1990s as a sex-role stereotyping issue [39], which would hypothetically lead to a gender effect on usability performance. However, recent studies have shown that gender differences are of little significance in this context [40,41]. Hypothetically, children born in the 21st Century have more experience with computers and other new information technology devices regardless of sex, which would explain similar performance in usability testing. These results partially differ from those of Ruggeri [32], who found that girls reported more difficulties in using the NUTRISIM, a new Web-based software for assessing diet of 10- to 14-year-old Brazilian schoolchildren.

As expected, children in higher grades exhibited better usability testing performance on the CAAFE questionnaire compared to those in lower grades. No other Web-based physical activity and/or diet assessment tool has reported such findings. This result is relevant to other Web-based questionnaires targeting a wider age range. The present study showed that children attending 2nd and 3rd grades needed more time to complete the task, asked for help more frequently, had a higher error count, and got a lower performance score. This indicates that special attention should be paid to younger children during data collection to minimize input data errors. However, it is interesting to note that our findings may not be generally applicable to all age groups. Younger children (11 year) demonstrated fewer difficulties in using the NUTRISIM compared to older children (12-14 year), although the latter reported fewer difficulties with regard to comprehension of the questions [32].

Another important factor in usability testing is computer knowledge and skills. Children who are more exposed to computers are expected to perform better in usability tests. In our study, having a computer at home was used as proxy of computer use. As expected, children with a PC at home showed improved usability performance compared to those without one. A preliminary question about computer ownership in the children's families may help teachers and other staff members recognize difficulties in Web-based surveys designed for schoolchildren.

Regardless of differences in usability performance across grade levels and in PC ownership subgroups, the time to complete the task, requests for help, and error count were all acceptable, particularly considering the young age of the participants. First, the mean completion time of 13.6 minutes is deemed reasonable for children, as this is a sufficiently short time to hold their attention and to motivate them to complete the task. This time was even shorter than that reported to complete similar questionnaires for assessing physical activity among young children [18,22,23]. Second, the median of help requests was near to zero. Unfortunately, other questionnaires similar to ours have not provided the necessary information for comparison purposes of the mean error count and performance score.

## Software Improvements

The primary aim of usability testing is to identify and correct usability deficiencies [38]. Based on usability test results with end users, some improvements have been made in the CAAFE questionnaire. The biggest challenge was to make the scroll bar "visible" for children. Despite the fact that it is a common component in Web pages, 50 of the 95 (53%) children could not manage to use the scroll bar correctly. Some of them tried to click on the bar instead of dragging it down. A study with 7-year-old children who were inexperienced with a computer mouse supports this observation, since they were quicker and more accurate in pointing compared to dragging [42]. To solve the scroll bar problem in the CAAFE questionnaire, automated scrolling was set on each screen with a scroll bar. This allows children to see how the scroll bar works and how many food and activity options they can select.



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In order to improve data quality from the question about the number of PE classes, we inserted the option "I don't know." Other minor changes were made without significantly altering the program. First, the "Continue" button was programmed to appear only after an answer was selected, thereby ensuring that children clicked on an option before proceeding to the next screen. Second, the intensity scale for physical activities illustrated in the first version was substituted by a new one.

The need to click two or more times to continue the questionnaire was probably related to the Internet speed, despite the fact that the software was designed and programmed to run with low-speed Internet connections. However, to minimize technical problems in future school-based surveys, the research team will provide minimal system and Internet access requirements to the computer labs of the participating schools, and will inform school principals about these requirements.

Error type II (response inconsistencies) and III (requests for help) were not solved by Web-design modifications. Instead, we expect to minimize these and other errors by way of appropriate training for the school staff where children will take part in the Web-based survey. In usability testing, the observers were trained to provide basic assistance to schoolchildren. However, school staff may be able to help children better with routine Web-based health surveys than outside observers. Tutorials and frequently asked questions on the CAAFE website will be made available to the school staff to standardize adult interventions during completion of the questionnaire.

## Strengths and Limitations

The present study exhibited a number of strengths that deserve to be mentioned. First, the participants and test setting closely mirrored the real context of future CAAFE Web-based surveys. Second, we gathered data using several methodological strategies (eg, direct observation, user interviews, test sessions recordings), which allowed us to obtain both quantitative and qualitative data for usability evaluation. Third, the number of participants was large enough to compare performance indicators across subgroups of interest. Nevertheless, some limitations must also be noted. The results should be interpreted with caution because methods and usability performance indicators were created especially for this study. Even though they are all natural extensions of existing performance indicators in various other contexts (eg, education, market research), direct comparisons with other studies in the field are limited. Furthermore, some children may have been unable to express their difficulties or to make appropriate suggestions for improving the software, or were too timid to do so during the testing sessions.

Accurate diet and physical activity assessment in young children is a challenge for researchers. Parents may help in reporting their children' food intake in the home but often do not know what their consumption is outside the home. More precise methods such as 24-hour recalls and food diaries are costly and put too much burden on the respondents, making them impractical in a school setting. Self-report assessment of diet and physical activity among young children has a number of limitations such as social desirability, difficulties in recalling past events, and classifying and quantifying activities and food consumed. Children younger than 10 years are still developing cognitive abilities to accurately recall diet and physical activity [43,44], which must therefore be taken into account with any instrument designed for this age group. The CAAFE was designed considering the cognitive skills and literacy levels of children aged 7-10 years to respond to the questionnaire. The CAAFE was designed neither to estimate energy and nutrient intake, nor to estimate energy expense or to quantify activities performed. Questions about the size of food portions, or the frequency and duration of physical activities, were therefore not included. In addition, the closed list of foods and activities is not intended to represent the diversity of diet and activities. On the other hand, this simplifies the task of recall by prompting only the relevant food items eaten and the types of physical activities performed on the previous day, and also keeps the questionnaire relatively brief and easy both for completion and for administration. The cognitive task required for estimating portion size, frequency, and averaging may not be compatible with the perceptual and conceptual capacities of children who have not reached the stage of abstract reasoning, at approximately 10-11 years of age [43,44].

## Future Developments

The next step in the Web-based survey system is to provide data on the validity and reproducibility of the CAAFE questionnaire. Data collection is currently under way. It is expected that self-reported diet and physical activities will match the data that will be obtained by trained researchers through direct observation. Once the validity and reproducibility of the CAAFE questionnaire have been properly tested, a Web-based survey will be conducted in all 37 elementary public schools in the city of Florianopolis. The survey will provide data to evaluate response rate, technical and operational problems, as well as the time needed to complete the investigation. After further improvements have been made, a new Web-based survey will be conducted in other Brazilian cities to evaluate its feasibility as a national survey instrument. General information on the survey system is available on a CAAFE questionnaire website [45].

## Conclusions

The profusion of technology and information tools to assess physical activity and eating behavior in children has not been accompanied by adequate assessment of their usability features. This study sought to detail the methodological procedures and to report major usability problems found with end users of the CAAFE questionnaire, as well as to relate them to user characteristics. The results helped to improve the Web design and methodological procedures for future CAAFE Web-based surveys for schools. We expect the methods developed in this usability testing to be applied in other similar Web-based tools to compare and discuss results regarding their potential effects on instrument validity and reliability.



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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CAAFE questionnaire flow.

[WMV File (Windows Media Video), 122MB - resprot_v2i2e31_app1.wmv ]

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## Abbreviations

**CAAFE:** Consumo Alimentar e Atividade Física de Escolares
**ICT:** information and communication technology
**PC:** personal computer
**PDFQ:** Previous Day Food Questionnaire
**PDPAQ:** Previous Day Physical Activity Questionnaire
**PE:** physical education

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Original Paper

# Development and Alpha Testing of QuitIT: An Interactive Video Game to Enhance Skills for Coping With Smoking Urges

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## Abstract

**Background:** Despite many efforts at developing relapse prevention interventions, most smokers relapse to tobacco use within a few months after quitting. Interactive games offer a novel strategy for helping people develop the skills required for successful tobacco cessation.

**Objective:** The objective of our study was to develop a video game that enables smokers to practice strategies for coping with smoking urges and maintaining smoking abstinence. Our team of game designers and clinical psychologists are creating a video game that integrates the principles of smoking behavior change and relapse prevention. We have reported the results of expert and end-user feedback on an alpha version of the game.

**Methods:** The alpha version of the game consisted of a smoking cue scenario often encountered by smokers. We recruited 5 experts in tobacco cessation research and 20 current and former smokers, who each played through the scenario. Mixed methods were used to gather feedback on the relevance of cessation content and usability of the game modality.

**Results:** End-users rated the interface from 3.0 to 4.6/5 in terms of ease of use and from 2.9 to 4.1/5 in terms of helpfulness of cessation content. Qualitative themes showed several user suggestions for improving the user interface, pacing, and diversity of the game characters. In addition, the users confirmed a high degree of game immersion, identification with the characters and situations, and appreciation for the multiple opportunities to practice coping strategies.

**Conclusions:** This study highlights the procedures for translating behavioral principles into a game dynamic and shows that our prototype has a strong potential for engaging smokers. A video game modality exemplifies problem-based learning strategies for tobacco cessation and is an innovative step in behavioral management of tobacco use.

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**KEYWORDS**

smoking cessation; health promotion game; tobacco, quitting self efficacy; behavioral medicine; virtual reality

## Introduction

### Background

Approximately 40-50% of smokers relapse to tobacco use even after a sustained period of abstinence [1-3]. Such high rates of relapse to smoking have stimulated extensive research and theory development directed toward prevention of relapse [4-7]. The effectiveness of relapse prevention interventions, however, has been mixed. A recent systematic review of studies on prevention of smoking relapse showed minimal efficacy for advice, written materials, mailings, and telephone contact [4]. However, the review showed that evidence exists for



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interventions based on behavioral rehearsal to help smokers identify, model, and practice coping strategies to identify and manage smoking cues. Treatment strategies based on these learning principles promote skill acquisition, bolster confidence in coping with smoking cues, and reduce relapse to smoking [8]. A computer game enables individuals to interact with realistic environments and thus is uniquely suited for engaging smokers in skill-building activities for managing urges to smoke. Games and simulations can serve as powerful tools because they encompass many aspects of human learning such as engagement, problem-solving, receiving corrective feedback, and repetition [9-11]. In addition, games are increasingly popular across a wide population. For instance, as of 2011, 47% of game players were women and 37% were over the age of 36 [12]. A recent systematic review of video games for promoting health outcomes showed that video games offer significant benefit for psychological therapy, health education, and disease management [13].

## Status of Cessation Games

Few e-games have been specifically created for promoting smoking cessation in adults. Of those that focus on smoking, one (Rex Ronan) is a game for prevention of smoking in adolescents [14] and another (Blast n Quit) is an arcade-type game in which the users shoot enemies that could compromise their quit attempts. In addition, mobile game apps have been developed, such as Nicot, which allows users to crush virtual cigarettes, and Lit 2 Quit, which guides users through breathing exercises. However, most apps primarily provide assistance in cigarette tracking [15]. None of these games or apps is deeply grounded in applying behavioral change theory to tobacco cessation. Effective tobacco cessation and relapse prevention interventions require a range of complex strategies such as identifying tobacco use triggers, engaging in new substitute coping behaviors, seeking social support from family and friends about tobacco use, modifying one's internal dialogue, and dealing with inevitable slips [6].

Translating these evidence-based strategies into a game calls for an interactive, immersive application in which the user can learn and practice these techniques in a realistic context. Through repeated exposure to conditioned cues to smoke (eg, socializing with friends who smoke), such a game environment may enable smokers to virtually practice and retain coping skills and build crucial self-efficacy skills for resisting smoking urges. In controlled pilot studies, virtually presented smoking cues have been shown to elicit more cravings than static photographs presented during traditional therapies [16-19]. Thus, a system that combines virtually presented tobacco cues with engaging narrative and personally relevant coping skills practice may help smokers overcome barriers to quitting and tobacco abstinence. Unlike virtual craving studies or existing game platforms, our project aims to develop a cessation treatment application using an immersive laptop or tablet-based game environment to help smokers cope with smoking urges and prevent smoking lapses.

## Design of QuitIT: Structure

We envision the game as a series of intertwining episodic stories [20], which link various characters with an ultimate goal. Ultimately, the player will be introduced to a group of 4 travelers stranded at an airport during a blizzard as they sit at a restaurant and relate stories of how they quit smoking. Then, the players will be taken to flashback scenarios in which they attempt to reenact the characters' trigger situations without smoking. Each flashback will open up only after the previous one is resolved with the goal for the player of ensuring that the characters ("travelers") get to tell their story of confronting smoking urges.

## Design of QuitIT: Behavioral Theory

We developed the game play on the basis of principles from Social Cognitive theory (see Figure 1), which have been associated with tobacco cessation [21].

The game employs a narrative story-based structure to promote immersion in the game, emotional arousal, and a sense of direct experience and change in attitude toward tobacco cessation [22,23]. In each episode, the players select some of the character's thoughts and dialogue, which increases narrative immersion. Game mechanic and parallel behavioral constructs are shown in Table 1.

Learning to monitor and manage urges to smoke is a core aspect of tobacco cessation treatment; therefore, an "urge meter" serves as the hook to engage decision-making and game play [24]. If a player fails to enact sufficient coping strategies their "urge meter" continues to increase until he or she "slips" and smokes followed by an opportunity to play the scene again to achieve mastery, which is a scenario similar to what the smokers would encounter in everyday life. Thus, our system has the core aspects of a serious game in that it presents a clear goal and rules for the player within the context of teaching behavior change [20].

**Table 1.** Game mechanics and related behavioral constructs.

| Game mechanic | Construct |
|---|---|
| Story, narrative, and internal dialogue | Identification |
| Menu of coping strategies appears in game | Knowledge |
| Players must match optimal coping strategy to each smoking cue | Skills |
| Characters act out coping methods | Self-efficacy |
| Characters succeed at avoiding smoking and are rewarded | Expectancies |



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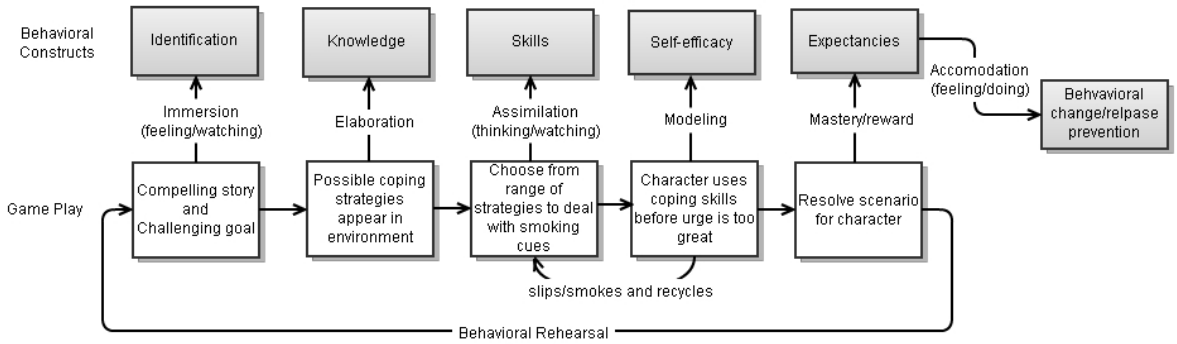
**Figure 1.** Integration of game mechanics with behavior change theory.




## Design of QuitIT: Prototype

To develop the initial prototype for testing, researchers from Memorial Sloan-Kettering Cancer Center (MSKCC) in New York City (Ostroff, Burkhalter, and Krebs) performed a series of in-person and remote meetings with the design team of Muzzy Lane (ML), a Boston-based game development company, to discuss methods for translating behavioral coping strategies into a game environment. The ML team then developed an initial game design approach consulting weekly with the MSKCC team and sharing files via a Web-based project management program to review screenwriting and design features. Our game design followed an iterative testing process generally recommended in software development, first creating and evaluating an alpha version of a functioning prototype [25]. Before creating a working prototype for alpha testing, we convened a patient advisory group of 4 volunteers from MSKCC's patient volunteer program who had a history of smoking. The advisory group was presented with a non-electronic mock-up (using board-game metaphors) to allow the team to review the game concepts and play. Their feedback (1) reinforced the idea of using a narrative storytelling element and (2) suggested that the characters should be able to enact internal struggles as well as confront environmental cues to smoke. This final element was integrated into the game play.

Our alpha version was based on one trigger episode in which a character, Ray, struggles with trying not to smoke after dinner. The scene and dialogue between the character (Ray) and other virtual characters (his wife and teenage daughter) were scripted by a professional screenwriter and recorded in a sound studio (see Figures 2-4 for screenshots). This paper describes feedback from the alpha testing phase performed with tobacco cessation experts (n=5) and current and former smokers (n=20) with the aim of providing information useful for development of the health game.



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**Figure 2.** Introduction to Ray, the main character.

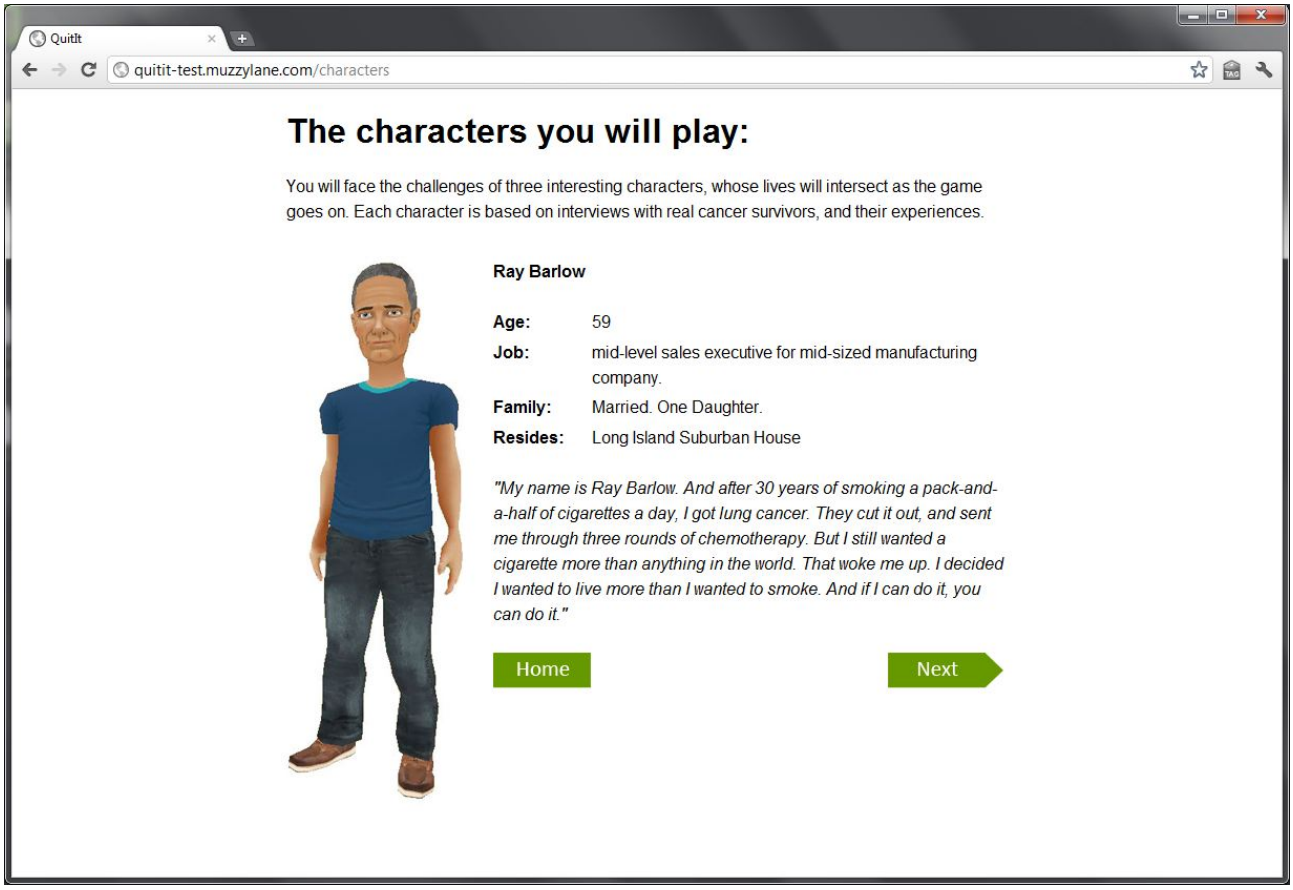


**Figure 3.** Players choose how Ray thinks through a cue situation.




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**Figure 4.** Example of using behavioral coping strategy.


## Methods

### Overview

Our evaluation methods were similar to those advocated by Moreno-Ger et al for assessing serious games and as applied in alpha testing protocols for health games [26,27]. We employed both expert and user methods, and the user methods consisted of dual observational and survey approaches.

### Expert Panel Review

A 90-minute semi-structured interview was conducted to introduce the game and solicit feedback on the prototype from 5 external consultants with expertise in the development and evaluation of tobacco cessation interventions. These consultants were provided with off-site access to the prototype game and were requested to provide specific feedback on the relevance, usability, and utility of the game. The group interview was digitally recorded for content analysis.

### Participant Recruitment

We recruited 20 adults who were former and current smokers treated by the MSKCC Tobacco Cessation Program to serve as game testers. Participants were contacted and screened for interest by phone. Eligible participants were individuals over 30 years of age, with a history of cancer and smoking, and with sufficient dexterity and vision to manipulate a computer and mouse. Interested smokers were scheduled to evaluate the game at the MSKCC Communication Skills Training Laboratory, a facility with large-screen monitors and digital video recording devices. Once the participants provided informed consent, Dr. Krebs conducted the patient feedback sessions. A $25 cash incentive for participation/travel reimbursement was provided. The study was approved by the MSKCC Institutional Review Board.

### End-User Testing

To gather user feedback on the prototype, we followed a mixed methods protocol (ie, structured questions and “talk aloud”), which is recommended for usability testing [26]. Game testers were given a brief introduction about the use of the game followed by 30 minutes of free-form game play. Testers used the same iteration of the game as that used by the expert panel. Because the ultimate goal is for the game to be self-directed, only minimal in-person instruction was provided. Testers were encouraged to verbalize their thoughts and raise questions as they played through the prototype of an after-dinner scene with the character “Ray” and his family. After exploring the scene, the testers were asked a series of open- and closed-ended Likert-type questions that assessed the game interface, relevance of tobacco cessation content, overall experience, and cultural appropriateness, as suggested for the evaluation of health communication programs [28]. In addition, usability was assessed using the 10-item System Usability Scale (SUS). The wording was slightly modified to represent “game” instead of “system.” The SUS is scored on a scale of 1-100 [29]. Testing sessions were video-recorded showing the screen and user for subsequent thematic analysis.

### Analysis

Data sources consisted of audio/video recordings of user testing sessions, session notes, and closed and open-ended responses to the assessment. Descriptive statistics were calculated for quantitative measures. Drs. Krebs and Ostroff reviewed recordings, open-ended responses, and session notes and identified key themes according to the standards of analysis for



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qualitative data [30]. Themes were discussed and finalized through a consensus process.

## Results

### Expert Panel Feedback

The Expert Panel provided the three primary themes and suggestions as follows:

1. *A clear and compelling initial orientation about the goal of game play and explicit instructions for using the game environment are required*. Experts recognized that our intended users are not experienced game players and therefore suggested that greater attention be paid to "setting the stage" and framing the game. Similarly, the experts suggested that less experienced game players might find it difficult to engage the interactive elements of the game environment and suggested that a narrator and/or "help" icon could help players more easily navigate the game environment. Although they liked the overall concept of selecting "Counter Thoughts" as coping strategies, the experts felt that either a demonstration or explicit coaching from a narrator would be required to reduce confusion in distinguishing between the bubbles showing "Counter Thoughts" versus those for Internal Dialog.
2. *The game characters should exemplify the demographics of a broad range of users.* Experts discussed the pros and cons of having users play themselves or a game character. One expert suggested that being able to build, select, and personalize the character is a fun way to increase the players' game engagement. All agreed that having choices with regard to character selection and options for play will enhance relevance.
3. *Make the game more engaging by amplifying feedback to the user for helpful versus unhelpful game decisions*. Several comments focused on the form and functionality of the "urge meter." The experts found the changing color (green, yellow, orange, red) to be too subtle and suggested that we add "happy" or "loser" sounds depending upon whether the player made a game decision that raised or lowered the urge meter ("the meter should be more lively"). Two of the experts suggested that some sort of familiar gauge (speedometer, gas tank [E/F] meter) would provide more compelling visual feedback. One expert suggested adding more explicit praise and encouragement for constructive use of coping strategies. Another suggested that effective use of coping strategies be reinforced with evidence of the character having powered-up (acquired some wisdom or mastery of coping strategy) or with a summary debriefing statement what the player has learned in prior game play.

### End-User Characteristics

The demographic characteristics of the current or former smokers (n=20) from the MSKCC Tobacco Cessation Program who were recruited as volunteers for testing are shown in Table 2. Participants spanned a wide range of ages from 31 to 74 years, with a mean age of 56 years. Participants were mostly women (14/20, 70%), with a high representation (40%) of racial/ethnic minorities. Current smokers comprised 65% (13/20) of the sample. Regarding computer and gaming experience, 30% (6/20) did not use a computer even occasionally and 80% (16/20) had little or no prior experience of games played on a computer or game console. We did not assess the use of other game modalities (eg, mobile apps).

### End-User Feedback

Items evaluated four important domains as follows: User Interface, Usability, Content, and Overall Experience. User interface, defined by the ability to figure out how to play the game, understand the instructions and text, know what a user is supposed to do, comfort in playing the game, and professionalism was rated at a moderate to high level using a 5-point Likert scale ranging from 3.00 to 4.65 (see Tables 2 and 3). Compared to other commercial computer systems, the SUS (1-100) summary score was in the average range (mean 67.00) (Table 3) [29]. The content items assessed the game's utility in helping users manage smoking urges (mean 2.90), prevent relapse (mean 3.65), and apply the content to their own lives (Table 4). Testers rated content relevance from a moderate to a high level (mean 4.10). In terms of their game experience, testers reported moderate to high satisfaction (mean 3.75), would strongly recommend it to others (mean 4.70), and felt that the game kept their attention (mean 3.50).

Finally, responses from open-ended questions and patient comments were transcribed and thematically coded. Six primary themes emerged from the qualitative feedback:

1. *The user interface was challenging until some instructions regarding game play were provided.* Testers described that it was easy to play "after initial guidance" and that the "meter going up meant I was doing well." On the other hand, testers said "Instructions needed to be more explicit." It became clear that our completed version will require the game to begin with a demonstration and orientation to the game features. The simple clickable user interface succeeded in making the game accessible in that as soon as testers were given a brief introduction, even players who had never used a computer before were able to use it easily.
2. *Testers strongly identified with the smoking-related trigger situations and Ray's (the primary character) struggle to remain smoke-free.* When asked what they liked most about the game, testers strongly affirmed the authenticity of the after dinner scene in which they played the character, Ray. For instance, testers said "I knew what he was going through. I related to the situations," and "I related to Ray; I was feeling everything he was feeling." Testing revealed that users strongly identified with the character and dialogue of the situation. No user stated that he or she would rather have played a character representing him or herself. Testers responded that: "I found myself projecting a lot" and "The thought choices were spot on with what you'd do or say to yourself."
3. *The process of game play demonstrated both behavioral and cognitive coping skills for remaining smoke-free*. Testers responded that the game play was useful for teaching and reinforcing coping skills: "I like that I was brought along as the character, since it introduced me to new ideas about how to not smoke," and "[The game] shows you how not to escalate situations and make things worse."



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4. *Testers made suggestions for broadening the characters' experience, adding coping situations, and for reflecting their own experiences with cancer.* "He needs to be able to do more things." Testers suggested puzzles, reading, going outside, exercising, doing artwork, praying, and clearing dishes. They noted that it should be "More in-depth about harsh realities [of smoking]." Testers expressed desire for a "Female character in a management job", that the game needed a "dark-skinned character" and that we should "Add more races and realistic situations for those races."
5. *Testers noted suggestions for making the game more fun and fast-paced.* While testers found the game interesting and engaging, they also expressed a desire for it to have more elements of fun. They stated that we "Need to perk it up," and that Ray was a "glum character." In line with typical expectations of a game, testers also wanted a reward structure: "I wanted a reward. I wanted it to keep score in the end", and that "Winning reinforces positive coping." They thought that the action should move along more quickly as well and found that "All the choices slowed you down" and "took too long to read."
6. *The game offers strong potential to be useful for preventing smoking lapses.* In their summary comments, testers remarked that the game "Reinforced tools and strategies I've learned," that it would "Help me in situations where I have a pattern and need to see it differently," and that "Because I'm slipping, it's a good reminder, feels motivating." Participants also liked the computer model in that "Interactive is the way people are going to be taught," that the "Computer idea is good because people can relate to it," and "I was fascinated because I've never seen anything like it." One patient noted that "It raised my awareness more so than ads on TV" in reference to graphic anti-smoking ads appearing in the New York City area.

**Table 2.** Phase I prototype evaluation: participant characteristics (n=20).

| Participant characteristics | | n (%) |
|---|---|---|
| **Sex** | | |
| | Male | 6 (30%) |
| | Female | 14 (70%) |
| **Race/ethnicity** | | |
| | African-American | 7 (35%) |
| | Hispanic | 1 (5%) |
| | Non-Hispanic White | 12 (60%) |
| **Education** | | |
| | High school or less | 4 (20%) |
| | Some college/degree | 6 (30%) |
| | Graduate/professional | 10 (50%) |
| **Smoking status** | | |
| | Current | 13 (65%) |
| | Former | 7 (35%) |
| **Use a computer at least occasionally?** | | |
| | Yes | 14 (70%) |
| | No | 6 (30%) |
| **Use a game console?** | | |
| | Seldom/never | 16 (80%) |
| | Every few days | 2 (10%) |
| | Once or more a day | 2 (10%) |



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**Table 3.** Phase I prototype evaluation: interface and usability results (n=20).

| Game evaluation | Scale | n (%) | Mean (SD) |
|---|---|---|---|
| **User interface** | | | |
| How easy or difficult was it to figure out how to play? | 1=Very difficult | 0 (0) | 3.55 (0.89) |
| | 2=Difficult | 2 (10) | |
| | 3=Neutral | 8 (40) | |
| | 4=Easy | 7 (35) | |
| | 5=Very easy | 3 (15) | |
| How easy or difficult was it to understand the instructions? | 1=Very difficult | 1 (5) | 3.70 (1.13) |
| | 2=Difficult | 2 (10) | |
| | 3=Neutral | 4 (20) | |
| | 4=Easy | 8 (40) | |
| | 5=Very easy | 5 (25) | |
| How easy or difficult was it to see the on-screen text? | 1=Very difficult | 0 (0) | 4.65 (0.59) |
| | 2=Difficult | 0 (0) | |
| | 3=Neutral | 1 (5) | |
| | 4=Easy | 5 (25) | |
| | 5=Very easy | 14 (70) | |
| How easy or difficult was it to know what you were supposed to do? | 1=Very difficult | 2 (10) | 3.00 (1.08) |
| | 2=Difficult | 4 (20) | |
| | 3=Neutral | 7 (35) | |
| | 4=Easy | 6 (30) | |
| | 5=Very easy | 1 (5) | |
| How easy or difficult was it to know whether you were doing well? | 1=Very difficult | 1 (5) | 3.65 (1.04) |
| | 2=Difficult | 1 (5) | |
| | 3=Neutral | 6 (30) | |
| | 4=Easy | 8 (40) | |
| | 5=Very easy | 4 (20) | |
| How comfortable or frustrated did you feel interacting with the game? | 1=Very frustrating | 0 (0) | 3.85 (1.14) |
| | 2= Frustrating | 4 (20) | |
| | 3=Neutral | 2 (10) | |
| | 4= Comfortable | 7 (35) | |
| | 5=Very Comfortable | 7 (35) | |
| How would you rate the professionalism or production value of the game? | 1= Poor | 2 (10) | 3.95 (1.23) |
| | 2=Somewhat poor | 0 (0) | |
| | 3=Moderate | 3 (15) | |
| | 4=Good | 7 (35) | |
| | 5=Very good | 8 (40) | |
| **Usability** | | | |
| Summary score | 0-25 | 0 (0) | 67.00 (14.81) |
| | 26-50 | 2 (10) | |



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| Game evaluation | Scale | n (%) | Mean (SD) |
|---|---|---|---|
| | 51-75 | 12 (60) | |
| | 76-100 | 6 (30) | |

**Table 4.** Phase I prototype evaluation: cessation content and overall rating (n=20).

| Evaluation questions | Scale | n (%) | Mean (SD) |
|---|---|---|---|
| **Smoking cessation content** | | | |
| How much did you learn about ways to manage smoking urges? | 1=Not much at all | 2 (10) | 2.90 (0.91) |
| | 2=Learned some things | 3 (15) | |
| | 3=Learned a little bit | 10 (50) | |
| | 4=Learned a great deal | 5 (25) | |
| Would you use this game to prevent smoking relapse in the future? | 1=Definitely not | 1 (5) | 3.65 (1.04) |
| | 2=Probably not | 3 (15) | |
| | 3=Might or might not | 4 (10) | |
| | 4=Probably would | 10 (50) | |
| | 5=Definitely would | 2 (10) | |
| Will you be able to apply what you learned to your home environment? | 1=Definitely not | 0 (0) | 4.10 (1.07) |
| | 2=Probably not | 3 (15) | |
| | 3=Might or might not | 1 (5) | |
| | 4=Probably would | 7 (35) | |
| | 5=Definitely would | 9 (45) | |
| **Overall experience** | | | |
| Please rate your overall experience with the game | 1=Extremely dissatisfied | 1 (5) | 3.75 (0.85) |
| | 2=Dissatisfied | 0 (0) | |
| | 3=Neutral | 4 (20) | |
| | 4=Satisfied | 13 (65) | |
| | 5=Extremely satisfied | 2 (10) | |
| Would you recommend the game to others? | 1=Definitely would not | 0 (0) | 4.50 (0.69) |
| | 2=Probably would not | 1 (0) | |
| | 3=Might or might not | 2 (10) | |
| | 4=Probably would | 6 (30) | |
| | 5=Definitely would | 12 (60) | |
| To what extent did the game keep your attention? | 1=Definitely not | 0 (0) | 3.50 (0.61) |
| | 2=Not very much | 1 (5) | |
| | 3=Somewhat | 8 (40) | |
| | 4=Very much | 11 (55) | |

# Discussion

## Principal Results

The aim of the present study was to inform the development of a game for enhancing the skills required for coping with smoking urges. We employed a combination of qualitative and quantitative evaluation methods from content experts and end-users. Findings from the tests centered on (1) usability, (2) character identification, and (3) player engagement.

For improved usability, the experts and users suggested the need for an introduction with clearer instructions, a demonstration of game play, and a help menu available throughout game play. User ratings of the interface ranged from difficult to easy, with the poorest scores for “knowing what you were supposed to do” and “figuring out how to play.” A usability score of 67 for this



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prototype falls at the 49th percentile compared to that obtained in other studies using the SUS scale [29]. Such usability results are in line with our qualitative data, which indicate that users and experts wanted more explicit instructions. This feedback is similar to that reported by a similar population of older cancer patients in evaluation of a treatment decision-making game [27]. In addition, patient testing showed problems with the design of the urge meter as many noted that they did not attend to it. During alpha testing of a dietary intervention game, Beltran et al [31] also found that testers wanted clear instructions and had difficulty attending to a similar feedback meter. More attention to setting up game play in the final version is warranted as clarity of goals and ease of use is critical for ensuring player engagement. These data indicate that the next iteration will need to improve the balance between story immersion and game mechanics.

Users identified with the characters, which indicated that the writing and script accurately reflected challenging situations smokers typically encounter. A player's ability to identify with and interact as a game character is particularly important for narrative suspension of disbelief and is the key difference between a game-based intervention and one that focuses on more traditional health education approaches. Comments indicating that players found themselves "projecting" and "feeling everything he was feeling" indicate that the narrative engaged players' emotions, which can be important for maintaining interest in playing, shifting attitudes toward behavior change, and promoting retention of learning [32,33]. Indeed, functional magnetic resonance imaging studies with the chemotherapy-related Re-Mission game have suggested that players take on the goals of the game characters, with the game activating brain centers related to reward and motivation [34]. The design team had lengthy discussions about the implications of having the players create characters representing themselves on engagement. It appears this option was not required as players readily identified as the characters with none stating they would rather have created their own avatars. On the other hand, both experts and users suggested adding characters and situations that reflect greater diversity across socio-economic and ethnic/racial backgrounds. It is interesting to note that testers who seemed to have less insight into their own smoking gave the game more positive reviews than others who could readily discuss quitting strategies. Thus, a game modality may be particularly suited to communicating and teaching cessation skills to those who benefit from experiential learning. This also suggests a challenge in designing a game that is equally interesting and helpful for smokers at various stages of change. It would need to employ and exemplify both cognitive and emotional processes most relevant in pre-Action stages as well as behavioral strategies to help those starting out with changes [35].

Third, the game held users' attention and promoted expansion of learning about their own behaviors. Comments such as, "[it taught me] to be mindful of thoughts and [that you can] can stop yourself to pause and make a choice" and "I learned substitution, distraction, and avoiding cues" indicate that players took away new ideas for how to cope with urges to smoke. One player even observed that choosing assertive and conflict-diffusing dialogue decreased the urge meter, a subtle yet important insight gleaned from the game mechanics. This evidence of high-level learning is encouraging as the game itself did not take a didactic approach to these concepts - players arrived at these conclusions simply via the characters' modeling within the game. On the other hand, users and expert reviewers wanted a more integrated scoring system and to improve the "fun" aspects of the game. This is important as perception of a game as enjoyable has been found to be positively correlated with self-efficacy and intentions for behavioral outcomes [36]. It is encouraging that users and experts clearly see the utility of the game, which is essential to achieving "buy-in" from both a health care provider and patient/client perspective.

## Limitations

The primary goal of this study was to gather feedback to inform further development of the game. Protocols specific to evaluating health games, such as those outlined by Moreno-Ger et al [26], were not yet available when we performed our testing. Nevertheless, we followed standard methods for developing health interventions [28], which were quite similar to those reported previously, and they yielded useful results. The number of individual interviews and testing sessions was adequate to achieve saturation of data [26,30]. One limitation of our study was use of the SUS, which as Moreno-Ger et al note is most applicable to assessing business software applications [26]. The items, however, primarily focus on ease of use and were helpful in quantifying that aspect of the game. The population was diverse in terms of age, race, and gender, but included only smokers with a history of cancer. While this is our target end-user population, it may limit the generalizability of the final game as applied to other populations.

## Comparison With Previous Studies

A multitude of smartphone apps and interactive "tailored" programs are available for smoking cessation [37-39], but these focus on straightforward education and behavioral management, what Winn [40] refers to as a "third-person symbolic" experience. On the other hand, health behavior change games represent a promising new application for games as they shift from an emphasis on objectivist representation of knowledge (ie, "smoking carries these risks", "use this method to stop") to a constructivist or problem-based approach. Problem-based learning engages the user on a first-person basis as one moves through an environment, encountering and working through situations. Such an engagement framework [10] facilitates key features of active learning, namely, defining a task, practicing skills, taking risks without negative consequences, and receiving immediate feedback, all of which increase motivation, which is key in effecting behavior change [22,23,41-43]. The immersion of a user into a game character's narrative allows the user to code information in a "first-person nonsymbolic" experience and likely engages emotional arousal more effectively than other types of interventions [32]. The process of making decisions and skill practice in a realistic environment thus improves the potential for meaningful learning and maintenance of behavior change [22]. Our game's focus on narrative structure and integration of a range of evidence-based



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strategies for tobacco cessation offer significant strength as an innovative behavioral intervention method.

## Future Directions

A large number of improvements to the game are being integrated into the next version as a result of the alpha testing feedback. We addressed a number of usability issues by replacing the thermometer-style "urge meter" with a large pressure gauge meter. The urge triggers encountered in the storylines now clearly affect the urge to smoke (urge needle) and the user interface displays the triggers that have the biggest impact on the urge needle (see Figure 5). This new interface clearly indicates to players when and why they are in danger of a slip-up. Our prototype had several different modes for coping that proved confusing, such as searching the environment for coping tools. This has been streamlined so all coping tools, strategies, or items are presented to the player as a menu with between two to four choices. When a coping method is selected, there is immediate feedback; the urge needle goes down as appropriate, the strongest urge triggers re-arrange themselves if necessary, and a scoring system rewards the player for effective choices. A tutorial is included in the first episode, and all episodes conclude with an After Action Report to further illustrate the relationship between the effectiveness of particular strategies against certain situations. These improvements are designed to facilitate quick understanding of the game, which allows the player to focus on recognizing triggers and analyzing the coping methodologies that are effective against specific triggers. In addition, there has been a marked improvement in character animation, storytelling, and overall production values.

**Figure 5.** Example of revised game interface.


## Conclusions

Consistent with recent survey findings that smokers would be interested in using a video game for cessation [44], our results from the alpha prototyping phase show strong potential for a video game modality to enhance skills for coping with smoking urges. Video games are increasingly popular; indeed, "strategy" games, the genre under which our game falls, was the most popular computer game genre in 2011 comprising 27% of sales [12]. A coping skills game offers significant advantages to traditional behavioral treatment in that it can be practiced multiple times at smokers' convenience to address their specific smoking triggers, can create realistic simulations that provide behavioral rehearsal opportunities that are not possible in real-world treatment settings (eg, social smoking situations), and can be readily disseminated to a broad audience of tobacco-dependent persons over a secure connection without resource-intensive one-on-one programs. In the next phase of game development, we will conduct a randomized clinical trial (Best Practices + Smoking Cues Coping Skills Game vs Best Practices Only) to test whether the game increases coping self-efficacy and smoking abstinence among hospitalized cancer patients.



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## Conflicts of Interest

The project was funded by the NIH under a Small Business Development Award mechanism provided to Muzzy Lane Software. The academic research team from Memorial-Sloan Kettering conducted all research and data analysis and declares no commercial interest in the outcome of the study.

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## Abbreviations

**ML:** muzzy lane
**MSKCC:** Memorial Sloan-Kettering Cancer Center
**SUS:** System Usability Scale



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Original Paper

# Development of an Electronic Alcohol Screening and Brief Intervention Program for Hospital Outpatients With Unhealthy Alcohol Use

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## Abstract

**Background:** Alcohol screening and brief intervention is recommended for widespread implementation in health care systems, but it is not used routinely in most countries for a variety of reasons. Electronic screening and brief intervention (e-SBI), in which patients complete a Web-based questionnaire and are provided with personalized feedback on their drinking, is a promising alternative to practitioner delivered intervention, but its efficacy in the hospital outpatient setting has not been established.

**Objective:** The objective of our study was to establish the feasibility of conducting a full-scale randomized controlled trial to determine whether e-SBI reduces alcohol consumption in hospital outpatients with hazardous or harmful drinking.

**Methods:** The study was conducted in the outpatient department of a large public hospital in Newcastle (population 540,000), Australia. Adults with appointments at a broad range of medical and surgical outpatient clinics were invited to complete an e-SBI program on a laptop, and to report their impressions via a short questionnaire. Follow-up assessments were conducted 2-8 weeks later by email and post.

**Results:** We approached 172 outpatients and 108/172 (62.8%) agreed to participate. Of the 106 patients capable of self-administering the e-SBI, 7/106 (6.6%) did not complete it (3 due to technical problems and 4 because they were called for their appointment), 15/106 (14.2%) indicated that they had not consumed any alcohol in the past 12 months, 43/106 (40.6%) screened negative for unhealthy alcohol use (scored less than 5 on the Alcohol Use Disorders Identification Test Consumption [AUDIT-C] questions), 33/106 (31.1%) screened positive for hazardous or harmful drinking (AUDIT-C score 5-9), and 8/106 (7.5%) screened positive for possible alcohol dependence (AUDIT-C score 10-12). Among the subgroup with hazardous or harmful drinking, 27/33 (82%) found the feedback on their drinking very, quite, or somewhat useful, 33/33 (100%) thought the intervention would appeal to most or some of the people who attend the service, and 22/30 (73%) completed the follow-up. We also found that some well established procedures used in trials of e-SBI in the primary care setting did not translate to the hospital outpatient setting (1) we experienced delays because the e-SBI program had to be developed and maintained by the health service's information technology staff for security reasons, (2) recruiting patients as they left the reception desk was impractical because patients tended to arrive at the beginning of the clinics with few arrivals thereafter, and (3) use of a laptop in a fixed location resulted in some patients rushing through the e-SBI so they could return to their seat in the area they had been advised to wait in.

**Conclusions:** e-SBI is acceptable to outpatients and with some adaptation to organizational and physical conditions, it is feasible to recruit and screen patients and to deliver the intervention without disrupting normal service provision. This suggests that e-SBI could be provided routinely in this important setting if shown to be efficacious.



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**KEYWORDS**

alcohol; drinking; screening; brief intervention; hospital; outpatients; Internet

## Introduction

### Alcohol Screening and Brief Intervention

Unhealthy alcohol use is a leading risk factor for premature death and disability globally [1]. Alcohol screening and brief intervention reduces unhealthy alcohol use in primary care patients who are not dependent on alcohol [2], and routine implementation in a variety of health care settings is recommended [3-5], but underutilized [6]. In Australia, for example, counseling or advice in relation to alcohol is provided at a rate of about .4 per 100 encounters in the primary care setting [7]. Provider-level barriers to the implementation of screening and brief intervention include time constraints, insufficient training, and the risk of damaging rapport with patients [8].

Electronic alcohol screening and brief intervention (e-SBI) is a promising alternative because it circumvents many provider-level barriers. Systematic reviews and meta-analyses of computer-delivered interventions have generally been positive [9-13], but most randomized controlled trials have studied computer literate young people with high rates of binge drinking [14], and most reviews have concluded there is a need for further research to establish the efficacy of e-SBI in other populations and settings [9,11,13,14]. Although there is solid evidence for the acceptability of e-SBI in primary health care [15] and the emergency department [16-18], and some evidence for efficacy in these settings [19-21], there appear to be no trials testing the acceptability, feasibility, or efficacy of e-SBI in the hospital outpatient setting aside from one trial of a brief computer-delivered intervention for alcohol use limited to pregnant women attending a hospital prenatal clinic [22]. Indeed, a recent systematic review of the effectiveness of drug and alcohol interventions offered opportunistically to patients aged 16 and older (excluding pregnant women) presenting to an acute hospital outpatient setting for any reason other than specifically for alcohol or illicit drug misuse treatment did not identify any trials testing the efficacy of e-SBI [23].

### Hospital Outpatient Settings

The hospital outpatient setting serves a large proportion of the population. In Australia, a country of 23 million people [24], 16.7 million service episodes were delivered in 2010-11 [25]. Although most research regarding the barriers to implementation of screening and brief intervention for unhealthy alcohol use by health care providers has been conducted in the primary care setting [8], the existing literature regarding alcohol interventions in the outpatient setting [26-31] suggests the barriers are similar. The overall aim of this study, therefore, was to determine the feasibility of conducting a full-scale randomized controlled trial (RCT) in the outpatient department of a large public hospital to determine whether e-SBI reduces alcohol consumption in hospital outpatients with hazardous drinking (a drinking pattern that increases the risk of harmful consequences for the user) [32], and harmful drinking (where damage to health is already occurring) [32]. The objectives of this study were to (1) adapt an existing e-SBI program for university students [33,34], to hospital outpatients, and ensure it complies with the health service's information technology (IT) systems, (2) assess the feasibility of recruiting hospital outpatients with hazardous or harmful drinking, (3) test delivery in the outpatient waiting area, (4) gauge acceptability and identify any refinements needed, and (5) estimate likely follow-up rates.

## Methods

### Ethical Approval

Ethical approval for this study was obtained from the Hunter New England Human Research Ethics Committee (08/12/17/5.16) and the University of Newcastle Human Research Ethics Committee (H-2009-0332).

### Study Design and Setting

This single-arm feasibility study was conducted in the Ambulatory Care Center (outpatient department) at the John Hunter Hospital, a large public hospital located in Newcastle (population 540,000) [35], Australia. A broad range of medical and surgical outpatient services are provided by the Ambulatory Care Center including rehabilitation, transplant, vascular access, vascular surgery, pain management, oral and maxillofacial surgery, colorectal care, ears, nose and throat and head and neck surgery, general surgery, neurosurgery, opthalmology, orthopaedics and urology. Patients attending these clinics must have a written referral from their primary care provider and may bypass smaller hospitals in order to access specialist services provided by this large public hospital. Accordingly, patients may come from up to 500 kilometers away.

### Participants and Study Procedure

Adult (18 years of age or older) outpatients capable of self-administering the e-SBI instrument were eligible to participate. The recruitment process was modelled on research conducted by Kypri and colleagues in a New Zealand university student primary care service [36]. Research assistants located in the waiting area of the outpatient department were trained in the application of a study protocol stipulating they should invite the next patient leaving the reception desk to participate and to log consenting participants into the e-SBI program using a unique identifier. This identifier allowed us to link the paper-based data provided by participants with the data collected electronically and made it possible for participants who were interrupted (eg, were called for their appointment before completing the e-SBI) to continue the e-SBI rather than start again. As each participant finished, research staff would approach the next patient leaving the reception desk. The aim of this procedure was to minimize the risk that the research staff would exercise discretion in who to invite that could bias estimates of participation.



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Eligible outpatients who gave written informed consent were invited to complete the e-SBI instrument and to provide feedback on their impressions of it via a short pen-and-paper questionnaire while waiting for their appointment. Participants were advised to stop the e-SBI if they were called for their appointment, so as not to interfere with normal service provision, but were asked to return to the waiting area to complete it before leaving the hospital.

Participants were followed-up using an adapted tailored design method [37] in which they received a letter reminding them about the study and advising that they would receive a brief follow-up questionnaire in the next few days. Although we sought ethical approval to include a supermarket voucher, an evidence-based strategy for increasing participation [38,39], we could only include a pen because the Hunter New England Human Research Ethics Committee had a policy of not approving "the offering of vouchers" as this was "regarded as an incentive and in breach of statement 2.2.10 of the National Statement on Ethical Conduct in Human Research (2007)."

Participants who reported consuming alcohol in the past 4 weeks (ie, those who might be eligible for inclusion in a trial) were followed-up in December 2010 (ie, 2-8 weeks after recruitment) regardless of the actual date of recruitment. This procedure was adopted in preference to rolling follow-up due to resource constraints. Participants who provided an email address received an email message with a link to the brief Web-based follow-up questionnaire, while those who did not provide an email address received a paper questionnaire by post. Up to three email/postal reminders were sent following the initial invitation to complete the follow-up surveys. Participants who did not respond to the initial and reminder emails/postal surveys were followed-up by telephone.

### e-SBI Program

The e-SBI program for hospital outpatients was based upon the Tertiary Health Research Intervention Via Email (THRIVE) program, which has been shown to reduce alcohol consumption among university students with hazardous or harmful drinking [33,34]. It comprised two parts (1) an assessment of drinking patterns, cognition, and alcohol-related harms, and (2) personalized feedback, including normative feedback, which some studies have shown to reduce alcohol consumption in heavy drinking students [40] and adult problem drinkers [41].

Page 1 provided a brief description of the Hospital Outpatient Alcohol Project (HOAP). Page 2 collected demographic data (gender, age, and postcode). Page 3 asked respondents if they had consumed alcohol in the last 12 months. Those who had not were sent to a "Thanks" page at this point, while those who had consumed alcohol proceeded to page 4. The Alcohol Use Disorders Identification Test (AUDIT) [42] comprised page 4 (Figure 1 shows this page). Page 5 asked questions concerning the largest number of standard drinks consumed in the patient's heaviest drinking occasion in the last four weeks, the duration of that episode in hours, and the patient's body weight, for the purpose of estimating their peak blood alcohol concentration (BAC). Page 6 comprised the 10-item Leeds Dependence Questionnaire (LDQ) [43], and page 7 comprised the 5-item History of Trauma Scale [44].

All participants (ie, including those who screened negative for unhealthy alcohol use and those who screened positive for possible alcohol dependence) received (1) feedback on their AUDIT score and guidance on its meaning [42] (Figure 2 shows this page), (2) an estimate of the BAC for their heaviest drinking episode in the previous month with information on the behavioral and physiological sequelae of various BACs, and crash relative risk (not shown), (3) an estimate of their spending on alcohol per month (not shown), (4) a bar graph comparing their typical episodic consumption with medical recommendations [45] and that of adults of the same age and gender [46] (Figure 3 shows this page), (5) a bar graph comparing their weekly consumption with medical recommendations [45] and that of adults of the same age and gender [46] (Figure 3), and (6) their score on the LDQ with an explanation of the associated health risk and information about how to reduce that risk [43] (not shown). It is important to note that normative feedback via the bar charts was withheld when participants' episodic or weekly consumption was lower than medical recommendations [45] in order to avoid the risk that participants might drink up to the norms [47]. In addition to the personalized feedback, three additional pages providing information about alcohol (eg, the consequences of unhealthy alcohol consumption), tips for reducing the risk of alcohol-related harm, and sources of support for drinking problems (eg, contact details for services available in the local health district) were provided. Participants had the option of emailing a copy of their personalized feedback to themselves. We chose not to provide a printed copy of the feedback because of concerns about confidentiality (eg, when printing is delayed, as a consequence of paper jams and so forth, people may see feedback other than their own).



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**Figure 1.** Screenshot from the pilot HOAP e-SBI program showing the AUDIT.


**Figure 2.** Screenshot from the pilot HOAP e-SBI program showing feedback regarding a hypothetical participant's score on the AUDIT.

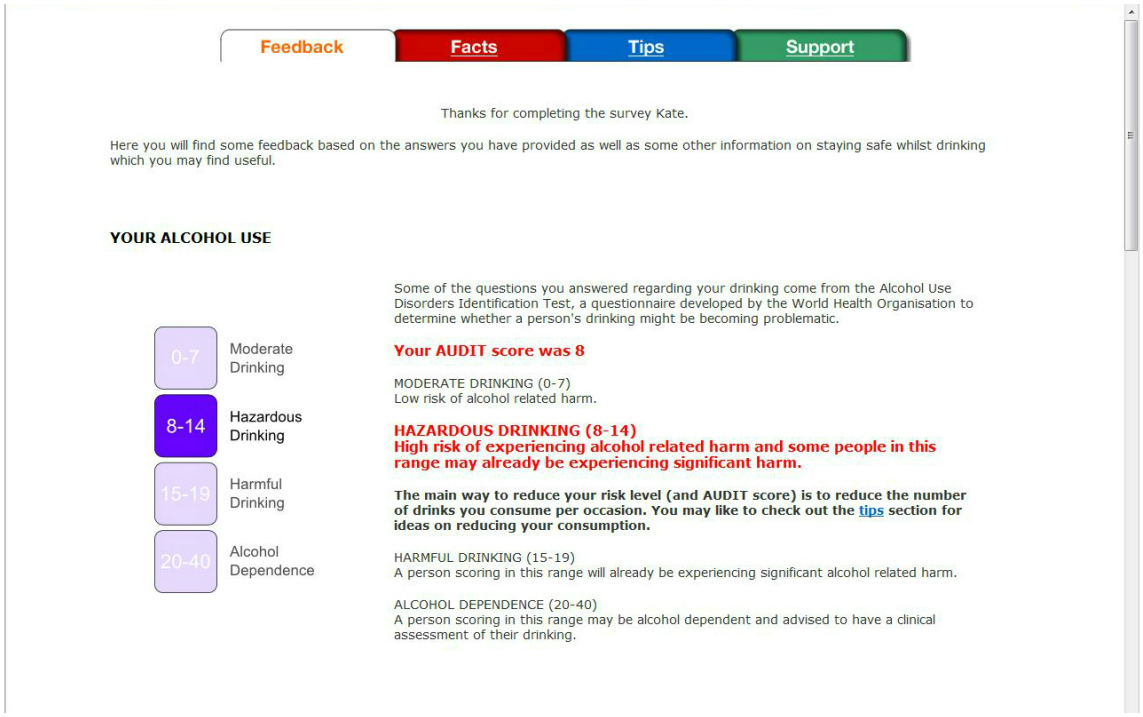




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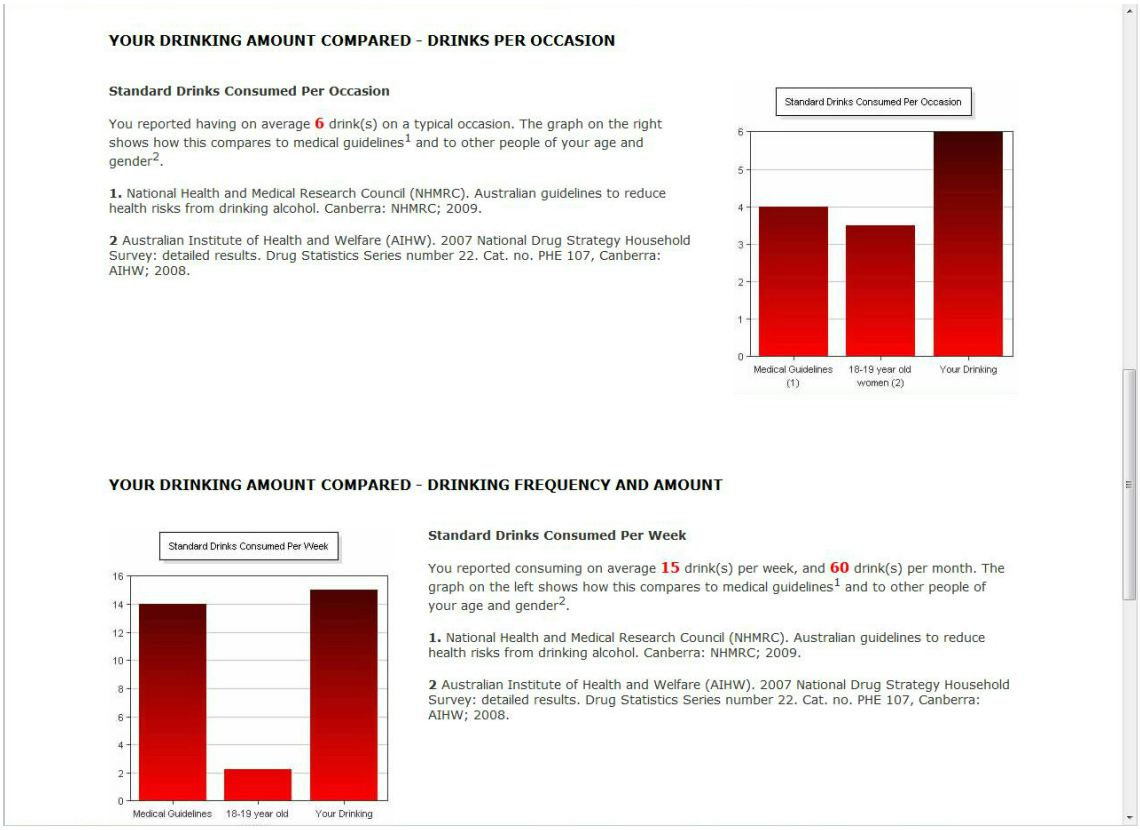
**Figure 3.** Screenshot from the pilot HOAP e-SBI program comparing a hypothetical participant's (1) typical episodic consumption and (2) weekly consumption with (3) medical recommendations and (4) adults of the same age and gender.




## Outcomes

### *Recruitment*

Participants in the proposed full-scale RCT will be screened for hazardous and harmful drinking using the AUDIT-Consumption (AUDIT-C) subscale [48]. This screening tool, which comprises the first three questions of the 10-item AUDIT and has similar specificity and sensitivity [48], will be used to minimize the risk of assessment effects [49] because administration of the full AUDIT alone has been shown to reduce self-reported drinking levels [50]. A minimum score of 5 points on the AUDIT-C will be used because it has high specificity while maintaining good sensitivity for identifying patients with hazardous or harmful drinking [48]. A maximum score of 9 will be used because the probability of alcohol dependence with a score above 9 is high [51], and these patients probably require more than brief intervention [52]. Thus although all participants in this study completed the AUDIT (ie, because they all received the intervention), the feasibility of recruiting outpatients with hazardous or harmful drinking was measured as the proportion of eligible consenting outpatients who scored 5-9 on the AUDIT-C.

### *Intervention Completion*

The feasibility of delivering e-SBI in the waiting area of the outpatient department of a large, public hospital was measured as the proportion of participants who completed the e-SBI.

### *Acceptability of e-SBI*

The acceptability of the e-SBI (eg, ease of completion, clarity of questions, privacy) was assessed using self-administered survey questions (1) immediately on completion of the e-SBI using a procedure described by Hallet et al [33], and (2) at follow-up. The questions and response options used at baseline and at follow-up are shown in the results section.

### *Retention*

The feasibility of contacting participants to complete assessments of their drinking was measured as the proportion who returned the follow-up questionnaire comprising nine questions: three seeking information on alcohol consumption ("On how many days in the last 4 weeks did you drink alcohol?", "On average, how many standard drinks did you have per drinking day?", and "On how many days in the last 4 weeks did you have 6 or more standard drinks on one occasion?"), and six questions seeking feedback regarding the e-SBI program.

### *Data Analyses*

Data were analyzed using STATA 11.1 (STATA Corporation, College Station, TX, USA). Descriptive statistics (frequencies and percentages for discrete variables and medians with interquartile ranges for continuous variables) were used to summarize the characteristics of study participants (gender, age group, and alcohol consumption) and outcomes related to recruitment, intervention completion, acceptability of e-SBI, and retention.

# Results

## e-SBI Program

The e-SBI program for hospital outpatients was essentially the same as the THRIVE program except for the addition of (1) the



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revised Australian drinking guidelines [45], (2) normative feedback regarding the amount of alcohol consumed by Australian men and women over 29 years of age [46], and (3) information regarding local sources of support for drinking (for example, contact details for services available in the local health district). Unplanned modifications associated with delivery of the intervention via the health service's information systems included programming to recreate the e-SBI program by IT staff employed by the health service to ensure compliance with its systems, and the removal of links to external websites because of security concerns, such that participants could not be offered access to additional information on drinking guidelines, standard drink measures, and drink-driving legislation.

## Outcomes

### *Recruitment*

Although research assistants were trained in the application of a study protocol stipulating they should invite the next patient leaving the reception desk to participate in the study, it quickly became apparent that this recruitment procedure was inefficient because patients arrived in large groups around the time that specific clinics opened, followed by long periods of time with very few arrivals. Our solution was to approach patients who occupied designated seats in rotation around the waiting area and it was often possible to approach all outpatients because of the long waiting times. Of the 172 outpatients we approached, 108/172 (62.8%) consented, 62/172 (36.0%) refused, and 2/172 (1.2%) were not eligible. Among those who consented, 2/108 (1.9%) were found to be ineligible and excluded (1 patient was unable to self-administer the e-SBI due to arthritis and the other person was not an outpatient). Among the 106 eligible consenting patients, 7/106 (6.6%) did not complete the e-SBI, 15/106 (14.2%) had not consumed any alcohol in the past 12 months, 43/106 (40.6%) screened negative for unhealthy alcohol use (scored less than 5 on the AUDIT-C), 33/106 (31.1%) screened positive for hazardous or harmful drinking (scored 5-9 on the AUDIT-C), and 8/106 (7.5%) screened positive for possible alcohol dependence (scored 10-12 on the AUDIT-C). Figure 4 shows the flow of participants through the study. The demographic characteristics of participants (n=99), and alcohol use among those who reported consuming alcohol in the past 12 months (n=84) are shown in Table 1.

### *Intervention Completion*

Of the 106 eligible consenting outpatients, 99/106 (93.4%) completed the e-SBI program. Among the 7 noncompleters, 3/7 (43%) could not complete it due to technical problems, and 4/7 (57%) were called for their appointment before completing the program and did not return. In addition, because the laptop used to deliver the e-SBI was located 10-15 meters from some sections of the waiting area where outpatients had been advised to wait and from where they would be called for their appointment, we noticed that some participants were rushing through the program so they could return to the area they had been advised to wait in. This was a concern because it would reduce the efficacy of the intervention if participants did not read and absorb the feedback.

### *Acceptability of e-SBI*

Feedback regarding the usability and acceptability of the program for all drinkers and the subgroup who screened positive for hazardous or harmful drinking is shown in Table 2.

### *Retention*

Of the 69 participants who were invited to complete the follow-up assessment, 52/69 (75%) completed it. The follow-up rate among the subgroup with hazardous or harmful drinking was slightly lower, (22/30, 73%). Information obtained at follow-up is shown in Table 3.

### *Feasibility of Delivering e-SBI Using iPads*

Due to concerns that arose during the pilot study regarding the usability of laptop computers, we returned to the outpatient waiting area six months later (June 2012) to assess the feasibility of using iPads. There were 9 patients (4/9, 44% male; 2/9, 22% aged 18-34 years; 4/9, 44% with an AUDIT-C score of 5-9) that agreed to participate. Although all were able to self-administer the e-SBI using the iPad, patients with larger fingers (mainly older men) would have found it easier if a stylus were available.



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**Table 1.** Demographic characteristics and alcohol use of participants.

| | | Total | All drinkers | AUDIT-C Score | | |
|---|---|---|---|---|---|---|
| | | | | <5 | 5 - 9 | >9 |
| | | (n=99) | (n=84) | (n=43) | (n=33) | (n=8) |
| Male, n (%) | | 53 (54) | 49 (58) | 16 (37) | 26 (79) | 7 (88) |
| Age group, n (%) | | | | | | |
| | 18-34 years | 33 (33) | 29 (35) | 11 (26) | 14 (42) | 4 (50) |
| | 35-54 years | 32 (32) | 26 (31) | 11 (26) | 13 (39) | 2 (25) |
| | 55+ years | 34 (34) | 29 (35) | 21 (49) | 6 (18) | 2 (25) |
| Access to email, n (%) | | 72 (73) | 63 (75) | 33 (77) | 24 (73) | 6 (75) |
| AUDIT score, median (25th and 75th percentiles) | | - | 5 (3, 12) | 3 (1,4) | 11 (7, 16) | 19 (14.5, 27) |
| LDQ score, median (25th and 75th percentiles) | | - | 0 (0, 3) | 0 (0, 0) | 3 (0, 6) | 5.5 (2, 11) |
| Consumed alcohol in the past 4 weeks, n (%) | | - | 69 (82) | 32 (74) | 30 (91) | 7 (88) |
| Consumed more than 4 drinks on a single occasion at least once in the last 4 weeks, n (%) | | - | 41 (49) | 5 (12) | 29 (88) | 7 (88) |
| Largest number of standard drinks consumed on a single occasion in the past 4 weeks, median (25th and 75th percentiles) | | - | 6 (3, 12) | 2 (2, 4) | 9 (7, 15) | 20 (7, 24) |



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**Figure 4.** Flow of participants through pilot study.

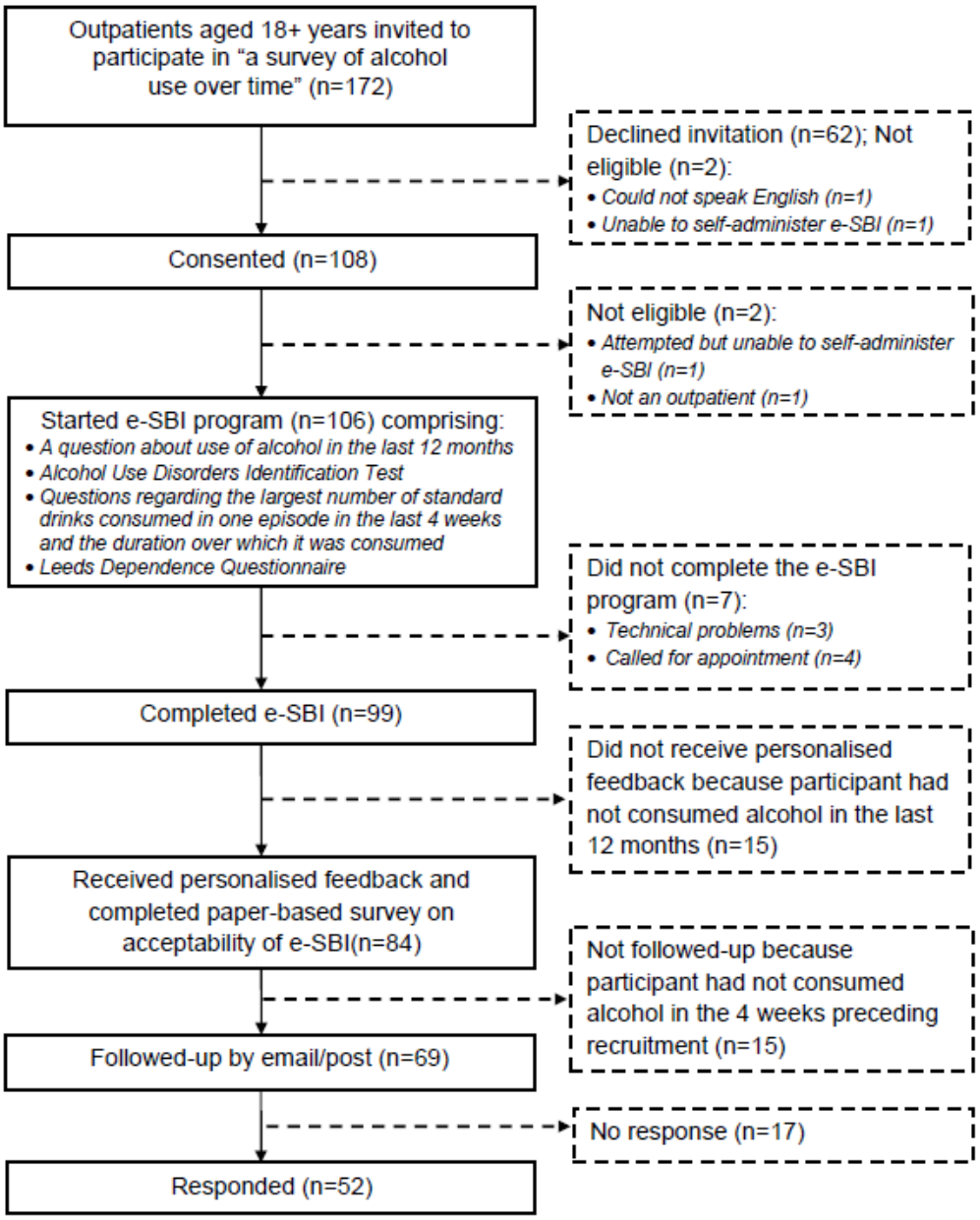




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**Table 2.** Acceptability of e-SBI.

| Question | | All drinkers | AUDIT-C Score | | |
|---|---|---|---|---|---|
| | | (n=84) | <5 (n=43) | 5-9 (n=33) | >9 (n=8) |
| | | n (%) | n (%) | n (%) | n (%) |
| **How would you rate the level of computer competence required to complete the online survey?** | | | | | |
| | Very low | 19 (23) | 9 (21) | 8 (24) | 2 (25) |
| | Low | 29 (35) | 15 (35) | 13 (39) | 1 (13) |
| | Moderate | 15 (18) | 7 (16) | 5 (15) | 3 (38) |
| | High | 9 (11) | 4 (9) | 3 (9) | 2 (25) |
| | Very high | 12 (14) | 8 (19) | 4 (12) | 0 (0) |
| **How hard was it to estimate how much or how often you drink?** | | | | | |
| | Very hard | 1 (1.2) | 0 (0) | 0 (0) | 1 (13) |
| | Hard | 5 (6) | 1 (2) | 2 (6) | 2 (25) |
| | Somewhat hard | 16 (19) | 2 (5) | 12 (36) | 2 (25) |
| | Not hard at all | 62 (74) | 40 (93) | 19 (58) | 3 (38) |
| **Did you respond honestly?** | | | | | |
| | All of the time | 79 (95) | 42 (98) | 31 (94) | 6 (75) |
| | Most of the time | 4 (5) | 1 (2) | 1 (3) | 2 (25) |
| | Some of the time | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | None of the time | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| **How surprising was the feedback on your drinking?** | | | | | |
| | Very surprising | 5 (6) | 3 (7) | 1 (3) | 1 (13) |
| | Quite surprising | 14 (17) | 3 (7) | 9 (27) | 2 (25) |
| | Somewhat surprising | 16 (19) | 4 (9) | 9 (27) | 3 (38) |
| | Not surprising at all | 48 (57) | 33 (77) | 13 (39) | 2 (25) |
| **Was the feedback on your drinking useful?** | | | | | |
| | Very useful | 21 (25) | 11 (26) | 6 (18) | 4 (50) |
| | Quite useful | 20 (24) | 7 (16) | 11 (33) | 2 (25) |
| | Somewhat useful | 25 (30) | 13 (30) | 10 (30) | 2 (25) |
| | Not useful at all | 17 (20) | 12 (28) | 5 (15) | 0 (0) |
| **Will this affect how much you drink in the future?** | | | | | |
| | Yes | 11 (13) | 5 (12) | 6 (18) | 0 (0) |
| | No | 51 (61) | 32 (74) | 16 (48) | 3 (38) |
| | Possibly | 21 (25) | 6 (14) | 10 (30) | 5 (63) |
| **Did the amount of privacy you had concern you? (Did it affect your answers?)** | | | | | |
| | Yes, all of the time | 1 (1) | 1 (2) | 0 (0) | 0 (0) |
| | Yes, most of the time | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| | Yes, some of the time | 1(1) | 1 (2) | 0 (0) | 0 (0) |
| | No, none of the time | 81 (96) | 41 (95) | 32 (97) | 8 (100) |
| **Were questions clear?** | | | | | |
| | Yes, all of the time | 71 (85) | 37 (86) | 26 (79) | 8 (100) |
| | Yes, most of the time | 11 (13) | 6 (14) | 5 (15) | 0 (0) |
| | Yes, some of the time | 1 (1) | 0 (0) | 1 (3) | 0 (0) |
| | No, none of the time | 0 (0) | 0 (0) | 0 (0) | 0 (0) |



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| Question | | All drinkers | AUDIT-C Score | | |
|---|---|---|---|---|---|
| | | (n=84) n (%) | <5 (n=43) n (%) | 5-9 (n=33) n (%) | >9 (n=8) n (%) |
| **Was the font size large enough to read?** | | | | | |
| | Yes | 79 (94) | 41 (95) | 30 (91) | 8 (100) |
| | No | 4 (5) | 2 (5) | 2 (6) | 0 (0) |
| **Do you think this online intervention will appeal to people who attend this service?** | | | | | |
| | Yes, all of them | 12 (14) | 11 (26) | 0 (0) | 1 (13) |
| | Yes, most of them | 41 (49) | 22 (51) | 15 (45) | 4 (50) |
| | Only some of them | 30 (36) | 10 (23) | 17 (52) | 3 (38) |
| | None of them | 0 (0) | 0 (0) | 0 (0) | 0 (0) |



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**Table 3.** Alcohol consumption and acceptability of e-SBI at follow-up.

| | All drinkers (n=52) | AUDIT-C Score <5 (n=26) | 5-9 (n=22) | >9 (n=4) |
|---|---|---|---|---|
| Number of days consumed alcohol in the past 4 weeks, median (25th and 75th percentile) | 9.5 (3, 20) | 4 (2, 10) | 11.5 (5, 20) | 23 (13.5, 28) |
| Number of standard drinks per typical drinking occasion in the past 4 weeks, median (25th and 75th percentile) | 2 (1, 4) | 2 (1, 2) | 3 (2, 6) | 9 (7, 10) |
| Number of times more than 6 standard drinks were consumed in past 4 weeks, median (25th and 75th percentile) | 0 (0, 3) | 0 (0, 0) | 2 (0, 4) | 10.5 (5, 15) |
| **I found the questionnaire easy to complete, n (%)** | | | | |
| No | 3 (6) | 2 (8) | 0 (0) | 1 (25) |
| Yes | 48 (94) | 24 (92) | 21 (100) | 3 (75) |
| **I found the feedback on my drinking useful, n (%)** | | | | |
| No | 7 (14) | 4 (15) | 3 (14) | 0 (0) |
| Yes | 33 (65) | 17 (65) | 13 (62) | 3 (75) |
| I did not receive this feedback but would like to receive it | 6 (12) | 4 (15) | 2 (10) | 0 (0) |
| I did not receive this feedback and am not interested in receiving it | 5 (10) | 1 (4) | 3 (14) | 1 (25) |
| **The feedback I received on my drinking included comparisons of my drinking with the average drinking levels of others the same age and gender as me. The averages presented were, n (%):** | | | | |
| About what I expected | 23 (46) | 11 (42) | 9 (45) | 3 (75) |
| Higher than I expected | 5 (10) | 3 (12) | 1 (5) | 1 (25) |
| Lower than I expected | 3 (6) | 1 (4) | 2 (10) | 0 (0) |
| I had no idea what the average was | 10 (20) | 7 (27) | 3 (15) | 0 (0) |
| I did not receive this feedback but would like to receive it | 5 (10) | 3 (12) | 2 (10) | 0 (0) |
| I did not receive this feedback and am not interested in receiving it | 4 (8) | 1 (4) | 3 (15) | 0 (0) |
| **As a consequence of receiving the feedback the amount of alcohol I consume has, n (%):** | | | | |
| Not changed | 39 (81) | 23 (92) | 13 (68) | 3 (75) |
| Decreased | 9 (19) | 2 (8) | 6 (32) | 1 (25) |
| Increased | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| **I have sought support to reduce my drinking as a consequence of receiving the feedback, n (%)** | | | | |
| No | 37 (77) | 19 (76) | 15 (79) | 3 (75) |
| Yes | 11 (23) | 6 (24) | 4 (21) | 1 (25) |
| **I would recommend this program to a friend if I were concerned about how much they were drinking? n (%)** | | | | |
| No | 77 (34) | 8 (31) | 6 (30) | 3 (75) |
| Yes | 23 (66) | 18 (69) | 14 (70) | 1 (25) |

# Discussion

## Principal Results

Our results show that e-SBI is acceptable to hospital outpatients and that it is possible to recruit, screen, and deliver e-SBI in the hospital outpatient setting without disrupting normal service provision. Almost two-thirds (108/172, 62.8%) of the patients we approached consented, almost two in five adults (41/106, 38.7%) reported unhealthy alcohol use (compared with one in five adults aged 18 years and over in the general Australian population) [53], and almost three-quarters (22/30, 73%) of the hazardous and harmful drinkers (ie, those who would be eligible for inclusion in a trial of the efficacy of e-SBI) completed the follow-up assessment.

In addition to obtaining estimates of the consent rate, the proportion that would be eligible for inclusion in a full-scale



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RCT, and the likely response at follow-up, we discovered that some well established procedures used in trials of e-SBI in the primary care setting did not translate to the hospital outpatient setting. First, we could not utilize the services of IT staff who had been involved in the development of the THRIVE program because of the health service's requirement that the program use a particular programming language. This reliance on personnel employed by another organization who had other priorities delayed the project considerably. Second, the health service did not allow the inclusion of links to external websites for security reasons. While suboptimal, this is not a major concern because previous analyses of the Web pages accessed by more than 1000 users of the THRIVE instrument showed the e-SBI was efficacious [34] even though very few (64/1251, 0.05%) participants accessed the hyperlinks to external websites [33]. Third, it was not efficient to recruit patients as they left the reception desk and an alternative strategy had to be developed. Fourth, delivery of the e-SBI using a laptop in a fixed location, because of the need to connect to the hospital's intranet, seemed problematic for participants who had to move 10-15 meters away from the area they had been advised to wait in. Delivery of the program via iPads, connected wirelessly to a server located in a room behind the reception desk, solved this problem as patients could participate without leaving their seats. This closed system, in addition to removing the problem of patients rushing through the e-SBI so they could return to their seat, had the advantage of returning control over the development and maintenance of the program to the research team (ie, we could employ IT staff familiar with our research to develop the program, and ensure a timely response to problems as they arose). Fifth, as some patients were called for their appointment before completing the program, we believe implementation of a trial would be facilitated by obtaining permission to send a hyperlink to the e-SBI program to participants who are interrupted in preference to asking them to return to complete it after their appointment. Finally, because undecipherable handwritten email addresses impeded follow-up contact, we recommend that patients be asked to enter their email addresses electronically, with the possibility of validating addresses also worth considering.

## Limitations

Limitations of the study include the short follow-up, attrition, and the small number of participants who completed the e-SBI using an iPad. The loss-to-follow-up is a concern because attrition reduces the effective sample size and can bias effect estimates [54]. We were prevented by an Ethics Committee policy from employing a key evidence-based strategy for increasing questionnaire completion rates [38], namely, the use of token incentives. Use of such strategies would probably increase the follow-up rate among hazardous and harmful drinkers from the 22/30 (73%) observed here to 24/30 (80%) or higher, putting it into an acceptable range for a trial of this type. Our finding that most participants could easily self-administer the e-SBI using an iPad is consistent with the findings of a Canadian study in which most (318/348, 91.4%) patients indicated that the iPad was easy to use [55]. Our observation that some patients would benefit from having a stylus available is also consistent with the Canadian study, which reported "some of the older users…seemed to struggle to adapt to the sensitivity and responsiveness of the touch screen" [55]. As 27/99 (27%) of our study participants did not have access to email (ie, did not have the option of emailing a copy of the feedback to themselves to read and reflect upon later), our decision not to provide printed copies of the personalized feedback may also be a limitation. Accordingly, we plan to devise a new process for generating and sending a printed copy of the personalized feedback to participants in the proposed RCT.

## Strengths

Strengths of the study include the use of an intervention informed by more than a decade of research on the development and evaluation of e-SBI in university students [34,36,56,57], the inclusion of a respected senior clinician with strong links to the health service and the university on the research team, and the mixed-mode follow-up. The fact that few modifications to the e-SBI program were required on the basis of feedback from our pilot study participants supports our view that the extensive developmental work on the THRIVE instrument and its predecessors [33] has produced an instrument that is acceptable to a wide range of people in a variety of settings and is a strength of this study. Inclusion of a senior clinician on the research team facilitated access to the outpatient department and gave us a "voice" when progress on the e-SBI stalled because of IT problems. Although the use of mixed contact modes for follow-up may be considered a limitation, it was a deliberate decision to facilitate inclusivity of people from households with lower incomes where home Internet access is less common [58]. Excluding patients without such access would make the findings less generalizable to poorer people; potentially further increasing health disparities [59]. In addition, offering different response modes sequentially-Web first with mail as the final contact-has recently been shown to improve response rates [39]. Since randomization protects against bias by modality of follow-up, especially where a large number of individuals is randomized, we intend to utilize mixed contact modes for follow-up in the proposed RCT.

## Conclusions

We obtained estimates of the consent rate, proportion with hazardous or harmful drinking, and response at follow-up, which are essential to the design of a full-scale RCT to determine whether e-SBI reduces hazardous or harmful drinking in hospital outpatients. In addition, our study demonstrated that e-SBI is acceptable to hospital outpatients with hazardous or harmful drinking and, given the feasibility of recruiting and screening patients, and of delivering the intervention without disrupting normal service provision, that it could be provided routinely in this important setting.



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## Conflicts of Interest

None declared.

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## Abbreviations

**AUDIT:** Alcohol Use Disorders Identification Test
**AUDIT-C:** Alcohol Use Disorders Identification Test Consumption subscale
**BAC:** blood alcohol concentration
**e-SBI:** electronic alcohol screening and brief intervention



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**IT:** information technology
**LDQ:** Leeds Dependence Questionnaire

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Original Paper

# Co-Creation With TickiT: Designing and Evaluating a Clinical eHealth Platform for Youth

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## Abstract

**Background:** All youth are susceptible to mental health issues and engaging in risky behavior, and for youth with chronic health conditions, the consequences can be more significant than in their healthy peers. Standardized paper-based questionnaires are recommended by the American Academy of Pediatrics in community practice to screen for health risks. In hospitals, psychosocial screening is traditionally undertaken using the Home Education, Eating, Activities, Drugs, Depression, Sex, Safety (HEEADDSS) interview. However, time constraints and patient/provider discomfort reduce implementation. We report findings from an eHealth initiative undertaken to improve uptake of psychosocial screening among youth.

**Objective:** Youth are sophisticated "technology natives." Our objective was to leverage youth's comfort with technology, creating a youth-friendly interactive mobile eHealth psychosocial screening tool, TickiT. Patients enter data into the mobile application prior to a clinician visit. Response data is recorded in a report, which generates alerts for clinicians, shifting the clinical focus from collecting information to focused management. Design goals included improving the patient experience, improving efficiency through electronic patient based data entry, and supporting the collection of aggregated data for research.

**Methods:** This paper describes the iterative design and evaluation processes undertaken to develop TickiT including co-creation processes, and a pilot study utilizing mixed qualitative and quantitative methods. A collaborative industry/academic partnership engaged stakeholders (youth, health care providers, and administrators) in the co-creation development process. An independent descriptive study conducted in 2 Canadian pediatric teaching hospitals evaluated the feasibility of the platform in both inpatient and ambulatory clinical settings, evaluating both providers and patient responses to the platform.

**Results:** The independent pilot feasibility study included 80 adolescents, 12-18 years, and 38 medical staff-residents, inpatient and outpatient pediatricians, and surgeons. Youth uptake was 99% (79/80), and survey completion 99% (78/79; 90 questions). Youth found it easy to understand (92%, 72/78), easy to use (92%, 72/78), and efficient (80%, 63/79 with completion rate < 10 minutes). Residents were most positive about the application and surgeons were least positive. All inpatient providers obtained new patient information.



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**Conclusions:** Co-creative design methodology with stakeholders was effective for informing design and development processes to leverage effective eHealth opportunities. Continuing stakeholder engagement has further fostered platform development. The platform has the potential to meet IHI Triple Aim goals. Clinical adaptation requires planning, training, and support for health care providers to adjust their practices.

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**KEYWORDS**

adolescent; adolescent health services; youth; eHealth; information technology; health surveys; delivery of health care; communication; chronic illness; mobile technology; questionnaires

## Introduction

### Overview

The Institute of Health Improvement (IHI) recommends that new health care strategies are designed to meet the Triple Aim goals. These goals are described as (1) improving the patient experience, (2) reducing or maintaining costs, and (3) improving health of the population. eHealth innovation, through harnessing both information technology (IT), communication technology, and layering capabilities, has the potential to meet the Triple Aim goals through "multitasking" by supporting efficient collection of patient information, distribution to providers and patients, and re-purposing for health research. eHealth commonly refers to health services and information delivered or enhanced through the Internet and related technologies. The "e"s in eHealth align with traditional medical practice in enhancing quality and evidence-based care, while providing the opportunity to achieve a number of other "e"s such as empowerment, efficiency, encouragement of new relationships between providers and patients, enabling information exchange, and extending the scope of health care [1].

While the face-to-face patient encounter remains a critical element of health care provision, a single eHealth intervention could improve the patient experience of the health care encounter, educate the patient, collect important clinical information, improve efficiency, and support aggregation of data, which in turn can support the development of evidence to inform health care interventions [1]. However, without good design and engagement of stakeholders, new tools can just as easily miss their targets [2]. Design strategies are important considerations in development when tools are created to bridge between different stakeholder groups. Simply integrating technology to existing practices does not ensure realization of the complete potential of the technology nor does it necessarily improve the existing practices. In health care, there are a variety of stakeholders who interact with the technology, who each come with their own expectations, priorities, and limitations. Youth are technology natives, health care providers (HCPs) are content driven but often fearful of new technology, while administrators and IT personnel are concerned with technical standards, safety, and cost. A successful tool needs to be accessible to multiple stakeholder groups, supporting each group's constraints and requirements as well as addressing their various perspectives and priorities.

Adolescence (12-18 years) and the extended period of youth (14-24 years) are a developmental life phase in which the opportunities for good health are great and future patterns of adult health are established. Youth health is influenced by social role changes, shaped by social determinants and risk and protective factors that affect the uptake of health related behaviors [3]. It is also a time when lifestyle choices and risky behavior can lead to significant morbidity. Adolescents are more likely than adults to binge drink, smoke cigarettes, have casual sex partners, and engage in violent behavior [4].

Comprehensive psychosocial health screening is a fundamental component of adolescent health care. Screening provides an opportunity to assess progress through adolescence and identify strengths and areas of concern. This information is essential to direct health promotion interventions. Several health organizations have written policy recommendations to encourage widespread practice of screening to promote optimal physical, mental, and social health [5-7]. These recommendations include annual health screening of all adolescents in settings where youth interact with HCPs such as clinical outpatient or inpatient settings, public health, and school settings.

For general patient visits in a community setting, the American College of Pediatrics has developed paper-based Guidelines for Adolescent Preventive Services (GAPS) as part of their Brighter Futures initiative [8]. The 15-item survey focuses on risk behaviors, and has been shown to identify risk factors in youth attending community settings. In the hospital setting, psychosocial screening is undertaken by semi-structured interview using the acronym HEEADDSS (Home, Education, Eating, Activities, Drugs, Depression, Sexual Health, Safety) [9] as part of the admission procedure. The guided interview format moves progressively from less general topics to more sensitive issues. However, this method for universal inpatient or outpatient screening has proven unrealistic for a number of reasons. It is time consuming, taking on average 30 minutes per interview [10] and furthermore it requires skill, knowledge, and a comfort level by HCPs to address sensitive issues. Reviews of inpatient psychosocial screening in a pediatric inpatient setting determined documentation rates of only 50% [11], and as low as 19% in a surgical setting [12]. Despite the low uptake in a surgical ward, screening resulted in a 30% increase in referrals, highlighting the value of HEEADDSS in uncovering new health issues [12].

A paper-based self-administered questionnaire the Adolescent Screening Questionnaire (ASQ) [13] improved identification of risk factors and documentation in an inpatient setting. Additionally, the ASQ increased efficiency, taking approximately 10 minutes to complete. However uptake was inadequate as 25% of adolescents declined to participate. Those who did fill in the questionnaire commented on the quality of



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experience, noting the questions could have a more positive focus [13].

Electronic (computer) based surveys are increasingly used in clinical settings in the clinic waiting rooms, generating a risk report for the clinician [14]. Olson reported a PDA based tool used in a community general pediatric clinic for adolescents attending a health checkup that improved the adolescents' perceptions of the visit. Specifically, it also improved the patients' perception that the clinician had listened carefully to them, and reduced the number of questions that they would have liked to discuss but did not [15]. Improving communication, changing focus from collecting information and redirecting it to focus on already determined risk and protective factors improved compliance of the assessment [16]. Paperny et al found computer assisted delivery of preventive services during a patient checkup in pediatric community practice was preferred (over face to face interview) by patients and reduced costs by 75% [17].

Building on the positive results from previous studies which used varied computer-based survey delivery as a means to collect psychosocial information to support clinical care, we attempted to bring traditional recommended standards of health care (the need for comprehensive psychosocial screening for youth) closer to the youth health space by creating an eHealth platform that was engaging and intuitive, while meeting other stakeholder requirements.

In this paper, our purpose is to both to demonstrate how mixed methods can contribute to effective design that meets stakeholder needs, and to highlight what we learned from a pilot study undertaken after initial development. Work reported here contributes to discussions about challenges of conducting research to inform ongoing design. Finally, this case demonstrates how engagement with stakeholders during design necessarily influences development of eHealth innovation.

Below, we outline the development of the platform, TickiT (Figure 1) from its inception as a mobile application, to a fully functional eHealth platform. The initial co-creation process was conducted with a collaborative industry and academic partnership with the Emily Carr University of Art and Design (ECUAD). After outlining the development process, we report on findings from an independent academic feasibility pilot study conducted in two Canadian teaching hospitals. Issues and challenges with platform development are discussed, as well as future directions for research.

**Figure 1.** TickiT process banner.


## Background

Uptake of technology is dependent upon the quality of experience during implementation and use. Three stakeholder groups—adolescents, HCPs, and administrators—were identified as integral to implementation of the eHealth innovation described here.

Many health related survey tools have been directly transcribed from paper-based to electronic format with little consideration of the opportunities that migration from a paper-based to computer-based medium can afford. Willingness to experiment with question wording, graphic format, or survey content when moving from paper-based to computer mediated survey instruments may be constrained by challenges associated with norms and standards related to survey instrument validation. Validated surveys are constrained to maintain the original text if they are transcribed onto an electronic format. During our graphic design development, we found paper-based questions often appear long and inappropriate on an electronic interface. While the questions developed in the ASQ questionnaire module were previously validated, participants indicated that the tool could be more youth friendly in a study by Lam et al, which aimed to improve documentation of psychosocial screening in an inpatient setting [13]. While altering the wording or format of a validated instrument undermines validation, ample evidence suggests that altering survey instrument format when migrating content to a computer-mediated platform may support other affordances. For example, cognitive psychological research suggests that respondents encode questions into a mental representation as a starting point for question answering, providing graphic representation serves as a signal for memory retrieval and improves comprehension [18]. Graphics create the opportunity to reduce the literacy level, improving accessibility for a broader and younger population [19]. Additionally, youth engagement with technology has been associated with their comfort in disclosing personal information online, termed the "online disinhibition effect" [20].

Our project sought to address limitations in administration of youth health questionnaires by both moving data collection to an online platform. We chose to leverage new technology in creating TickiT, to improve the quality of youth experience and respond to youth preferences by altering the wording of questions from validated psychosocial screening instruments, while maintaining their meaning and enhancing the text with graphics on an interactive UI.

## The Co-Creation Method: Stage 1

We chose to utilize co-creation processes and methods with the goal of increasing patient engagement and simplifying HCP work, thereby improving patient/provider communication and experience while meeting regulatory requirements. Co-creation process shifts away from the traditional method of involving



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passive stakeholders during the latter phase of prototype testing towards viewing them as active contributors with knowledge and skills for co-creation during the ideation phase [21].

A design student from ECUAD undertook the initial co-creative research and subsequent preliminary development of TickiT with youth from the Youth Advisory Committee (12-20 years old, n=8; Co-Creative process: Development of psychosocial survey on an iPad platform, Ethics approval Emily Carr University of Art and Design). The youth participated in three 2-hour co-creation sessions. Subsequent co-creation sessions were held with adolescents in a high school (n=16) and a 1st year design class at ECUAD (n=24). HCP staff (n=6) at British Columbia Children's hospital (BCCH) were invited to participate in individual open-ended interviews about application development. Individual meetings reflected their time constraints and logistic challenges associated with arranging group sessions. The HCPs were professionally diverse and included a physician, 2 nurses, 2 social workers, and a developmental psychologist, each of whom could contribute a different viewpoint about the clinical encounter and inform the creation of developmentally appropriate content and context.

The patient visit trajectory (before appointment, registration, waiting room interaction with providers, after appointment, and back home) was presented to all the participants, youths, and HCPs through storyboarding which used the experience continuum design method [22] to evoke the varied contexts in which the tool might be used. The patient experience during a visit was considered using the domains of physical action, social interaction, and emotional reaction. Sessions were documented and participants were encouraged to write on material provided. All participants were offered the opportunity to send suggestions via email between and after the co-creation sessions.

The feedback from the co-creation sessions was used for the first functional prototype. This prototype platform was evaluated in an independent cognitive processing study to explore whether the type of icons are comprehensible and acceptable to ethnically diverse youth (E Saewyc, personal phone and email communication, July 27, 2013).

### Using the Platform in Practice: Stage 2

#### *Overview*

Once the application was functional, we needed to develop a better understanding of how it was being used, and what, if any issues, arose during implementation. A pilot study investigated the feasibility of using the platform in a hospital setting from both the youth and HCP perspectives. Lam et al [23] conducted a feasibility study as a 2nd stage investigation of introducing standardized psychosocial screening in the hospital setting. In the 1st stage of the study at BC Children's Hospital, a chart review had determined that psychosocial screening was documented in 47% of the medical charts. Introduction of a standardized paper-based tool, the ASQ, had improved documentation, but 25% (10/40 invited to participate) of the youth refused to participate in completing the questionnaire and two youth suggested the questions could be more positive [13]. This low uptake rate was considered unacceptable, and a more youth friendly solution was sought as a means of improving compliance with the use of the psychosocial screening tool.

#### *Goals*

The goals of the 2nd stage of the study were to determine if uptake of administration of psychosocial screening was improved by moving from a paper-based to tablet based administration of the psychosocial screening platform, to describe the youth and provider experience with using the user interface (UI) and questions both in the inpatient medical and surgical setting as well as the outpatient ambulatory care setting and to evaluate the efficiency of the eHealth platform. Efficiency was determined by time taken for the youth to complete the questionnaire as compared to standard provider/patient times for completing a HEADDSS interview [10]. Detailed information regarding the security features of the tool was provided in the ethics submission.

## Methods

### Stage 1

#### *Co-Creation Sessions: Stakeholder Domains*

##### Overview

Specific co-creation activities and processes undertaken to insure that application development responded to the needs of our three target stakeholder groups are outlined below.

##### Co-Creation Method: Youth

Many youth are disengaged from health care and uncomfortable in a clinical setting. Our primary consideration in the design of the UI was a Youth friendly approach [24-26]. Challenges related to process of engagement—uptake, engagement, efficiency, and confidentiality—were balanced with ensuring that the content was developmentally appropriate, comprehensible, and that the youth felt comfortable with how sensitive questions were being asked.

In the first group co-creation session, the youth brainstormed about the concept of psychosocial screening, in an attempt to determine strategies that could be followed to align their ideas with those of health professionals. The ASQ was used as a guiding text template for the survey as it was initially developed for use in a hospital setting [13]. Further, the ASQ used the categories derived from the HEADDSS assessment as the framework for sequencing the questions.

Focus groups were set up to discuss youth perception of content and language from the ASQ questionnaire and to suggest alterations to questions which would improve clarity, comprehension, engagement, and comfort [27]. As a result of youth co-creation input, the TickiT UI was initially implemented on paper, used 9 question categories (Home, Education, Eating, Activities, Depression [which at the suggestion of youth co-creators was changed to Emotions], Drugs, Safety, and Sex).

In subsequent sessions youth were provided with paper PDF copies of a version of questions reflecting revisions suggested from their previous feedback sessions (Figure 2). These were presented on color templates with icons for responses. Session



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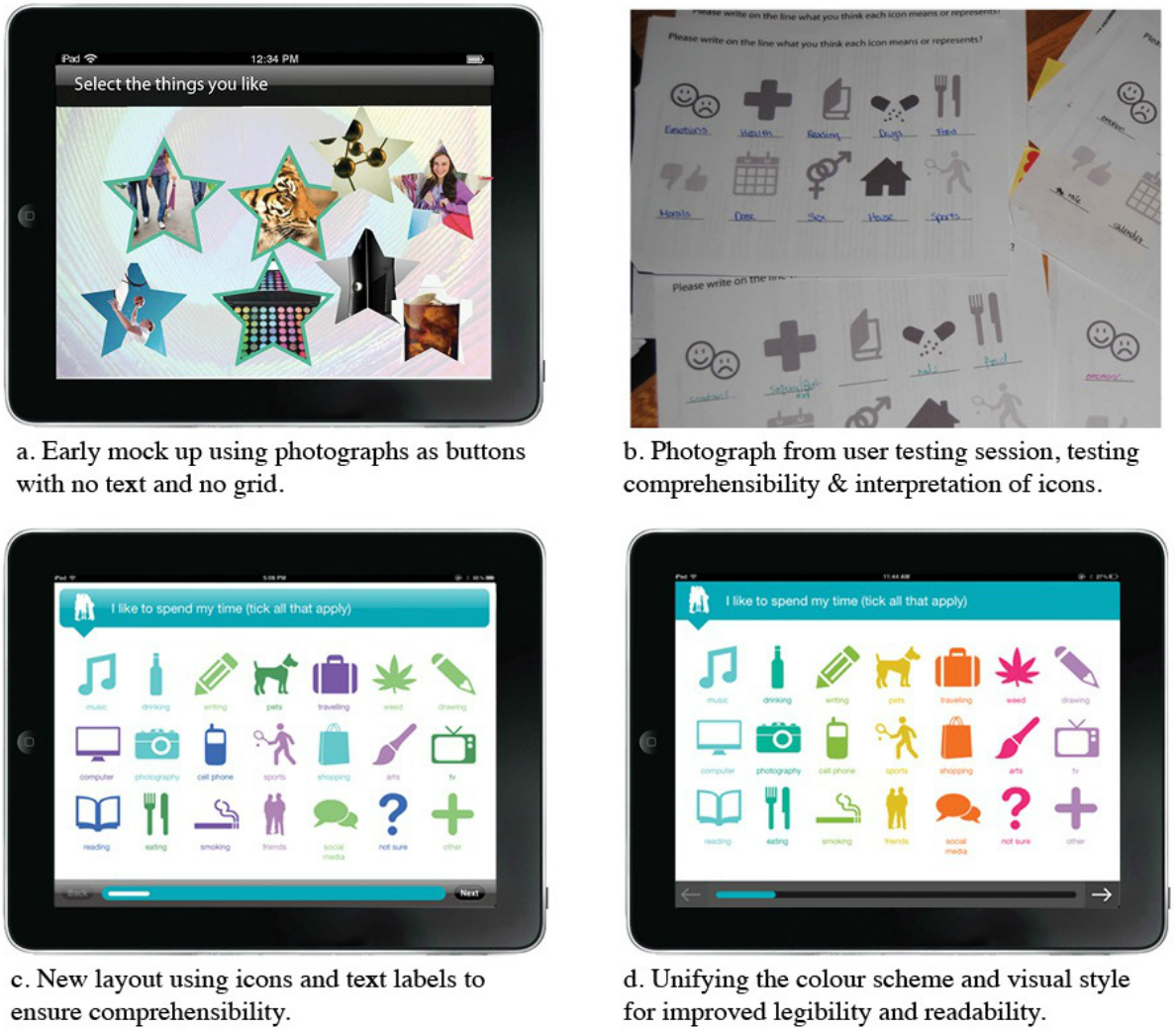
participants were asked to interact with the interface, provide comments on the copies, and discuss their feelings about the UI. Feedback at this stage was sought specifically about the colors, size and readability of the text, comprehension of the questions, the youth's sense of identification with the icons, and the mechanisms for answering questions. In the design development it was critical to ensure that the graphic elements and gestural interactions were universally understood and people with limited fine motor skills, for example, youth with neuromuscular conditions, could control the mobile device.

Youth were encouraged to discuss their attitudes towards the UI overall. They were asked their opinions regarding technical and feasibility issues of implementing the platform. This information was grouped using the subscales of Computerized Lifestyle Assessment Scale (CLAS) multidimensional computer survey evaluation [14] and included perceived (1) benefits, (2) concerns regarding privacy (consent, confidentiality, personal identifiers, data storage, connection with electronic health record), (3) interaction barriers (such as potential interference in their interaction with the physician), and (4) general interest. Responses were categorized using the CLAS themes, and youth commented on the relevance of the responses at the final co-creation session.

**Figure 2.** The Co-Creation process.




a. Early mock up using photographs as buttons with no text and no grid.

b. Photograph from user testing session, testing comprehensibility & interpretation of icons.

c. New layout using icons and text labels to ensure comprehensibility.

d. Unifying the colour scheme and visual style for improved legibility and readability.

All Images Copyright © 2011 Shift Health Paradigms Inc., TickiT ®.

### Co-Creation Method: Health Care Providers

An initial priority was to understand from HCP experts the requirements of developmentally appropriate care, which includes self-advocacy, lifestyle and risk, independent behaviors, sexual health, social supports, and educational, vocational, and financial planning.

The HCP goals for the tool included facilitating discussion, collecting information, generating a patient profile that could be uploaded into the electronic health record (EHR), a mechanism to collect aggregated anonymized data and a mechanism to track a patient's progress when they used the survey on a subsequent occasion. Process issues for HCPs included time constraints, administration of the tool (who would administer it and how it would alter the workflow of clinical



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interactions), access to results, prioritizing information, data collection, and support for technical problems. Many were concerned about their lack of familiarity with technology.

Content was a high priority for HCPs. They recommended use of the HEEADDSS format, adopted such that it progressed from less personal to more personal questions. They were interested in obtaining the maximum amount of information depending on their special interests. For example, one participant commented that "I would like to have a more complete set of questions for my eating disorder clinic." The HCPs were concerned that the quotes, which demarcated "chapters" of the questionnaire, endorsed healthy behaviors and were relevant – for example one HCP commented, "change the quote so that it is more appropriate for people with eating disorders."

The HCPs made recommendations regarding report format, emphasizing simplicity, easy access, and attachment to an EHR. They confirmed the value of alerts on reports that reflected risk (red) and protective (green) factors and issues for concern (orange). The HCPs were keen to add other surveys onto the TickiT format. They prioritized future research validation and evidence of effectiveness.

### Co-Creation Method: Institutional Requirements on Security and Regulation

Introducing new tools and technology into health care institutions require approval from administrative and IT departments. We undertook a detailed literature review and engaged security experts to ensure the system architecture and company policies complied with regulatory standards.

The management and implementation of an eHealth tool in Canada are governed by the provincial privacy legislation that is in place in each jurisdiction in which it does business, and by the federal Personal Information Protection and Electronic Documents Act (PIPEDA) [28,29]. Consideration of both provincial and federal jurisdictional laws were important as our first implementation sites were British Columbia (BC Children's Hospital) and Ontario (McMaster University). Hence we had to meet various provincial regulations early in the development process of our software.

Privacy and security fall under 3 categories: organizational privacy, solution privacy, and risk analysis. Organizational privacy requires developing a comprehensive privacy program consisting of appointment of a Chief Privacy Officer, establishment of corporate privacy and information security policies, agreements with health organizations that address privacy roles and responsibilities, privacy training, monitoring and audit of all system activity, access to Personal Health Information (PHI) and implementing a breach management protocol**.** Solution privacy features relate to architectural design of the software and include features such as capturing consent, audit logging, secure storage of records, role based access control, end-user authentication, secure transmission of PHI over the Internet and ensuring PHI is not stored on tablets or end-user workstations. The privacy risk analysis uses risk mapping tools and criteria to evaluate risk, and analyze threat agents that might compromise PHI in some way. Privacy risk analysis also assesses threat agent motivation and capability, and identifies current safeguards in place as well as known vulnerabilities [28,29].

### Stage 2

Two Canadian hospitals participated in this stage of the study: McMaster Children's Hospital and BCCH. The physicians involved in this study were exposed to the platform for the first time as a completed product and not aware of any previous developmental research with the platform. After obtaining both physician and youth consent (Behavioral Research Board Ethics approval, BC Children's Hospital, and McMaster Children's Hospital), 80 patients aged 12-18 years were invited to participate. In each of the clinical settings, every youth who met the eligibility criteria (age range and ability to read English), was consecutively approached for recruitment. No incentive to participate was provided. Inpatients were recruited from the BC Children's Hospital Clinical teaching unit medical ward (n=15), a surgical ward (n=15), and ambulatory clinics including a cystic fibrosis clinic (n=15) and a youth health clinic (n=15). All the patients from McMaster were recruited from a gastroenterology clinic (n=20). One inpatient refused to participate (with the reason of being too sick) and one ambulatory patient did not complete the survey, resulting in 78 completed surveys and youth evaluations of the tool. Thirty-eight physicians who were caring for the youth patient participants in a Clinical Teaching Unit assessed the platform. This group included 13 staff physicians (3 inpatient medical, 2 surgical, 8 ambulatory) and 25 resident trainees who were working under the staff physicians. After consenting both patients and staff, the patients filled out the survey independently, either in their hospital room or in the ambulatory care waiting room. Thirty minutes later the research nurse collected the device, and the patients completed a paper-based evaluation of the UI and questions. The survey was presented as a series of short questions with a 5 point Likert scale and a small section at the end for further comments. The questions were the same for the youth from both centers, although the question regarding feeling comfortable with the survey questions was omitted from the McMaster cohort, due to a technical error. The research nurse then collected the report and provided the report with a paper-based survey evaluation of the report and questions to the available physician staff that was caring for the patient. If this was a trainee, another evaluation survey was provided for the responsible attending staff physician to complete as well. The provider evaluation survey was similar in format to the youth survey with Likert scale and a place for comments. The paper-based evaluation surveys were transcribed into Excel and uploaded to RedCAP for analysis. The patient questionnaire asked about comfort with the questions asked, comprehensibility and ease of use of the platform, and time taken to complete the survey. The provider questionnaire asked about the format of the report, the usefulness of the platform whether new information was obtained, and their comfort with receiving this information.



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## Results

### Stage 1

#### *Youth From Youth Co-Creation*

The youth participants gave an overall very positive response regarding the concept of the tool. Some were concerned about privacy, and it was suggested that identifiers be limited to a number, age, and gender [30]. Many youth participants had suggestions regarding specific design constructs. For example they recommended graphic design be gender neutral with positive images and a colorful interface, and "different from school," implying that it should not look like a test or school report. They suggested that many of the ASQ questions and the categorical headings they were grouped under had negative implications (eg, they pointed out that the category heading "Depression" is not neutral, and so this heading was subsequently changed to "Emotions"). They identified problems with the text, simplified questions and commented that it was more inviting to respond to text in the first person than the second person (eg, "I am male/female" instead of "Are you male/female?"). The youth identified potential judgmental icons (eg, the use of a check mark or "x" vs "yes/no"). They felt that "yes/no" was less subjective than a tick or cross that had positive or negative implications, reminiscent of a school marking system. The sexual health questions were the most controversial, and many found the question, "Which sex do you most identify with?" intimidating.

The youth were also concerned with technical issues. For example, one participant noted that "(we) need a way to select multiple icons." They found the graphic format familiar. One commented that it "looks very apple-y" (Figures 3 and 4).

**Figure 3.** TickiT screenshot.

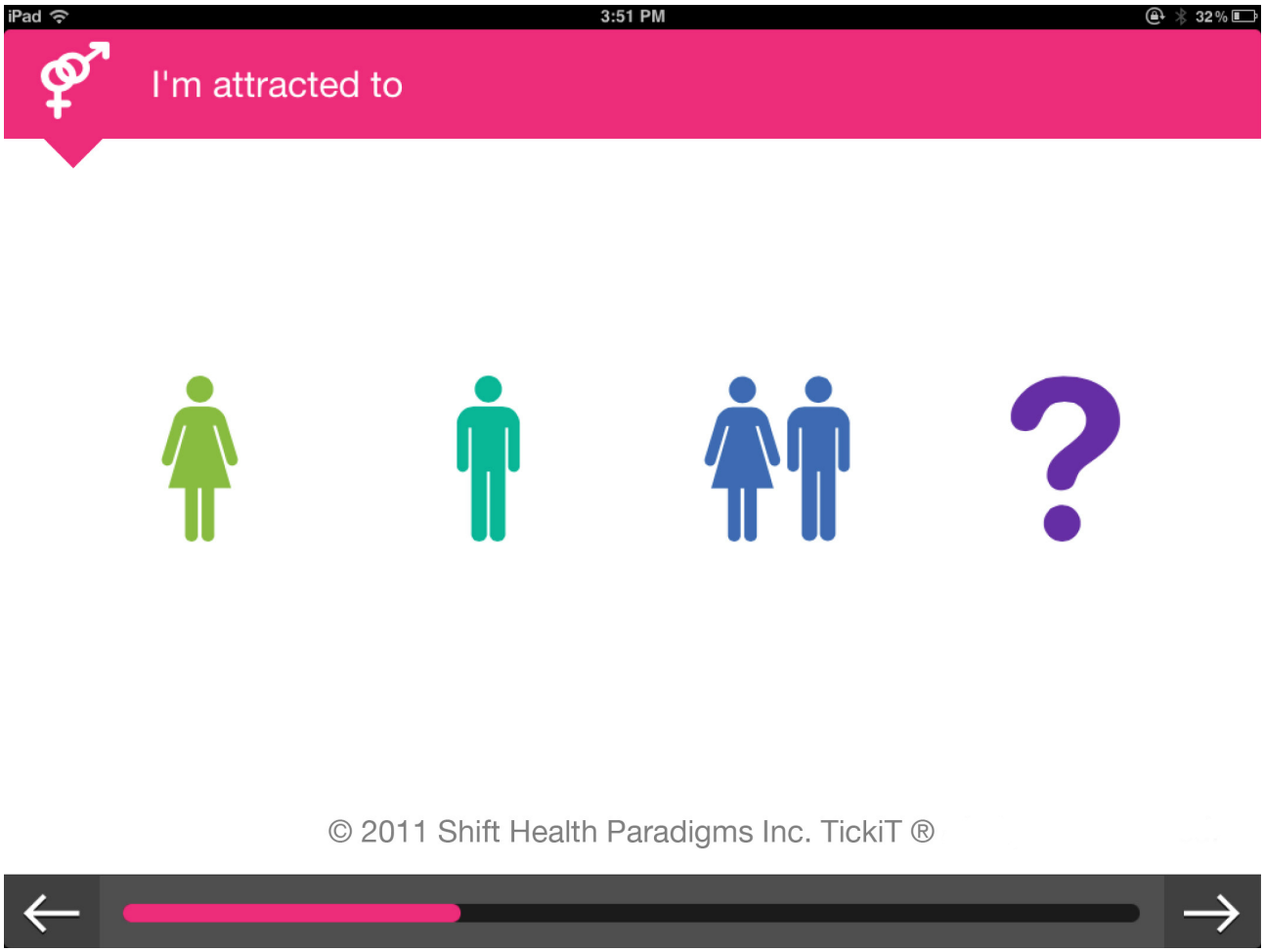




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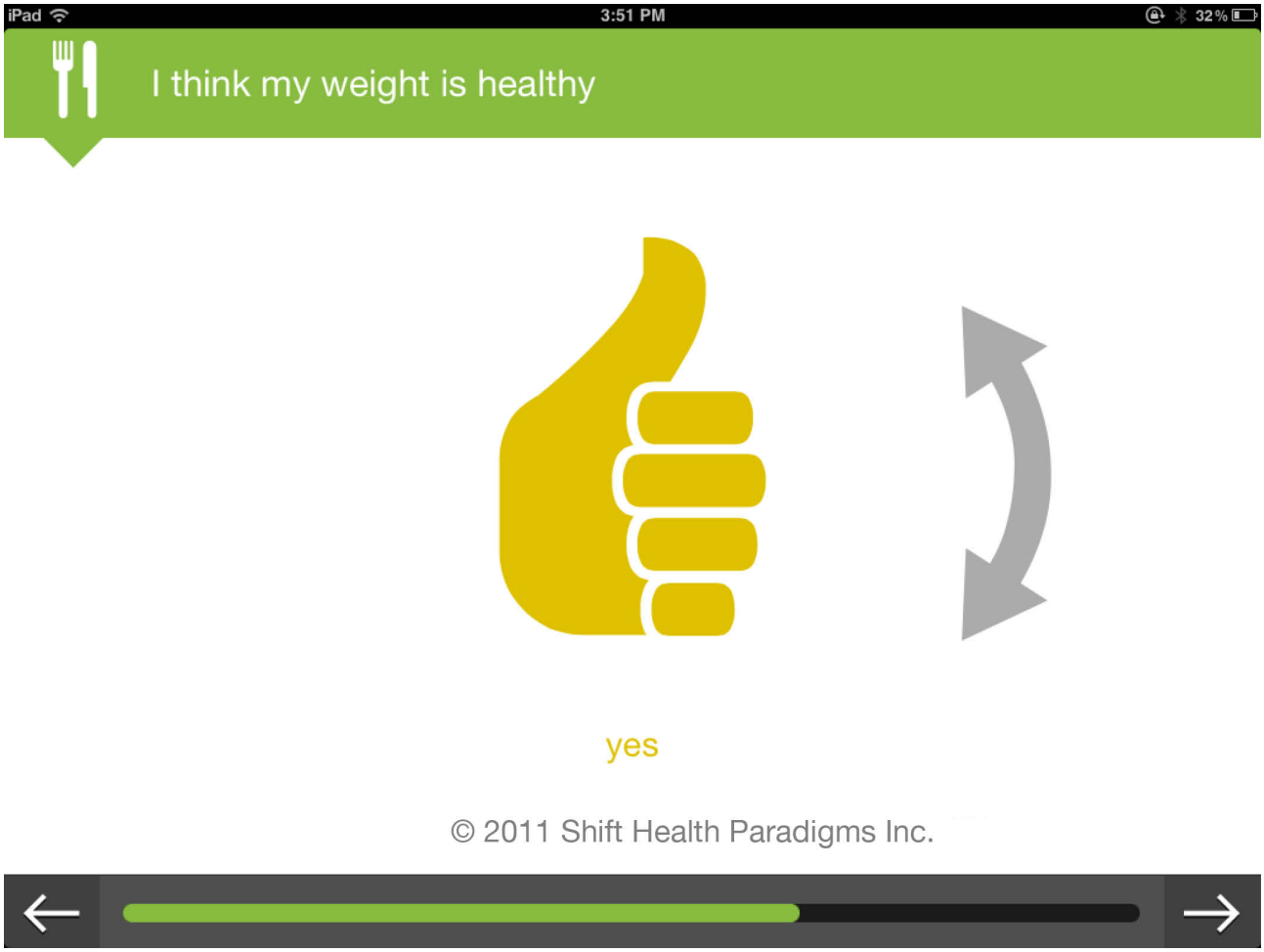
**Figure 4.** TickiT screenshot.




### *HCP Co-Creation*

The flexibility of the UI platform architecture enabled us to meet many of the HCPs content requests, without making the survey cumbersome or seem overwhelming. The templates used made provision for detailed responses. For example, scales produce more variance than a simple True/False format and involve sliding a button. On the UI, Likert scale responses were made on a 4-point Likert-type scale (such as False, Mostly False, Mostly True, and True) rather than the more commonly used 5 point scales as it allowed us to avoid a tendency for youth to select a neutral response [31].

The survey was broken into sections, so that initial responses to questions could direct the survey in a variety of directions. This addressed the HCP concern of delving more deeply with further directed questions when indicated. As the platform was being used in a hospital setting with adolescents with a variety of physical and cognitive issues. Gestural and interactive responses had to be easy to use for adolescents with motor difficulties, and text had to be large enough to accommodate poor visual acuity. Language was kept at a Grade 4 literacy level.

The youths' responses were accessed on a password protected website in the form of reports. Reports needed to be very simple to use, responding to many HCPs general anxiety with technology. The topic headings in the reports used the standardized format of the HEADDSSS assessment irrespective of the manner in which they were filled out as this was familiar to providers. The colored flagging system was enhanced with graphics for users with access only to black and white printers. Another feature of the website was the ability to download aggregated data for uploading into a database.

### *Security and Regulatory Domains: Tool to Platform*

While we had originally conceived the development of a relatively simple eHealth tool, the security and regulatory requirements for data management necessitated considerable architectural design for data protection and auditing purposes, and ultimately supported evolution of TickiT from a survey tool to a data collection and management platform. For example, multiple levels of administrative permissions were built into the software to allow for multiple levels of administration, from changing the number of digits for the ID number, generating different user roles with varying levels of permissions, password management and restrictive security templates. The platform was allowed for more flexibility to meet different jurisdictional mandates, and provide a framework for further expansion and broader functionality in the future. Rigorous documentation of the platform's security features together with policies and procedures to protect personal health information were required to ensure compliance with jurisdictional legislation on the management of personal health information, and for institutional ethics approval for the research studies. The program was



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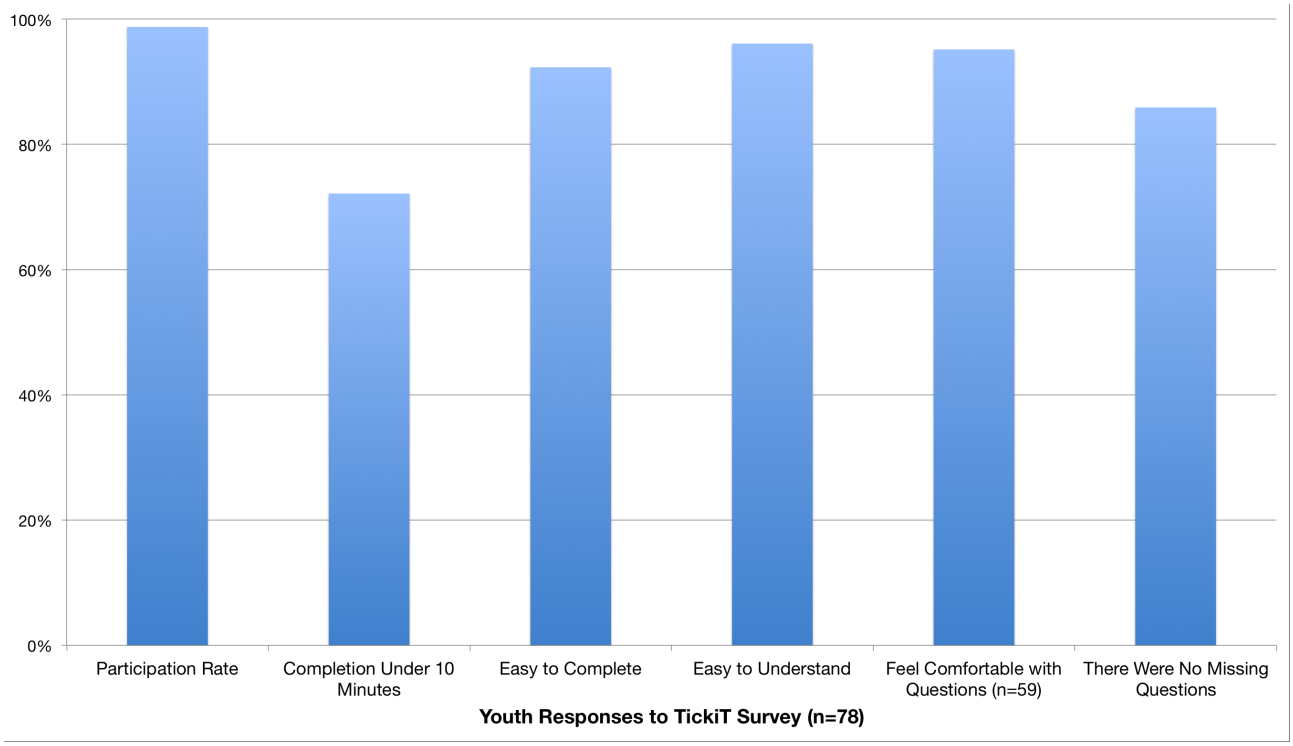
designed to work with Internet Explorer 5, reflecting that many hospitals use older Web servers.

## Stage 2

### *Youth*

The youth participants were 56% (45/80) male ranging from 14-18 years old. Ninety-nine percent (79/80) of the youth agreed to participate. The single youth who declined was an inpatient that stated he felt too unwell to participate. Of the 79 youth who agreed to participate, 99% (78/79) completed all the questions. The number of questions ranged from 56-90 depending on the responses provided. Youth commented about their experience with the tool on a paper-based survey provided after they completed the questions. Eighty percent (63/79) of the youth reported they completed the questionnaire in less than 10 minutes and all completed it in less than 15 minutes. With respect to the user experience with the interface, 92% (72/78) of the youth reported the survey tool was easy or very easy to use. As far as content of the questions, 92% (72/78) found the questions easy or very easy to understand. While 91% (71/78) of the youth felt comfortable or very comfortable with the questions asked, 9% (7/78) were neutral and none of the youth reported that they felt uncomfortable with the content of survey questions (Figure 5). Youth were asked if they felt there were questions missing and were provided an opportunity to suggest questions to be added to the survey. One youth commented there could be more depth on some topics, but did not offer specific examples.

**Figure 5.** Youth perception of TickiT.




### *Health Care Provider*

The HCPs responses varied between different professional groups, but were internally consistent. The resident trainees (n=25) gave universally positive evaluations of the platform. They found the information to be useful (25/25,100%), it met their needs as a screening tool (25/25,100%), and they felt that it had an acceptable report format (25/25,100%). Most residents (23/25, 92%) indicated that they would use TickiT in their future practice if it were available. All inpatient HCPs (pediatricians: n=3; surgeons: n=2) indicated that the reports provided new information about their patients. All the pediatricians felt comfortable with the survey platform (100%) and indicated that they would like to use TickiT in the future. However the two surgeons did not feel comfortable with the content of the reports, and commented that they did not have the skill set to manage the issues raised. They noted that they did not regularly obtain information gathered through the tool in their clinical practice. In the outpatient setting, the survey tool was given to follow-up patients with chronic health conditions who were receiving long-term medical care under a pediatric specialist (n=8). In this setting many of the HCPs (90%) did not receive new information, and most (85%) felt neutral about using the platform in the future. A couple (n=2) commented that they collected this information through other means. Despite their ambivalence, none of the physicians in any of the clinical settings recommended that any of the questions be changed. A summary of findings from these questionnaires is provided in Figure 6.



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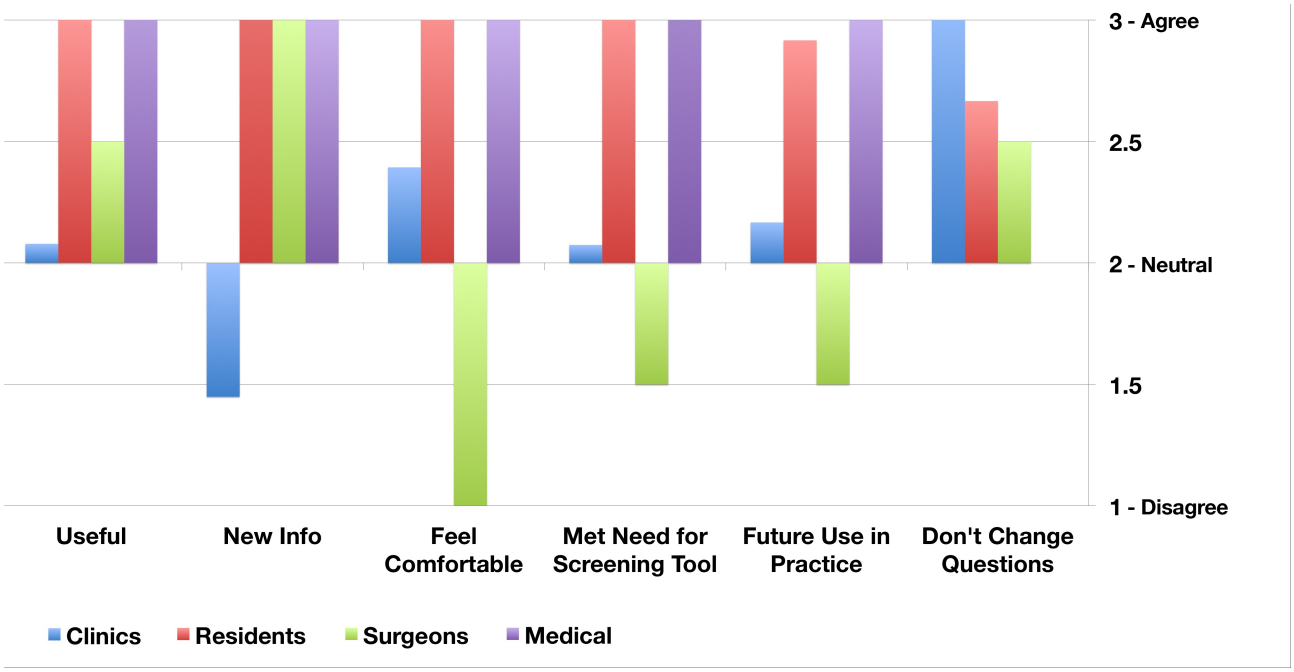
**Figure 6.** Health care provider perception of TickiT.




## Discussion

### Principal Findings

Here we have outlined the co-creation processes used during the development of an eHealth application which was initially conceived as a computer mediated means of conducting psychosocial screening of youth in varied health care settings and improving patient and HCP experiences. Over time, it emerged into a patient friendly data collection and management platform that can provide a report to HCPs, and securely captures screening data for subsequent use for research purposes.

We have presented findings from two pilot studies performed to evaluate the degree to which to the tool could increase compliance with psychosocial screening and to identify issues arising in participation by HCPs in varied settings. The co-creative process was used to develop the youth UI as youths are discerning users of technology who have high expectations, many of which are not being met by developers [32].

Youth participation, acceptance, and comfort using the tool in the Canadian hospitals study were exceptional, demonstrating the importance of being responsive to user suggestions from inception. Our findings suggest that this tool not only meets the standards recommended by health organizations for psychosocial screening but has the ability to improve health outcomes by easily providing the HCPs with valuable information [25,33]. However the relationship of the use of the platform and improved health outcomes can only be further evaluated with increased uptake of the tool and subsequent evaluation. The design strategy for development was effective for the HCP interface. The HCPs universally found the reporting interface acceptable, which indicated the information was readily available and easy to access.

Despite its potential effectiveness, the acceptance of the platform by the HCPs in the Canadian Hospitals study differed depending on their professional background. Some HCPs were not entirely comfortable with the content of the questions and the information made available to them through using TickiT.

Interestingly, resident trainees, who are generally responsible for collecting this patient information on admission, universally accepted the tool. This population may be younger, and thus more comfortable with technology than the more senior HCPs, and compared to the more established senior HCPs, the resident trainees may be less rigid in their work practices. Low acceptance by the surgeons, who felt uncomfortable with the questions which formed the substantive backbone of the tool, is consistent with the low incidence of screening in this setting [12]. While the tool had many affordances and has the potential to meet the criteria outlined in the Triple Aim framework which evaluates innovations in the health care setting using 3 evaluation criteria: to improve the patient experience,. maintain or decrease costs, and improve care. These were not sufficient for overcoming some HCP's discomfort with the content of questions.

The resistance shown by senior physicians to adopting this platform may be attributed to the challenges associated with changing the typical work practice in an established traditional workplace setting. In this setting the introduction of the platform could be considered eHealth disruptive technology [34], where technology initially disrupts the status quo but over time reconfigures clinical services. Increasing universal screening is providing a wealth of new information to a clinician and it may be threatening if he/she does not feel comfortable managing it, although the collection of such information may be considered standard of care. The introduction of a new technology such as ours in a clinical setting needs to be accompanied with strategies for supporting physicians in managing new health issues that arise from screening. In addition, as comfort with integrating information resulting from psychosocial screening into clinical encounters increases, additional evaluation will be required (eg, assessing how HCPs' workflow changes in relation to the



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availability of psychosocial data, how length of appointments changes, etc). Future acceptance of the platform will depend in part on ensuring that there is a good fit between the content of the questions and HCP comfort in addressing the issues raised through the availability of that information.

The IHI has established a Triple Aim framework to evaluate changes in innovations in the health care setting. This framework uses three evaluation criteria to improve the patient experience, maintain or decrease costs, and improve care [35]. The Canadian Hospitals study [23] suggests that implementation of the platform has the potential to meet all these criteria. Our platform was universally accepted by the patients and provided an excellent patient experience. It was efficient and required less than 15 minutes to complete by the patient with no physician input, and had the potential to add value by improving compliance with recommendations for psychosocial screening of youth, and by contributing to low cost for obtaining data for research. Findings from the pilot study undertaken by Lam et al [23] suggest that psychosocial patient information can be collected from youth using the platform in considerably less time than a 30-minute face-to-face interview. In clinical settings where HCPs were unfamiliar with the patient, all HCPs obtained new information about their patients from the platform, highlighting the potential value of using TickiT to collect new patient information about sensitive issues. While this is a precursor for improved patient care, it does not guarantee improved care. Therefore, as the use of TickiT progresses from pilot applications into everyday clinical use, additional evaluations (eg, to determine whether or not physicians act on information gathered through TickiT, and to assess use through survey and/or interview of practitioners together with an analysis of pre-and post-use referral patterns) will have to be performed.

Given the variability in deliverey of health care from hospital to hospital and across clinical settings, an action-oriented approach to implementation [36] may be required in order to identify and address issues and challenges that arise as the TickiT platform is integrated into work practices in different clinical settings. In each setting where TickiT is introduced, decisions will need to be made about how the mobile device containing the questionnaire is administered, and which members of a care team receive and act upon results of the survey. Clinical adaptation requires planning, training, and support for HCPs to modify their practices.

Studies undertaken in the development of TickiT has been valuable in many respects. The co-creation model has led to numerous enhancements to the platform, and, since completion of the pilot studies summarized here, the basic platform design has expanded to accommodate new stakeholder requests (such as providing immediate feedback based on responses entered and links to health promotion resources). While co-creation processes have been successful and preliminary results from these studies have suggested that uptake and success of the platform are likely to continue, more widespread adoption may require more robust research to demonstrate the value of TickiT in meeting IHI Triple Aim evaluation criteria. Preliminary research has been invaluable in informing design of the platform and identifying issues (eg, discomfort among some HCPs with the content it yields) warranting further attention. In an environment where there is ample competition for health care dollars, evidence is required to demonstrate value. Undertaking additional research will increase the purchase appeal of TickiT and continue to contribute to product enhancements. Examples of such research could be aimed at addressing questions about costs of implementation and use of TickiT, changes in clinical practice which are proxy measures for improved health outcomes, and evaluation of research functionality of TickiT. Already the platform has been expanded to be available in any language, and the number of clinical scenarios for data collection has grown in the public health arena and specific sensitive clinical areas such as urology.

## Limitations

Pediatric outpatient clinical care is usually provided by a clinical team of HCPs, and allied health HCPs such as nurses often manage psychosocial issues. However due to the variety of clinical settings, there was considerable variability concerning how allied health were engaged in patient care from setting to setting. Hence they were omitted as participants from this study. Future studies would benefit from engaging all HCPs involved in the patient's care.

Additionally, in the ambulatory care setting most of the visits were for follow-up care, and the clinical team already had a good understanding of the patient's psychosocial status. Finally, the HCPs were not asked for detailed information regarding their experience with the platform design as this particular study focused on the feasibility of obtaining the information in clinical settings rather than on the means through which the content was received. Variations in response between study sites (eg, to the last questions) may reflect differences in how the application was introduced, time in waiting area, or other variables.

### Challenges in the Research Process

While this paper has described two studies involved in the developmental process to create and evaluate an eHealth platform, there were a number of informal, iterative short feedback cycles performed with both youth and health care professional user groups that have not been reported, because they did not fall within the academic framework.

There are significant practical challenges of embedding the development of eHealth technology within a research environment. In an ideal world, there would be better mechanisms to support long-term research collaborations between industry and academic institutions. None of Canada's research councils have programs to support independent assessment of software developed for health sector use. Additionally, industry timelines are inconsistent with academic timelines. For example, industry requires more rapid uptake of investigation, which is not feasible with the granting cycle process, and academic research is constrained by funding, duration, and a specifically described framework prior to commencement of the work that limits investigative exploration beyond the specific research project. The co-creation study provided the recommendations for and evaluation of early prototypes. Further development occurred outside the research environment to create a functional product. The feasibility study was conducted once the product met "industry standards" by



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an academic, impartial team. These choices were made by Shift Health Paradigms to uphold a priority of arms-length independent research evaluation, to garner the best evidence available within a reasonable timeframe.

## Conclusions

In this paper, we have described the early developments of the TickiT eHealth platform that was initially designed to engage the patient, enhance the relationship between patient and provider and improve efficiency. A Canadian Hospital pilot study suggested that TickiT was an effective and efficient means to perform psychosocial screenings of youth during health care encounters. The platform was exceptionally well received by patients and residents. However some HCPs appeared to be uncomfortable with the information obtained from the TickiT HEEADDSS questionnaire, highlighting the importance of considering both the content of information collected and the means of collection when introducing new technology. While eHealth strategies can enhance the quality of data collection and encourage new relationships between providers and patients, the technology alone will not suffice if the results do not align with the objective of the clinician, even if the technology promotes standard of care. Since completion of the pilot study, the basic platform design has expanded to accommodate new stakeholder requests, and new research teams have commenced further investigations with the platform in a variety of health settings. Further studies are indicated to determine cost effectiveness, utility, and implementation in other health care settings where patients face sensitive issues. The co-creative design approach addressed the needs of the various stakeholders envisioned as the first target users of TickiT and created a framework for development that can continue to leverage the powerful potential of eHealth technology in future development for a variety of clinical settings and scenarios.

## Acknowledgments

We would like to thank and acknowledge the work being done by the current team at Shift Health Paradigms. Stephanie Rosinski and Brad Nauta have been influential in transforming the knowledge learned in the development of TickiT into a sustainable and transformative communication tool. Additionally, Terry Viczko played a key role in coordinating the research.

## Conflicts of Interest

TickiT is a registered product of Shift Health Paradigms Inc. S Whitehouse is Chief Executive Officer and a shareholder in Shift Health Paradigms Inc. D Penn is an employee of Shift Health Paradigms.

## Multimedia Appendix 1

TickiT video.

[MP4 File (MP4 Video), 19MB - resprot_v2i2e42_app1.mp4 ]

## Multimedia Appendix 2

TickiT features.

[PDF File (Adobe PDF File), 743KB - resprot_v2i2e42_app2.pdf ]

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## Abbreviations

**ASQ:** adolescent screening questionnaire
**BCCH:** British Columbia Children's Hospital
**CLAS:** computerized lifestyle assessment scale
**ECUAD:** Emily Carr University of Art and Design
**EHR:** electronic health record
**HCP:** health care providers
**HEEADDSS:** home, education, eating, activities, drugs, depression, sexual health, safety
**IHI:** Institute of Healthcare Improvement
**IT:** information technology
**PHI:** personal health information
**PIPEDA:** personal information protection and electronic documents act
**UI:** user interface


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Original Paper

# The Comparative Validity of Interactive Multimedia Questionnaires to Paper-Administered Questionnaires for Beverage Intake and Physical Activity: Pilot Study

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## Abstract

**Background:** Brief, valid, and reliable dietary and physical activity assessment tools are needed, and interactive computerized assessments (ie, those with visual cues, pictures, sounds, and voiceovers) can reduce administration and scoring burdens commonly encountered with paper-based assessments.

**Objective:** The purpose of this pilot investigation was to evaluate the comparative validity and reliability of interactive multimedia (IMM) versions (ie, IMM-1 and IMM-2) compared to validated paper-administered (PP) versions of the beverage intake questionnaire (BEVQ-15) and Stanford Leisure-Time Activity Categorical Item (L-Cat); a secondary purpose was to evaluate results across two education attainment levels.

**Methods:** Adults 21 years or older (n=60) were recruited to complete three laboratory sessions, separated by three to seven days in a randomly assigned sequence, with the following assessments–demographic information, two IMM and one paper-based (PP) version of the BEVQ-15 and L-Cat, health literacy, and an IMM usability survey.

**Results:** Responses across beverage categories from the IMM-1 and PP versions (validity; $r$=.34-.98) and the IMM-1 and IMM-2 administrations (reliability; $r$=.61-.94) (all $P$<.001) were significantly correlated. Paired $t$ tests revealed significant differences in sugar-sweetened beverage (SSB) grams and kcal ($P$=.02 and $P$=.01, respectively) and total beverage kcal ($P$=.03), on IMM-1 and IMM-2; however, comparative validity was demonstrated between IMM-2 and the PP version suggesting familiarization with the IMM tool may influence participant responses (mean differences: SSB 63 grams, SEM 87; $P$=.52; SSB 21 kcal, SEM 33; $P$=.48; total beverage 65 kcal, SEM 49; $P$=.19). Overall mean scores between the PP and both IMM versions of the L-Cat were different (both $P$<.001); however, responses on all versions were correlated ($P$<.001). Differences between education categories were noted at each L-Cat administration (IMM-1: $P$=.008; IMM-2: $P$=.001; PP: $P$=.002). Major and minor themes from user feedback suggest that the IMM questionnaires were easy to complete, and relevant to participants' typical beverage choices and physical activity habits.

**Conclusions:** In general, less educated participants consumed more total beverage and SSB energy, and reported less engagement in physical activity. The IMM BEVQ-15 appears to be a valid and reliable measure to assess habitual beverage intake, although software familiarization may increase response accuracy. The IMM-L-Cat can be considered reliable and may have permitted respondents to more freely disclose actual physical activity levels versus the paper-administered tool. Future larger-scale investigations are warranted to confirm these possibilities.

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**KEYWORDS**

validity and reliability; multimedia; dietary assessment; beverages; physical activity



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## Introduction

### Assessment Methods

Multiple unannounced 24-hour recalls, food records, and physical activity recalls have historically been recognized as gold standard approaches to assessing dietary and physical activity behaviors [1-3]. However, these assessment methods often require trained staff to administer and analyze, and are labor-intensive for both researchers and participants [1,2]. For these reasons, other valid methods of diet and physical activity assessments have been developed, such as food-frequency questionnaires as well as brief assessments of diet and physical activity. Recently, computerized diet and physical activity assessments have emerged as a way to decrease literacy barriers for participants, as well as decrease the research burden of processing paper-based surveys in large studies [4-8]. However, attention to the reliability, validity, and usability of computerized approaches to assessing diet and physical activity behaviors are imperative.

Due in part to the increased use and accessibility of computers in multiple settings (eg, homes, libraries, churches, recreational community centers, grocery stores, and schools) [7,9], the use of Web and computer-based assessments in large research trials have increased over the past 10 years [4,6,10]. The National Institutes of Health has recognized the need for novel/innovative assessment methods using technological advances in physical activity and dietary assessment (eg, PAR-12-198). There is no consensus to whether a paper-based assessment is superior to a computerized one [11]; however, computer-based tools can provide an alternative means to collect and analyze data [12] and may be appealing to practitioners and researchers because of their proposed benefits. Computer-administered assessments may overcome difficulties sometimes associated with paper-based surveys as they allow for interactivity-two-way communication between computer and participant through photographs, videos, and displayed text with or without audio [7]. Other advantages of computerized questionnaire administration include-complete responses (ie, prompting individuals to answer all questions), written and narrated text, visual cues of portion sizes, immediate and rapid data entry and scoring, decreased scoring errors, increased attentiveness from participants, instantaneous feedback, and a greater ability to access understudied populations [6,8,10,13,14]. Additionally, multi-part questions of computerized assessments can be programmed to reduce administration time by providing only relevant data and information for the participant [7]. In low health literacy populations, computerized questionnaires may be advantageous since text can be narrated and visual aids can be used, which may reduce response errors and the necessity of advanced reading skills [7]. Another potential advantage of computer-based assessments is that response-bias and intimidation may be reduced with computer-administered surveys, although additional research addressing this possibility is needed [5,7,15]. However, when using identical computerized versions of paper assessments comparability cannot be assumed because interface characteristics like font size, line length, scrolling ability, and amount of information visible on the screen can all influence user performance [16,17].

### Two Paper-Based Questionnaires

Prior research has demonstrated the reliability and validity of two self-administered paper-based questionnaires. One assesses habitual beverage intake (BEVQ-15) [18], and the other measures usual physical activity level, Stanford Leisure-Time Activity Categorical Item 2.2 (L-Cat) [19]. There are several computerized nutrition education delivery [7,20,21] and dietary assessment tools [8,13,22-28] and a few Web-based physical activity questionnaires [12,29,30] currently available; however, to the best of our knowledge, no computer-based beverage intake questionnaire exists. The recently developed Automated Self-Administered 24-hour Recall [31] is computer-based and does contain questions about beverage intake; however, results on its validity and usability have yet to be published [32]. The purpose of this pilot investigation was to evaluate the comparative validity and reliability of newly developed interactive multimedia (IMM) versions compared to validated paper-administered (PP) versions of the BEVQ-15 [18] and L-Cat [19]. Individuals with lower educational attainment and/or health literacy levels may be at increased risk for health complications associated with poor dietary and health behaviors such as obesity, diabetes, hypertension, and coronary heart disease [33]. Therefore, a secondary purpose of this investigation was to evaluate the validity and reliability of the major BEVQ-15 categories, for example, total water, sugar-sweetened beverage (SSB), and total beverage grams and kcal, and L-Cat category across two education levels, in order to determine the suitability of the IMM versions for individuals from varying educational backgrounds.

## Methods

### Recruitment

Adults 21 years or older (n=60) were recruited from several community settings (a local university community, free medical clinic, area Community Services building, and church congregation) between January and August 2012 in southwest Virginia. The Virginia Tech Institutional Review Board approved the study protocol and participants provided written informed consent prior to enrollment.

### Protocol

Participation entailed three laboratory sessions with three to seven days between each session. Sessions were completed in one of two randomly assigned visit sequences that differed in questionnaire administration format (ie, taking the paper or computerized instruments initially). Randomization was done to avoid a potential effect of session order on study outcomes. In addition to providing demographic information, each participant completed a total of two identical self-administered IMM BEVQ-15 [18] and L-Cat [19] questionnaires (denoted IMM-1 for the first administration and IMM-2 for the second administration), one PP BEVQ-15 and L-Cat (ie, one set being BEVQ-15 and L-Cat at each of the three lab sessions), the Newest Vital Sign tool to assess health literacy [34], and an open-ended feedback survey on the IMM questionnaire to address usability; a total of five questionnaires were completed by each participant. Responses from the feedback survey were either "yes" or "no", or rated on an ordered-response scale



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(1=easy, 5=hard) with open-ended areas for comments following each question. Investigators supervised the assessments and provided limited instructions, but were available to answer questions during the survey if needed. Participants were compensated in the form of a $25 gift card upon completion of all three study visits.

### Measurements

Participants provided information on demographic characteristics (ie, age, race/ethnicity, income level, and highest education level attained), and this was used to categorize participants into one of two education categories: (1) less than high school/high school, and (2) some college/college degree. Prior research suggests that the level of education reached can be a strong socioeconomic determinant of beverage intake [33,35]. Descriptive measurements were conducted by a graduate research assistant who is a registered dietitian (SKR) and a trained research assistant (ACP) and included the following-height measured in meters without shoes using a wall mounted stadiometer (Seca 216, Hamburg, Germany); body weight measured in light clothing without shoes to the nearest 0.2 kg using a digital scale (Scale-Tronix, Wheaton, IL); and body mass index (BMI), calculated as $kg/m^2$. The Newest Vital Sign (NVS) is a valid and sensitive tool that was used to assess health literacy and includes six questions based upon information contained in a nutrition facts label for a pint of ice cream. The scores range from 0-6 (0=limited health literacy, 6=adequate health literacy) [34].

### The BEVQ-15 and L-Cat

The BEVQ-15 [18] is a brief, valid, and reliable quantitative food frequency questionnaire providing an estimate of habitual beverage intake across 15 beverage categories, which evaluates total beverage and SSB intake (ie, grams and kcal) over the past 30 days. Details regarding the development and evaluation of the BEVQ-15 have been previously published [18,36]. The PP BEVQ took 2 minutes-15 seconds to complete during its initial testing [18]. Self-reported physical activity was assessed using the brief L-Cat [19]. This tool was developed from the Stanford Brief Activity Survey [37-39] and consists of six descriptive categories (eg, 3="About three times a week, I did moderate activities such as brisk walking, swimming, or riding a bike for about 15-20 minutes each time. Or about once a week, I did moderately difficult chores such as raking or mowing the lawn for about 45-60 minutes. Or about once a week, I played sports such as softball, basketball, or soccer for about 45-60 minutes.") ranging from inactive (1=I did not do much physical activity) to very active (6=Almost daily, that is five or more times a week, I did vigorous activities). In a randomized trial involving 267 obese women, the L-Cat was found to be valid and reliable [19]. The paper versions of these tools were read and completed by the study participants independently with an investigator available for questions throughout the administration.

Using the validated PP versions of these two tools, computerized versions were developed. The IMM BEVQ-15 began with narrated text and graphic on-screen directions taking approximately three to four minutes. For each drink category, which replicated the paper-based BEVQ-15 in content and sequence, a photo of the beverage was presented on-screen (Figure 1 shows an example of the water intake category). Silhouettes of portion sizes with the quantities they represented in fluid ounces and cups were presented for each beverage category. For example, a soft drink can silhouette was pictured with other beverage containers with the text stating, "a typical beverage can represents 12 fluid ounces or 1 ½ cups." Once the IMM BEVQ-15 was completed, the participant was directed to an instructional page with narrated text (approximately 25 seconds) describing the L-Cat. As with the IMM BEVQ-15, the IMM L-Cat provided audio for each category wherever the mouse's cursor was placed. When the participant chose the physical activity/leisure time activity statement that best reflected their usual physical activity level another completion page was displayed which informed the participant that they were through with the computerized assessment. Completion time was covertly monitored for the IMM BEVQ and L-Cat. After finishing the first IMM administration, participants were invited to complete a user feedback survey that contained seven questions with ordered-response (eg, 1=easy and 5= hard), "Yes" or "No," and open-end response formats.



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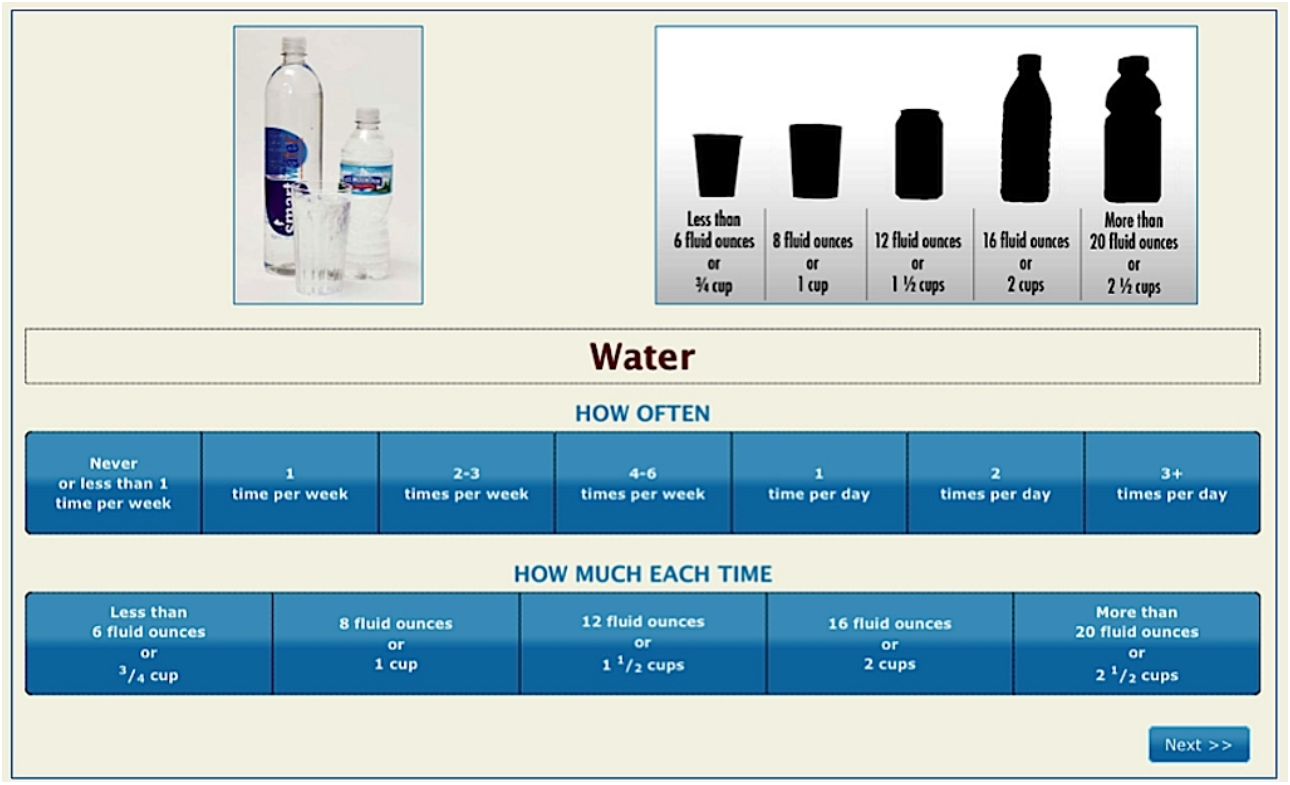
**Figure 1.** Screenshot example of the water beverage category from the interactive multimedia Beverage Intake Questionnaire-15.




### Statistical Analysis

Statistical analyses were performed using SPSS statistical analysis software (version 20.0 for Macintosh, 2011, IBM Corporation, Chicago, IL). Demographic characteristics and mean daily beverage consumption (grams, kcal) for the two IMM and one PP BEVQ are reported as mean and standard error of the mean (SEM) or as frequencies (categorical variables). Paired sample *t* tests and bivariate correlations (Pearson's *r*) were used to assess validity (first IMM administration vs PP) and reliability (first vs second IMM administration, or IMM-1 vs IMM-2). Due to multiple *t* tests being conducted, data were reanalyzed to evaluate major outcomes using repeated measures analysis of variance with covariates where appropriate (eg, education), and results were consistent across analytical approaches. Chi square analyses and independent sample *t* tests were used to assess differences between education groups on categorical variables (eg, gender, race/ethnicity) and continuous variables (eg, BMI, beverage consumption), respectively. The alpha level was set *a priori* at $P \leq .05$. Responses from the open-ended ease of use questions on the IMM feedback survey were grouped into themes and quantified. *Major themes* were considered similar responses from ≥50% of participants (≥30 of 60 participants), while *minor themes* were considered similar responses from 25%-49% of participants (15 to 29, of 60 participants) [40]. A second investigator independently verified themes.

## Results

### Demographic Characteristics

Demographic characteristics of the study sample are presented in Table 1. Participants were predominantly white (88%, 53/60 participants), but balanced with respect to gender (55% female, 33/60 participants). Age ranged 21 to 70 years, with a mean age of 37 (SEM 2) years. There were no significant differences between education categories for age ($P=.38$), gender ($P=.17$), or race/ethnicity ($P=.33$); however, there were differences in BMI ($P=.01$), income ($P<.001$), and health literacy ($P<.001$) with those in the lower educational category having a higher BMI, and lower income level and health literacy score compared to those in the higher educational category. Differences were found by testing sequence, which was attributed to an unintentional greater random allocation of more participants in the "less than high school/high school" education group being assigned to one of the two sequences.

Completion times for the PP, IMM-1 BEVQ-15 and L-Cat, and IMM-2 BEVQ-15 and L-Cat were approximately three, five, and four minutes, respectively. The paper-based questionnaire time to completion was significantly shorter than both IMM-1 and IMM-2 (both $P<.001$). Time to completion on IMM-2 versus IMM-1 was also significantly different ($P<.001$) with the IMM-1 administration taking longer. There were no differences between education categories for time to completion between the PP ($P=.69$) and the computer-administered versions (IMM-1: $P=.44$; IMM-2: $P=.73$).



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**Table 1.** Participant demographic characteristics.[a]

| | Less Than High School/High School n=21 | Some College/College Degree n=39 | Full Sample N=60 |
|---|---|---|---|
| **Gender, n (%)** | | | |
| Male | 12 (57) | 15 (39) | 27 (45) |
| Female | 9 (43) | 24 (62) | 33 (55) |
| Age, years | 39 (SEM 3) | 36 (SEM 2) | 37 (SEM 2) |
| **Race/Ethnicity, n (%)** | | | |
| White | 19 (91) | 34 (87) | 53 (88) |
| Black/African-American | 2 (10) | 1 (3) | 3 (5) |
| Asian | 0 | 3 (8) | 3 (5) |
| Other | 0 | 1 (3) | 1 (2) |
| BMI, kg/m$^2$[b], mean (SEM) | 31.8 (2.7) | 26.3 (0.7) | 28.2 (1.1) |
| **BMI Category (kg/m$^2$), n (%)** | | | |
| Underweight (<18.5) | 1 (5) | 1 (3) | 2 (3) |
| Normal (18.5-24.9) | 6 (29) | 15 (39) | 21 (35) |
| Overweight (25-29.9) | 4 (19) | 14 (36) | 18 (30) |
| Obese (≥30) | 10 (48) | 9 (23) | 19 (32) |
| Newest Vital Sign (Score[c])[d] | 4.1 | 5.8 | 5.2 |
| **Total Annual Household Income, n (%)** [d] | | | |
| ≤$25,000 [e] | 19 (90) | 8 (21) | 27 (45) |
| $25,000-50,000 | 1 (5) | 9 (23) | 10 (17) |
| ≥$50,000 | 1 (5) | 22 (56) | 23 (38) |

[a]Frequency variables are expressed as n (%), other variables are expressed as mean (SEM).

[b]Significant difference between education groups ($P$=.01).

[c]Scored from 0-6, with 0-1 (high likelihood of limited health literacy), 2-3 (potential limited health literacy), and 4-6 (adequate health literacy) representing the number of correct responses.

[d]Significant difference between education groups ($P$<.001).

[e]Representative of a family of four at or below the current federal income guidelines [41].

## Comparative Validity of the IMM BEVQ-15 and L-Cat

Results from the comparative validity (ie, comparison of the responses from the IMM BEVQ-15 with the validated PP BEVQ-15) assessment of IMM and PP tools for beverage categories are presented in Table 2. Responses from all beverage categories from the IMM-1 and PP versions were correlated ($r$=.34-.98, all $P$<.001), and SSB and total beverage gram and kcal responses were correlated on IMM-1 and PP versions ($r$=.92-.95, all $P$<.001). Between IMM-1 and the PP version, no significant differences in beverage category responses were noted. The mean scores for the PP and IMM-1 L-Cat were 3.5 (SEM 0.2) and 2.4 (SEM 0.2), respectively. The paper-based and IMM-1 L-Cat responses were correlated ($r$=.85, $P$<.001), but mean values were different ($P$<.001).



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**Table 2.** Comparative validity of the IMM BEVQ-15: a comparison of the individual beverage category responses from the first IMM administration to the PP BEVQ-15.

| Beverage category | Validity | | | |
|---|---|---|---|---|
| | IMM-1 | Paper | Difference with IMM-1[a] | |
| | Mean (SEM) | Mean (SEM) | Mean (SEM) | Correlation (*r*) |
| Water (g) | 804 (87) | 725 (66) | -79 (45) | .866[b] |
| **100% Fruit juice** | | | | |
| g | 101 (23) | 87 (17) | -14 (14) | .827[b] |
| kcal | 58 (13) | 50 (9) | -8 (8) | .827[b] |
| **Juice drinks** | | | | |
| g | 137 (47) | 92 (13) | -45 (28) | .817[b] |
| kcal | 64 (22) | 43 (15) | -21 (13) | .817[b] |
| **Whole milk** | | | | |
| g | 75 (30) | 75 (35) | 0 (8) | .981[b] |
| kcal | 56 (23) | 56 (26) | 0 (6) | .981[b] |
| **Reduced-fat milk** | | | | |
| g | 52 (16) | 84 (36) | 32 (34) | .339[c] |
| kcal | 32 (10) | 51 (22) | 19 (21) | .339[c] |
| **Fat-free milk** | | | | |
| g | 68 (19) | 83 (19) | 15 (11) | .829[b] |
| kcal | 26 (7) | 31 (7) | 6 (4) | .829[b] |
| **Regular soft drinks** | | | | |
| g | 324 (73) | 361 (75) | 38 (23) | .951[b] |
| kcal | 143 (32) | 160 (33) | 17 (10) | .951[b] |
| **Diet soft drinks** | | | | |
| g | 263 (65) | 255 (57) | -8 (37) | .828[b] |
| kcal | 3 (1) | 3 (1) | -1 (0) | .828[b] |
| **Sweet tea** | | | | |
| g | 211 (54) | 186 (52) | -25 (26) | .879[b] |
| kcal | 68 (17) | 60 (17) | -8 (8) | .879[b] |
| **Sweetened coffee** | | | | |
| g | 298 (59) | 277 (57) | -21 (34) | .823[b] |
| kcal | 83 (16) | 77 (16) | -6 (9) | .831[b] |
| **Regular coffee/tea** | | | | |
| g | 168 (48) | 246 (60) | 78 (39) | .762[b] |
| kcal | 2 (1) | 3 (1) | 1 (1) | .758[b] |
| **Beer** | | | | |
| g | 101 (32) | 98 (32) | -3 (6) | .983[b] |
| kcal | 35 (11) | 34 (11) | -1 (2) | .983[b] |



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| Beverage category | Validity | | | |
|---|---|---|---|---|
| | IMM-1 | Paper | Difference with IMM-1[a] | |
| | Mean (SEM) | Mean (SEM) | Mean (SEM) | Correlation (*r*) |
| **Liquor** | | | | |
| g | 17 (8) | 19 (10) | 3 (4) | .936[b] |
| kcal | 39 (19) | 45 (23) | 6 (9) | .936[b] |
| **Wine** | | | | |
| g | 23 (6) | 18 (6) | -5 (4) | .745[b] |
| kcal | 16 (4) | 13 (4) | -3 (3) | .745[b] |
| **Energy drinks** | | | | |
| g | 120 (47) | 73 (35) | -47 (30) | .780[b] |
| kcal | 54 (21) | 33 (16) | -21 (13) | .780[b] |
| **Sugar-sweetened beverage** | | | | |
| g | 1107 (212) | 989 (182) | -177 (72) | .944[b] |
| kcal | 417 (82) | 373 (70) | -44 (28) | .945[b] |
| **Total beverage** | | | | |
| g | 2792 (261) | 2678 (263) | -115 (106) | .918[b] |
| kcal | 682 (116) | 657 (122) | -25 (42) | .938[b] |

[a]Mean difference according to paired sample *t* test; slight difference may be noted from the preceding columns due to rounding, as whole numbers are presented in the table.

[b]*P*<.001

[c]*P*=.01

## Test-Retest Reliability of the IMM BEVQ-15 and L-Cat

All beverage category responses on IMM-1 and IMM-2 administrations were correlated (Table 3; *r*=.61-.94, all *P*<.001). SSB and total beverage gram and kcal responses were correlated on both IMM versions (*r*=.73-.96, all *P*<.001). No significant differences in beverage category responses were noted between IMM-1 and IMM-2 with the exception of SSB grams and kcal (*P*=.02 and *P*=.01, respectively) and total beverage kcal (*P*=.01). However, when comparing the responses from the paper and IMM-2 questionnaire administrations on these categories there were no significant differences (mean differences: SSB 63 grams, SEM 87; *P*=.52; SSB 21 kcal, SEM 33; *P*=.48; and total beverage 65 kcal, SEM 49; *P*=.19). The mean L-Cat score on IMM-2 was 2.5 (SEM 0.2), and the IMM L-Cat responses were correlated (*r*=.86, *P*<.001). No significant differences were observed between L-Cat responses on the IMM-1 and IMM-2 questionnaires (*P*=.72); however, differences were noted in IMM-2 and PP L-Cat responses (*P*<.001).



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**Table 3.** Reproducibility of the IMM BEVQ-15: Comparison of the first and second IMM administrations.

| Beverage Category | | Reliability | | | |
|---|---|---|---|---|---|
| | | IMM-1 | IMM-2 | Difference with IMM-1[a] | |
| | | Mean (SEM) | Mean (SEM) | Mean (SEM) | Correlation (*r*) |
| Water (g) | | 804 (87) | 756 (76) | -47 (62) | .721[b] |
| **100% Fruit juice** | | | | | |
| | g | 101 (23) | 76 (17) | -24 (18) | .666[b] |
| | kcal | 58 (13) | 44 (10) | -13 (10) | .665[b] |
| **Juice drinks** | | | | | |
| | g | 137 (47) | 134 (48) | -3 (23) | .888[b] |
| | kcal | 64 (22) | 63 (22) | -1 (10) | .888[b] |
| **Whole milk** | | | | | |
| | g | 75 (30) | 54 (26) | -20 (13) | .898[b] |
| | kcal | 56 (23) | 41 (20) | -15 (10) | .898[b] |
| **Reduced-fat milk** | | | | | |
| | g | 52 (16) | 33 (10) | -19 (10) | .807[b] |
| | kcal | 32 (10) | 20 (6) | -12 (6) | .807[b] |
| **Fat-free milk** | | | | | |
| | g | 68 (19) | 74 (18) | 6 (11) | .811[b] |
| | kcal | 26 (7) | 28 (7) | 2 (4) | .811[b] |
| **Regular soft drinks** | | | | | |
| | g | 324 (73) | 289(69) | -35 (35) | .881[b] |
| | kcal | 143 (32) | 128 (31) | -15 (15) | .881[b] |
| **Diet soft drinks** | | | | | |
| | g | 263 (65) | 246 (63) | -16 (42) | .784[b] |
| | kcal | 3 (1) | 3 (1) | 0 (0) | .784[b] |
| **Sweet tea** | | | | | |
| | g | 211 (54) | 172 (53) | -39 (31) | .834[b] |
| | kcal | 68 (17) | 55 (17) | -12 (10) | .834[b] |
| **Sweetened coffee** | | | | | |
| | g | 298 (59) | 254 (52) | -44 (45) | .676[b] |
| | kcal | 83 (16) | 71 (14) | -13 (12) | .689[b] |
| **Regular coffee/tea** | | | | | |
| | g | 168 (48) | 199 (51) | 31 (44) | .616[b] |
| | kcal | 2 (1) | 2 (1) | 0 (1) | .610[b] |
| **Beer** | | | | | |
| | g | 101 (32) | 121 (42) | 19 (24) | .830[b] |
| | kcal | 35 (11) | 42 (15) | 7 (8) | .830[b] |
| **Liquor** | | | | | |



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| Beverage Category | | Reliability | | | |
|---|---|---|---|---|---|
| | | IMM-1 | IMM-2 | Difference with IMM-1[a] | |
| | | Mean (SEM) | Mean (SEM) | Mean (SEM) | Correlation (*r*) |
| | g | 17 (8) | 19 (8) | 3 (3) | .944[b] |
| | kcal | 39 (19) | 45 (19) | 6 (6) | .944[b] |
| **Wine** | | | | | |
| | g | 23 (6) | 24 (6) | 1 (4) | .827[b] |
| | kcal | 16 (4) | 17 (4) | 1 (3) | .827[b] |
| **Energy drinks** | | | | | |
| | g | 120 (47) | 78 (34) | -42 (30) | .771[b] |
| | kcal | 54 (21) | 35 (14) | -19 (14) | .771[b] |
| **Sugar-sweetened beverage** | | | | | |
| | g | 1107 (212) | 927(189) | -180 (71[c]) | .944[b] |
| | kcal | 417 (82) | 351 (75) | -65 (26[d]) | .948[b] |
| **Total beverage** | | | | | |
| | g | 2792 (261) | 2755 (296) | -38 (207) | .731[b] |
| | kcal | 682 (116) | 592 (107) | -91 (34 [d]) | .955[b] |

[a]Mean difference according to paired sample *t* test; slight difference may be noted from the preceding columns due to rounding, as whole numbers are presented in the table.

[b]Significant correlations (*P*<.001)

[c]Significant difference between IMM-2 and IMM-1 (*P*=.02).

[d]Significant difference between IMM-2 and IMM-1 (*P*=.01).

## Comparative Validity and Reliability Within Educational Categories

Figures 2-4 show the results of the major beverage outcomes (water, SSB, total beverage intake) and L-Cat according to educational level. The IMM version of the beverage questionnaire demonstrated comparative validity across the major beverage outcomes with the exception of water intake in the "some college/college degree" participants (mean difference between PP and IMM-1 119, SEM 59; *P*=.048) with correlation coefficients ranging from .76-.95 (all *P*<.001). However, responses to the L-Cat were significantly higher with the PP version in both educational groups (mean differences between PP and IMM-1 in less than high school/high school 0.9, SEM 0.2; and in some college/college degree 1.1, SEM 0.1; both *P*<.001).

No differences were noted in repeated IMM responses for beverage intake or physical activity. Differences were noted in the repeated IMM responses from the "less than high school/high school" participants for SSB grams and kcal (both *P*=.02) and total beverage energy (*P*=.03), with lower intake reported on the second administration. However, pair samples *t* tests results revealed no significant differences between the PP and IMM-2 tools (mean differences–SSB 99 grams, SEM 245; *P*=.69; SSB 24 kcal, SEM 92; *P*=.79; total beverage 152 kcal, SEM 134; *P*=.27). There were no significant differences on L-Cat responses in the "less than high school/high school" participants (*P*=.67).



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**Figure 2.** Beverage intake in grams for education categories. The following abbreviations mean: Low Ed=Less than high school/high school; High Ed=Some college/college degree; SSB=Sugar-sweetened beverages; IMM=Interactive Multi-media, 2 separate administrations; and PP=Paper and Pencil version. The "Water" "Low Ed" solid black and solid grey bars and the "Total Beverage" "Low Ed" grey-striped bar show a significant difference from "High Ed" group (*P*=.02). The "SSB" "Low Ed" solid black, solid grey, and grey-striped bars and "Total Beverage" "Low Ed" solid black and solid grey bars show a significant difference from "High Ed" group (*P*<.001).

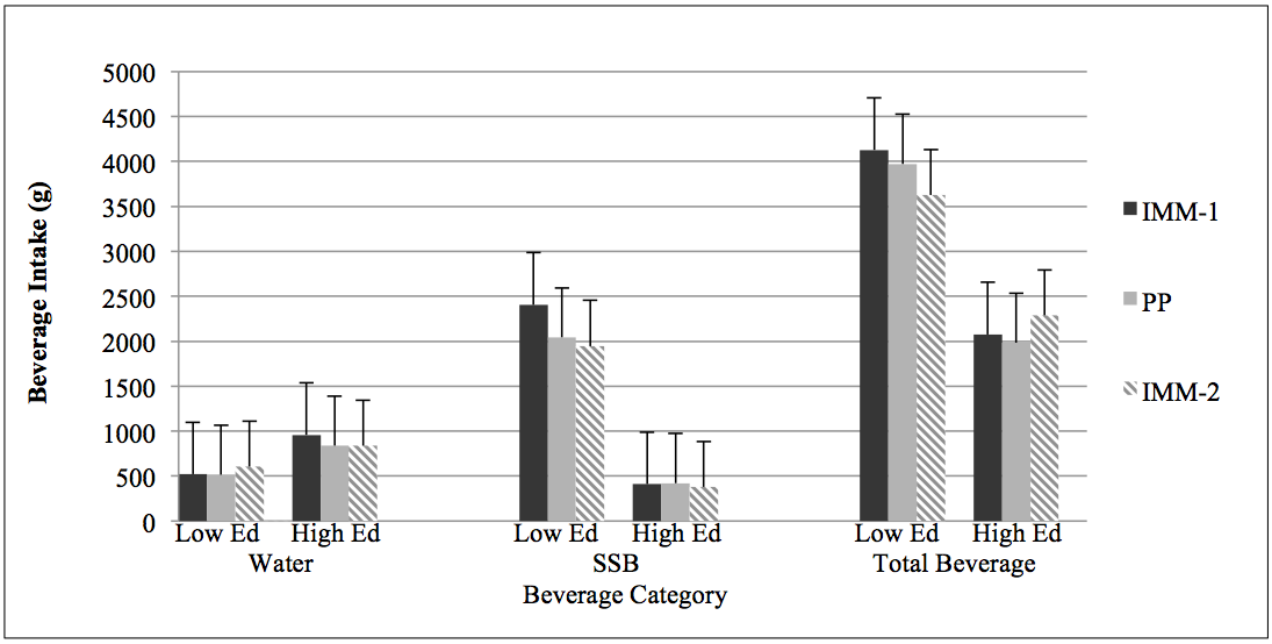
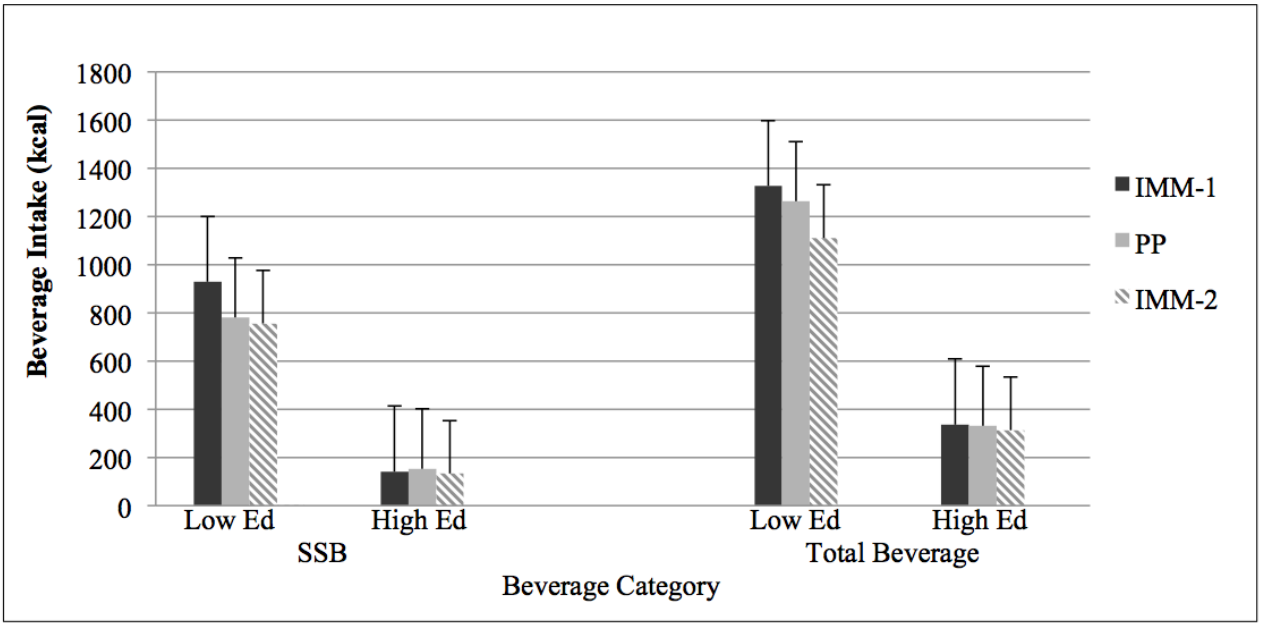



**Figure 3.** Beverage intake in calories (kcal) for education categories. The following abbreviations mean: Low Ed=Less than high school/high school, High Ed=Some college/college degree; SSB=Sugar-sweetened beverages; IMM=Interactive Multi-media, two separate administrations; and PP=Paper and Pencil version. The six "Low Ed" solid black, solid grey, and grey-striped bars show a significant difference from "High Ed" group (*P*<.001).




## Comparison of Lower and Higher Educational Groups

Differences in water consumption between education categories on the first IMM and PP questionnaire administrations were significant (both *P*=.02), but not on the second IMM (*P*=.14), with the "less than high school/high school" participants reporting significantly lower water consumption than the "some college/college degree" participants (Figure 2). Daily SSB (grams and kcal) and total beverage consumption (grams and kcal) were different between education categories at each questionnaire administration (IMM-1, IMM-2, PP) (Figures 2 and 3). Differences between education categories were noted at each L-Cat administration (IMM-1: *P*=.008; IMM-2: *P*=.001; PP: *P*=.002) (Figure 4).



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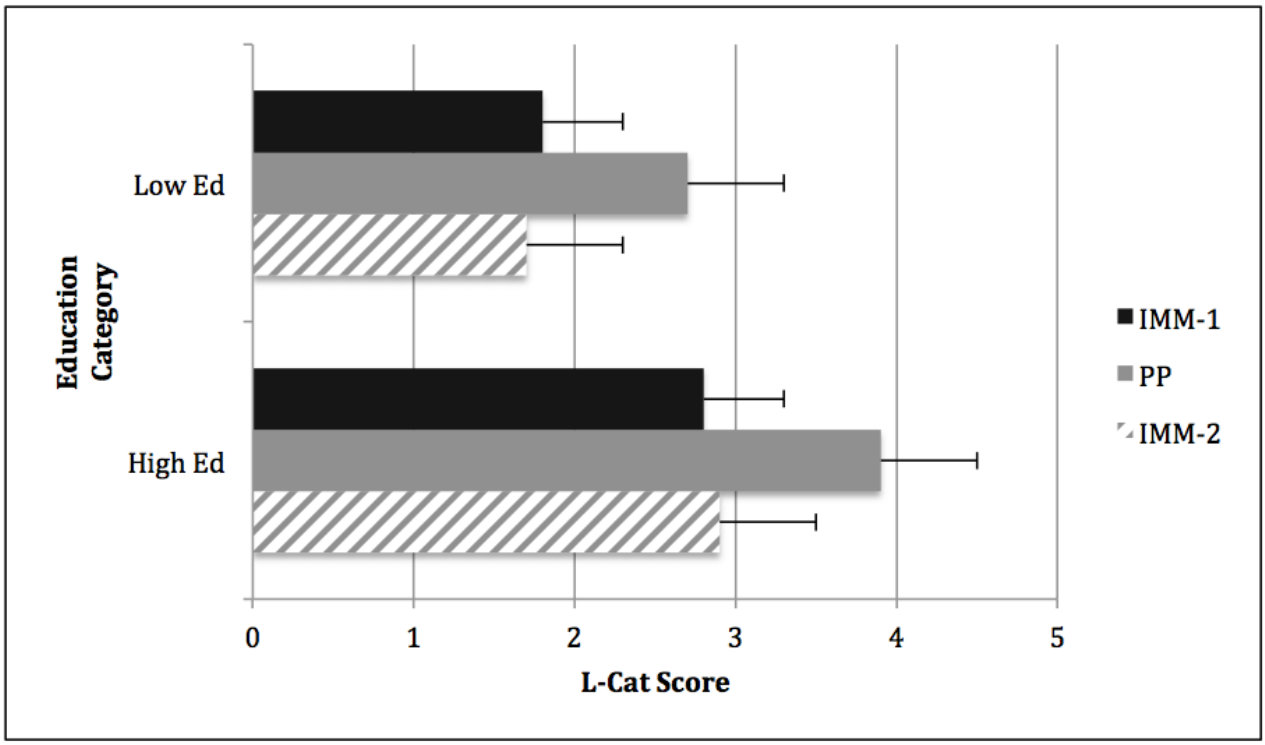
**Figure 4.** Comparison of education group responses on the Stanford Leisure-Time Activity Categorical Item (L-Cat). The following abbreviations mean: Low Ed=Less than high school/high school; High Ed=Some college/college degree; IMM=Interactive Multi-media, two separate administrations; and PP=Paper and Pencil version. The "Low Ed" top black solid bar shows the significant difference from the "High Ed" group (*P*=.008). The "Low Ed" center grey solid bar shows the significant difference from the "High Ed" group (*P*=.002). The "Low Ed" bottom grey-striped bar shows the significant difference from the "High Ed" group (*P*=.001). The "Low Ed" and "High Ed" center solid grey bars show the significant difference from "IMM-1" and "IMM-2" (both *P*<.001).




### User Feedback

Of the 60 participants, 59 completed the feedback survey. *Major themes* were as follows. Most believed that the IMM BEVQ-15 was "easy"(mean ordered-response rating 1.2, SEM 0.1; n=54), that it was "clear" or "straightforward"(mean 1.4, SEM 0.1; n=30), and that it covered beverages consistent with their usual intake habits (mean 1.1, SEM 0.0; n=56). Most also reported that the computerized L-Cat was "easy" (mean 1.2, SEM 0.1; n=49), and that they were able to identify a physical activity statement relating to their lifestyle with the L-Cat (mean 1.1, SEM 0.1; n=49). *Minor themes* were that the graphics, images, and voiceover made completing the questionnaires "easy" (mean 1.4, SEM 0.1; n=15), and that nothing needed to be changed in the IMM BEVQ-15 (mean 1.0, SEM 0.1; n=22). Many participants reported that the IMM L-Cat assessment was "clear" or "straightforward" (mean 1.6, SEM 0.1; n=23), and recommended changing nothing about the IMM L-Cat (mean 1.0, SEM 0.1; n=23). Eighteen participants of 60 (30%) suggested that the speed of the narrated text be increased on both the IMM BEVQ-15 and L-Cat. Only two participants (one in each education category) reported the computerized BEVQ-15 as being "hard."

## Discussion

### Comparative Validity and Test-Reliability of the IMM BEVQ-15 and L-Cat

With the exception of reduced-fat milk, all correlations were greater than .74 (Table 2) and this can be considered superior to other validation studies where typical *r* values range from .4 to .7 [3], and consistent with initial BEVQ testing [36]. The lower correlation coefficient for reduced-fat milk may be due to participants not being familiar with the form of milk they consume. Some participants may not be the primary food shoppers in their home and not read product packaging prior to consumption; they may not know if the milk they choose to consume is skim, 1%, 2%, or whole milk, and thus choose an option arbitrarily on the questionnaire. The differences between PP and IMM-1 for total beverage intake were 25 kcal, and between PP and IMM-2, while higher at approximately 90 kcal, were not statistically significant. However, we recognize that a 90 kcal difference can be clinically significant at the individual level. Compared to the original BEVQ validation studies, the present differences are higher than what was observed for SSB and total beverage kcal intake. The lower mean age, smaller sample size, and the beverage intake patterns of the "less than high school/high school" education group may have contributed to differences across studies. Future investigations including a larger sample size could provide greater insight into this possibility.



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While no significant differences in beverage category responses were noted between IMM-1 and the PP version, mean values were different on the PP and both IMM physical activity items (both $P<.001$). Computer-based tools can be perceived as more private and less intimidating [7]. If this were so in the present study, the IMM L-Cat responses may be more reflective of actual physical activity levels. Participants may have felt more comfortable reporting a less socially desirable level of physical activity on the computerized assessment versus on the paper-based tool since, when taking the paper version, responses were immediately observable to study personnel, while computerized responses would be accessed following the participant's departure. Overall, the findings of this pilot investigation indicate that the IMM BEVQ-15 is a valid measure of beverage intake when compared to the PP version. Further research is warranted to assess the comparative validity of the IMM L-Cat.

Differences were observed between SSB grams and kcal and total beverage intake ($P=.02$ and $P=.01$, respectively) and total beverage kcal ($P=.01$) between IMM-1 and IMM-2; however, no differences were apparent when comparing these responses on the paper and IMM-2 responses. Thus, the lower responses for the reported usual intake on the second IMM administration were closer to that reported in the PP tool. This may be attributed to a familiarity effect as observed in other computerized assessments [42-44]. In a trial investigating how test mode may impact assessment outcomes, content familiarity and not computer familiarity, gender, or competitiveness positively influenced test performance [16].

Food frequency questionnaires are considered reliable with correlations ranging from .5 to .7 [3,45,46], and many of the coefficients observed for reliability testing of the IMM questionnaires are within or exceed this rage. Thus, the IMM BEVQ-15 and L-Cat can be considered reliable measures of habitual beverage intake and physical activity patterns.

### Comparative Validity and Reliability Within Educational Categories

With the exception of water intake in the "some college/college degree" group, the IMM version of the BEVQ-15 demonstrated comparative validity across the major beverage categories. As depicted in Figure 4, both educational groups responded significantly higher on the paper version versus the computerized version of the L-Cat. Since the layout and appearance of computerized surveys can impact participant responses [16,17], differences between the IMM and PP modes of assessment may have occurred in the present investigation. Although lower intakes of SSB grams, kcal, and total beverage kcal were reported on IMM-2 compared to IMM-1 from the "less than high school/high school" participants, no differences were observed between the paper and IMM-2 tools. These results may be attributed to participants being more familiar with the IMM version at the second administration, as stated earlier. Participants potentially had a greater awareness of the upcoming beverage categories within the IMM tool, and thus were able to answer each question more accurately, better reflecting their usual consumption habits.

### Comparison of Lower and Higher Educational Groups

In the present investigation, the "less than high school/high school" participants reported significantly lower water consumption than the "some college/college degree" participants (Figure 2). Similarly, the National Health and Nutrition Examination Surveys from 1999-2006 revealed that adults with higher education attainment had a higher plain water intake [47]. In addition, daily grams and kcal were different between educational categories at each questionnaire administration (Figures 2 and 3). Consistent with prior research addressing the influence of educational level and health literacy on beverage consumption patterns [48-50], participants in the lower educational category consumed significantly more total beverage and SSB (grams, kcal). This is noteworthy since excessive SSB consumption has been related to the development of some chronic diseases [51-54]. Similar to the discrepancies observed between physical activity engagement and education attainment in a recent report from the American Heart Association Statistic Committee and Stroke Statistics Subcommittee [55], the "less than high school/high school" category reported lower physical activity engagement than those with "some college/college degree" (Figure 4). However, neither group reported a level of physical activity that met current guidelines [56], exemplifying the need for continued efforts to promote the benefits of regular participation in physical activity.

### Usability and User Feedback

Although no differences in completion time were observed between educational categories, the IMM-1 administration took significantly more time to complete versus IMM-2. This is possibly due to unfamiliarity with page-to-page navigation and questionnaire content at the first IMM administration [16].

Participants found the IMM questionnaires easy to use, and that they "fit" their usual beverage intake and leisure-time activity habits. Our results are comparable to others who have reported positive feedback with IMM delivery of nutrition education and dietary and physical activity assessments [7,8,12,14], suggesting acceptability and promise for the use of computer-administered surveys in future research. One area for potential improvement in the IMM tools is the speed of narrated text. Analogous to prior research [7], approximately one-third (n=18) of participants suggested that the speed of the voiceover be increased. The present study received positive feedback overall; however, improvements can be made with the IMM itself (eg, touch screens) [7], which may further increase ease of use and administration.

### Limitations

Strengths of this pilot investigation include the random assignment of participants to study session sequences, the novel method to assess dietary intake and physical activity engagement, and the inclusion of participants with lower and higher educational attainment levels. However, several limitations are recognized. The short duration between participant sessions could have caused acclimatization to the questionnaires or participants to be more aware of their beverage intake patterns, thus biasing their responses. Subsequent trials should consider both familiarity with computers and



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questionnaire content [16,57,58] during participant screening and longer intervals between study sessions. Second, we used validated paper versions of the BEVQ-15 and L-Cat as our comparative criterion; however, self-reported diet and physical activity assessments may not reflect an individual's true intake [1,3,59] or physical activity engagement [60]. In addition, some consider paper versions of computerized surveys to be anything but a "gold standard" when assessing computerized versions of similar assessments [6]. Future studies should not only use validated paper forms of computerized questionnaires, but multiple modes of dietary and physical activity assessment (eg, 24 hour recalls and doubly labeled water) for the greatest degree of accuracy. Although different circumstances may impact beverage intake from day to day (eg, illness, activity level, social events), we do not believe this influenced our overall findings, since the BEVQ-15 has been found valid in estimating group habitual beverage intake [18]. Another potential limitation of the present investigation is the limited racial representation and small sample size. Subsequent larger-scale investigations should include a more diverse sample in terms of race/ethnicity and educational attainment.

## Conclusions

There is a need for reliable and valid dietary and physical activity assessment tools that are brief and easily administered [61]. As many as 20% of American adults read at a fifth-grade level or less [62,63], and health literacy is thought to better predict a person's health than ethnicity, employment status, age, income, and education level [64]. Using computer-based assessments can overcome some common barriers preventing the collection of complete dietary data [13], particularly in populations with lower educational achievement [8]. Interactive multimedia versions of dietary and physical activity questionnaires have the potential to decrease participant and study personnel burden, allowing for high quality data to be collected and analyzed [6-8,10,13,14]. Further, computerized assessments could be advantageous for large epidemiological studies [6] as they may reduce costs [8] by streamlining data collection and analysis [4,6-8,13,14]. Overall, the results of the present investigation show that the IMM BEVQ-15 may be used to evaluate habitual beverage intake; although, familiarizing participants with the software prior to data collection may assist in obtaining more accurate data. Respondents may have answered differently on the IMM L-Cat due to computerized tools being considered more confidential and less intimidating [7]. Further research is necessary to fully evaluate the validity of the IMM L-Cat due to its consistency between IMM measures, but differences from the PP version. Future investigations are warranted to include more participants from racially diverse and hard-to-reach audiences (ie, low educational and health literacy levels), develop assessment tools that may be administered to both younger and older individuals (eg, children, adolescents, seniors), and utilize contemporary technological features to further reduce participant burden.

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## Conflicts of Interest

None declared.

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## Abbreviations

**BEVQ:** beverage intake questionnaire
**BEVQ-15:** beverage intake questionnaire
**BMI:** body mass index
**IMM:** interactive multimedia
**L-Cat:** Stanford Leisure-Time Activity Categorical Item
**NVS:** Newest Vital Sign
**PP:** paper-administered
**SSB:** sugar-sweetened beverage


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Original Paper

# Using Goal-Directed Design to Create a Novel System for Improving Chronic Illness Care

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## Abstract

**Background:** A learning health system enables patients, clinicians, and researchers to work together to choose care based on the best evidence, drive discovery as a natural outgrowth of patient care, and ensure innovation, quality, safety, and value in health care; all in a more real-time fashion.

**Objective:** Our paper describes how goal-directed design (GDD) methods were employed to understand the context and goals of potential participants in such a system as part of a design process to translate the concept of a learning health system into a prototype collaborative chronic care network (C3N), specifically for pediatric inflammatory bowel disease.

**Methods:** Thirty-six one-on-one in-depth interviews and observations were conducted with patients (10/36, 28%), caregivers (10/36, 28%), physicians/researchers (10/36, 28%), and nurses (6/36, 17%) from a pediatric gastroenterology center participating in the ImproveCareNow network. GDD methods were used to determine the context and goals of participants. These same methods were used in conjunction with idealized design process techniques to help determine characteristics of a learning health system for this pediatric health care ecology. Research was conducted in a clinic and, in the case of some patients and caregivers, at home.

**Results:** Thematic analysis revealed 3 parent-child dyad personas (ie, representations of interviewees' behavior patterns, goals, skills, attitudes, and contextual information) that represented adaptation to a chronic illness over time. These were used as part of a design process to generate scenarios (potential interactions between personas and the learning health system under design) from which system requirements were derived. These scenarios in turn helped guide generation, prioritization, design, measurement, and implementation of approximately 100 prototype interventions consistent with the aim of C3N becoming a learning health network.

**Conclusions:** GDD methods help ensure human goals and contexts inform the design of a network of health care interventions which reflect the shape and purpose of a C3N in pediatric chronic illness care. Developing online and in-person interventions according to well-documented context and motivations of participants increases the likelihood that a C3N will enable all participants to act in ways that achieve their goals with grace and dignity. GDD methods complemented quality-improvement methods to generate prototypes consistent with clinical and research aims, as well as the goals of patient disease management.

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**KEYWORDS**

goal-directed design; learning health care system; chronic illness care; health system design; quality improvement, pediatrics



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## Introduction

### Problem Statement

Our current health care system is far too costly, with less than impressive returns in health. The Institute of Medicine (IOM) considers this a systemic issue rather than one owing to any particular set of isolated factors. As such, the IOM champions "learning health systems that enable patients and providers to work together to choose care based on the best evidence, drive discovery as a natural outgrowth of patient care, and ensure innovation, quality, safety, and value in healthcare; all in a more real-time fashion" [1]. Despite the appeal of such a system, there are only a few specific instances of learning health systems [2,3].

Instantiating the vision of a learning health system requires a systematic method for translating a promising concept into actual tools and processes that work together as new characteristics of existing systems of care. Understanding the needs of potential participants in a learning health system is central to generating new ideas that will lead to a fundamental redesign to better meet the needs of patients, parents, clinicians, and researchers alike. Meanwhile, communication and information technologies are seen as key to success of a learning health system; indeed a significant majority of patients and their advocates undertake Internet-enabled health-seeking and health-making behaviors [4]. However, these technologies too often fail to live up to their promise [5-10]. Only a minority of software project initiatives succeed, the disappointing numbers largely owing to difficulties in accurately ascertaining requirements in advance of design and construction [11].

Kano et al [12] identified 3 different types of participant needs: (1) revealed needs (wants) are typically achieved by just asking people what they want, (2) expected needs are often so basic that people may fail to mention them until a service or product fails to perform them, resulting in dissatisfaction, and (3) exciting needs, which are difficult to discover, are unspoken, and expand the customer's expectations.

### Product Research and Design Methods

Goal-directed design (GDD) is a research-based software-design method for anticipating how people will respond to a new or modified product, service, or system [13]. GDD also precisely articulates the shape and purpose of online and offline system elements that will help people meet their goals. GDD is employed at the outset of the product-definition process so as to define human requirements of a system before design and construction take place. GDD's synthesis and design methods guide generation, communication, and specification of products to the larger team.

Human-computer interaction (HCI) methods are used to facilitate more productive interactions between people and software programs [14,15]. User-centered design (UCD) emerged in response to HCI by situating humans at the center of product-development process through "user research" and other techniques that reveal responses people have to an existing product to which they are exposed [16]. UCD's application in health care has included designing and developing patient monitors [17], clinical decision-making tools used in clinical situations [18], and patient health technologies for the aging population [19]. It is often restricted to involving potential participants after the product is developed [20,21].

GDD is an outgrowth of HCI and UCD. GDD explicitly acknowledges that there are no "users" of a product not yet designed; so, instead, GDD offers techniques (personas, scenarios, interaction-design patterns, and principles) for positing a future where a new or modified product exists to satisfy human goals. Other research and synthesis methods such as contextual inquiry [22] emphasize a cross-disciplinary team-based approach to determining needs and opinions of "customers" (ie, purchasers) largely through ethnographic methods, analysis, and synthesis techniques performed by large teams of software developers, product managers, designers, and others. GDD methods hinge on the observation that software is infrequently used by purchasers and so offers methods for determining the needs and context of people likely to use the software and those who will be effected by somebody else's use of software; teams are smaller and the process is far less time-consuming (ie, several weeks vs several months).

GDD serves the inherently subjunctive nature of the design process by distinguishing goals from tasks, thereby equipping designers with means to design what will satisfy goals of future participants through alternate and possibly superior means than the current means. GDD begins with ethnographic and observational methods that help a team understand what is required of a new system built to engage and satisfy those for whom it is intended. GDD uses fictional composites of potential participants of the new system, called "personas," which are defined according to their contexts, capabilities, and goals. Designers then create "scenarios" that describe specific interactions that may occur between personas and the system, from the beginning of a task through goal achievement, keeping in mind the personas' contexts and motivations. Creating a set of personas and scenarios serves several purposes. Doing so helps identify and communicate critical characteristics of both the technical and human parts of a system featuring which specific innovations. This method takes into account how people will likely interact with the system; what aspects of the new system are worth the design, development, and testing of potential solutions; and how interactions can be re-designed to achieve desired behavior while balancing the contexts and needs of all concerned. This diminishes a design team's temptation to project their own needs onto system participants, curbs proliferation of unnecessary features, and prevents centering the system design around "edge cases" or outliers [23]. Finally, personas and scenarios serve to inform detailed design specifications for constructing the online and complementary offline processes.

### Objectives

Our paper provides an illustration of how GDD methods were used as part of an effort to translate the IOM's vision of a learning health system for chronic care management into a prototype system that we call a collaborative chronic care network (C3N). The aim is to demonstrate that GDD methods



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can yield a design of a learning health system to which participants will respond favorably.

## Methods

### Setting

The ImproveCareNow network [24] is a multisite practice network of pediatric gastroenterology practices treating children and youth with inflammatory bowel disease (IBD; Crohn's disease and ulcerative colitis [UC]). ImproveCareNow was formed with support of the American Board of Pediatrics and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition as the pilot program for development of performance-based maintenance of board certification [25,26]. ImproveCareNow sites have population-based registries with common data elements, share process and outcomes data, and use quality improvement methods to make changes in care delivery. Through this process of clinician-led collaboration and standardization of care, the network has dramatically increased the proportion of patients in remission [27].

### Participants

Patient, parent, and nurse participants were recruited from Cincinnati Children's Hospital Medical Center (CCHMC), one of the pediatric gastroenterology centers participating in the ImproveCareNow network. Physicians/researchers were recruited from CCHMC, the University of North Carolina at Chapel Hill, the Children's Hospital of Philadelphia, Children's Hospital, Oakland, and Dell Children's Hospital of Central Texas, in Austin. Adolescent/young adult patients (age, 12-22 years) with IBD and their parents/caregivers were recruited by their physicians or responded to fliers posted in the IBD clinic. Interested patients and parents were contacted, provided with further explanation of the study, and asked for a convenient time to schedule the interview. This study was approved by the CCHMC Institutional Review Board (IRB).

### Data Collection

In-depth, face-to-face interviews and direct observations were conducted in January and February 2010. The topics in the semi-structured interview guide were designed to obtain an in-depth understanding of the participant's expressed and observed contexts, goals, and attitudes related to having and managing a chronic disease in general and IBD specifically [28]. Interviews were conducted by 2 of 3 experienced interaction designers with training in GDD methods. One designer led the interview while the other took notes and probed to ensure complete understanding of the answers provided. Interviews took place in a private room at the hospital, the interviewee's home, another location as desired by the parent, or by phone or video conferencing (in the case of researchers). Patients and their parents were interviewed separately to reduce undue influence on responses. Sample topics for the patient/parent interview are provided in Textbox 1. While each topic was discussed with each subject the sessions were conducted in a conversational style that permitted interviewees to express themselves extemporaneously. Interviews lasted 1.5 hours, were audio-taped, then transcribed verbatim. Families were offered a US $20 gift card for participation. Observations took place in the IBD clinic, where one designer observed and took notes, shadowing patients/parents and clinicians. Observations also took place at a network "learning session" where participating care sites met to share methods to improve care.

**Textbox 1.** Sample of semi-structured interview questions.

1. Tell me what it is like to manage your disease.
2. Walk me through a typical day, like yesterday.
   (a) A particularly difficult day? A carefree day?
   (b) What are the hardest parts?
3. What works well for you in terms of managing your disease?
4. If you were to describe to someone who had no idea about Crohn's or ulcerative colitis, or what it's like living with it, what would you say?
5. If you could change one thing about what you have to do to manage your disease, what would it be?
6. Do you have friends who also have Crohn's or ulcerative colitis? Tell me what that is like.
7. Do you ever use the Internet to get information about Crohn's or ulcerative colitis? In what way does this help you?
   (a) Do you ever use the Internet to connect with other kids with Crohn's or ulcerative colitis? Tell me more about that.
   (b) Can you tell me about the kinds of things would you like on the Internet that would be useful to you, but you've not been able to find?

### Analysis

Transcripts were coded with an identification number then de-identified. Notes from each session were reviewed and incorporated into the transcripts if they provided additional information. All three team members analyzed the patient and parent transcripts independently and analyzed, synthesized, and categorized overarching common themes and subthemes based on similar characteristics, context, and goals. The themes were incorporated into a spreadsheet and given a color code that allowed for pattern recognition. The respondents' comments were categorized within themes and subthemes that emerged from the data. Patterns of comments within and across theme/subthemes were identified to assess goal-related relationships across interviewees. Differences in coder opinion were discussed and agreement was achieved before final decisions on existing patterns were made. The identified patterns were used to create the personas and scenarios. The personas



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and scenarios were shared with a subset of the original sample of patients, parents, clinicians, and researchers. Qualitative feedback was elicited regarding the extent to which these represented the participants' goals, contexts, and capabilities and were illustrative of potential interactions in a new system.

## Results

### Overview

The demographic characteristics of IBD patients and their parents are presented in Table 1. The 3 male and 7 female patients ranged from 14 to 22 years of age; 5 had a diagnosis of Crohn's disease and 5 had UC. The 8 male and 3 female physicians/researchers ranged from 33 to 55 years of age and had 3-31 years of clinical experience. The 6 nurses (all female) ranged from 36 to 60 years of age and had 7-30 years of clinical experience. Patients included 5 with Crohn's disease and 5 with UC. Three were less than 2 years post-diagnosis, while the rest were more than 5 years post-diagnosis. Daily regimens ranged from 1 to 40 pills, and the range of surgeries per patient ranged from 0 to 3. Comorbidities included juvenile idiopathic arthritis, asthma, primary sclerosing cholangitis, autoimmune hepatitis, attention-deficit hyperactivity disorder, depression, and allergies. For parents, 8 were married, with 2 divorced, 5 were employed full-time, 2 part-time, and 3 unemployed. Educational attainment ranged from no high school (1/10), to high school (4/10), to college graduate (5/10).

### Themes

The strongest themes that emerged around patients included time since diagnosis, symptom control, degree of reliance on parents for treatment decisions, and degree of isolation or connection with others with the disease. Predominant emergent parent themes consistently reflected their child's condition: time since diagnosis, child's level of coping, and experience with chronic disease. In fact, the differences among parents had less to do with their own personal psychographic characteristics and almost everything to do with their child's dimensions and themes. Demographic characteristics (eg, ethnicity, income, and gender) were analyzed for salience and found to be insignificant compared with the aforementioned themes. Themes were not predetermined but rather emerged from patterns in the research, and coalesced into 3 patterns as illustrated in Table 2.

### Personas

Because the themes were so similar, in this sample, between parents and patients, we created familial dyad narrative descriptions for personas. Given that 3 patterns emerged from the interviews, we developed 3 dyads. These dyads were: Orleans (daughter)-Floyd (father), Bianca (daughter)-Bram (father), and Uri (son)-Jody (mother). They vary on demographic characteristics, the degree to which they understand disease processes, adherence, and self-management behaviors, and, most importantly from the design perspective, their disease-related goals. Table 3 presents personas for Orleans and Floyd. Other personas, including those of a physician, a nurse, and a researcher, are available in Multimedia Appendix 1.

**Table 1.** Demographic characteristics of ImproveCareNow IBD patients and their parents (N=20).

| | Patients, n=10 | Parents, n=10 |
|---|---|---|
| **Age (years)** | | |
| Range | 14-22 | 35-55 |
| Mean (SD) | 18 (3) | 42 (6) |
| **Gender, n(%)** | | |
| Males | 3 (30) | 3 (30) |
| Females | 7 (70) | 7 (70) |
| **Race, n (%)** | | |
| White | 7 (70) | 8 (80) |
| Black | 2 (20) | 1 (10) |
| Other | 1 (10) | 1 (10) |



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**Table 2.** Examples of patient and parent themes used to create personas.

| | Patients | | | Parents | | |
|---|---|---|---|---|---|---|
| | Pattern 1 | Pattern 2 | Pattern 3 | Pattern 1 | Pattern 2 | Pattern 3 |
| **Themes and characteristics** | | | | | | |
| | Diagnosed recently to 2 years ago | Diagnosed 5+ years ago | Diagnosed >5 years ago | Child was diagnosed 2 or fewer years ago | Child diagnosed more than 2 years ago | Child was relatively old when diagnosed |
| | On meds, symptoms not under control | Symptoms under control | Complicated medical history | None to very little experience with chronic conditions | Experience with chronic disorders | Child now a young adult |
| | Relies on parents and practitioners for treatment decisions | Relies on parents for managing care, taking more responsibility | Transitioned into adult care | Feels overwhelmed by the child's disease | Taking the child's disease in stride | |
| | | | Symptoms under control | | | |
| | | | Care and treatment are driven by personal preferences | | | |
| | | | Involved with IBD communities | | | |
| **Goals** | | | | | | |
| | Control symptoms | Feel normal | Keep symptoms controlled | Make sure child is independent and adherent, charts pills, and keeps appointments | Reduce stress by reducing overall burdens of care | Manage stress particularly during patient's flare-ups |
| | Find community | Get on with life | Be a leader | | | |
| | Be understood | | | | | |



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**Table 3.** Illustrative personas.

| | Persona | Goals | Characteristics |
|---|---|---|---|
| **Orleans—Patient** | | | |
| | Age 13, African-American, and diagnosed 2 years ago with UC and autoimmune hepatitis | Control symptoms | Still getting her bearings |
| | | | Flares are frequent |
| | | | Often on prednisone, which makes her look and feel unusual |
| | | Be understood | Struggles with dad on how to care for herself |
| | | | Has to take many pills that do not always seem to work |
| | | | Recently diagnosed with depression |
| | | | Hard to watch what she eats, particularly when she is with other kids |
| | | | Socially isolated, repeatedly absent from school, trusts only a few friends |
| | | | Tries to stay active, practices yoga, and plays basketball when she is feeling well |
| | | | Uses the Internet for playing games, downloading music, email, and MySpace |
| | | | Leaves the Internet IBD research to her dad |
| | | Illustrative quote: "I like to play video games." | |
| **Floyd Jackson—Orleans' Dad** | | | |
| | Age 38, married, 3 children, and self-employed auto repair shop owner | Make the right choices | Has no experience with chronic disease |
| | | | Orlean's primary caretaker: makes appointments, picks up prescriptions, and communicates with the nurse |
| | | | Is concerned about paying for Orleans' ongoing treatment, especially if she gets worse and his wife has to stop working to care for her |
| | | Keep track of it all | Skeptical about medications, has heard about some long-term side effects |
| | | | Is interested in nonpharmaceutical therapies |
| | | | Seeks advice from many sources, including friends and websites |
| | | Find a healing community | Worried that Orleans is becoming irritable and solitary and that she is depressed |
| | | Maintain financial stability | |
| | | Illustrative quote: "It would be good for her if she knew someone else with ulcerative colitis." | |

## Scenarios

Scenarios started from 2 design premises: (1) better-informed and more productive interactions (both online and offline in face-to-face or phone interactions) between and among patients, parents, and clinicians will result in improved health outcomes and (2) systems that encourage open and safe access to people and information are necessary for facilitating these interactions. The scenarios aimed at enabling a persona to achieve personal goals starting from the premises stated above and also be based on realistic technical possibilities of an online and face-to-face system that could be developed. Pediatric patients from whom personas were derived strongly suggested that scenarios should also provide feedback that measures progress, incorporate small tasks that encourage learning, establish a community to support public commitments, and make interaction engaging and fun.

The personas' context, disease state, goals, and other characteristics were used in a scenario-generating process (which also included environmental scanning, review of the literature, role playing, and input from clinicians and others who comprise C3N) to develop scenarios describing potentially viable and desirable ways a new C3N system and its potential participants would interact with about 80 prototypes. One example of a scenario supporting a prototype ("personal experiment" or N=1 trial) is presented in Textbox 2 for the personas of Orleans and her father, Floyd.

Feedback from participants indicated that the personas and scenarios accurately captured the goals and contexts of participants and realistically portrayed potential experiences of patients and parents with a new health care system. These scenarios, in turn, drove detailed requirements that contributed



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to detailed descriptions for prototypes of digital health care interventions; ultimately the scenarios drove the design, construction, and operation of a learning health network which deploys such interventions. Further example scenarios and design screenshots are available in Multimedia Appendix 2.

**Textbox 2.** Scenario 1: Orleans and Floyd—Pursuing a personal experiment trial.

1. Because of Floyd's interest in Orleans safely experimenting with nonpharmaceutical approaches to managing her symptoms, he asks Dr Roan, at Orleans' next appointment, about probiotics for her cramps and diarrhea.

2. Dr Roan talks with Orleans and Floyd about a personal experiment trial to test whether probiotics will work. Together they decide to begin a personal experiment to see how she responds to over-the-counter probiotics while remaining on her current course of treatment.

3. Dr Roan opens the online C3N Portal and links to the template for a personalized experiment trial. She selects the type of probiotics they will use and, since Orleans has a phone that can text-message, uses the SMS survey function to create 2 daily SMS messages for Orleans to (1) remind her to consume the probiotics and her current meds and (2) assess the 2 symptoms in question.

4. The personal experiment trial system suggests three 2-week experimental periods: 2 weeks on probiotics, 2 weeks off, and 2 weeks on again.

5. Invitation to and information about the trial is sent to the email services used by Orleans and because of the personal settings Floyd also gets the email. They watch a short video explaining what personal experiment trials are about and complete an online survey about her health and views. The system confirms the submission to all parties and provides next steps for each to follow.

6. At the same time, the personal experiment system accurately identifies Orleans and protects her privacy and that of her father while ensuring adherence with other elements of the IRB protocol.

7. As Orleans shares observations of her health the system stores data in such a way that Orleans and her father have continuous access to it for their own use, and so that they can offer clinicians and researchers permission to access and use those data for Orlean's benefit and for population studies.

8. In collaboration with her doctor, Orleans and her father learn to observe and share health-related behaviors with one another and with Dr Roan, and learn to modify those behaviors based upon correlations Dr Roan identifies between behaviors and Orleans symptoms and her clinical data.

### System Requirements for Prototypes

The chief reason to employ GDD methods is to arrive at content, data, technical, scientific, and regulatory requirements for the purpose of furthering the goals of multiple participants in the health care ecology simultaneously. The scenario described in Textbox 2 yields in-person and online design requirements for a prototype self-experimentation system that centers around the patient (Orleans) and her caregiver (Floyd), with her clinician (Dr Roan) and researchers playing supporting roles. These included:

- An online clinician portal to craft and share experiments with others.
- Templates for experiments.
- Ability for clinician to revise templates for particular patient needs and to submit revisions to system.
- Ability for others to use the revised templates.
- Patient and caregiver access to experiment templates prepared by clinician.
- Mobile phone tools that make it natural for a teenager to participate in her own personal experiment.
- Media (videos, etc) that a pediatric patient and her parents will find compelling and which clinicians judge consistent with best medical guidance.
- A survey function for collecting baseline, ongoing, and closing observations of patients and caregivers for personal use and for purposes of population studies.
- System for unique identification that protects the privacy of patients and caregivers while ensuring IRB adherence.
- Data storage system that provides access to patients and caregiver for their own use, and allows them to provide conditional permission to clinicians and researchers to access those data.

## Discussion

### Themes

We envision a C3N as one way to create a learning health system, but translating the concept of a learning health system to an actual one requires a systematic process for identifying patterns of participant goals and realistic ways that patients, researchers, and clinicians might interact within the newly constructed ecosystem. Using GDD methods, we collected and synthesized a range of critical qualitative data from stakeholder representatives about their goals and values. We identified 3 major segments of patient participants, as well as 3 clinician/researcher participants, differentiated by an understanding of needs and goals. We then developed scenarios to help guide the design of a network of prototypes that comprise C3N. These prototypes are now in use in the C3N population.

Several themes common in the literature of pediatric care are not directly addressed in this paper even where such themes arose in our research. For example, the theme of independence and the related theme of transition to adult care characterize both "Pattern 2" and "Pattern 3" the patient/parent dyads depicting an older teen and a young adult, respectively. In interest of space, however, the authors draw our examples exclusively from "Pattern 1" (Orleans and Floyd); this pattern merits focus owing to intense challenges associated with a patient/parent dyad with a relatively recent diagnosis of a serious chronic condition, and the consequent needs they have for well-designed interventions that will help forge richer connections between patient and caregivers.

### Literature

Although the medical and public health literature contains numerous studies describing the use of qualitative methods for gathering participant-specific data for developing and evaluating



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interventions, only a few studies in the literature describe the use of personas and scenarios for the definition of novel health care interventions [17,18]. Most have focused on specific, mostly technology-driven, components of the larger system. None demonstrated use of personas and scenarios to design a large system that integrates clinical quality-improvement and research—a learning health system.

### Utility

Deriving dyads of personas based upon interviews with pediatric patients and their parents proved valuable in at least 2 ways. Interview data could be cross-checked with the other family members, helping to clarify dates, diagnostics, treatments, etc, particularly for those events that happened years in the past in the life of a child. Equally important, the success of pediatric medicine can hinge on identifying the underlying values of patients and parents, the qualities of their interactions, and ways for improving communication among all parties. Employing research-based personas and scenarios also helped design of this new health care model whose explicit intent is to level the uneven "authority gradient" common to clinician-patient relationships by providing patients novel means to collaborate more fully in treatment and self-care alternatives [29].

### Limitations

Several limitations of this study should be noted. While the small sample size raises questions of the validity of our results, previous work in this field suggests that a relatively small number of immersive qualitative interviews and observations reveals behavioral patterns necessary for system design, provided that the sample pool represents a range of likely potential participants [13]. This is similar to the concept of theoretical saturation in qualitative research. Moreover, patients, families, clinicians, and researchers who reviewed the resulting personas judged them as valid and useful. The goal of persona development is not to comprehensively portray all potential system participants, but rather to represent distinct types of participants so that a variety of thematic continua can be incorporated into the design. This yields designs that can work for a variety of potential participants represented by those personas.

Another limitation is that it is unlikely health care researchers will find success with these methods unless a trained and experienced interaction designer plays a key role during the initial research and synthesis phases and the first handful of intervention designs. If the work is well documented and other professionals take part in those activities, then those other professionals should be (and indeed in the case of C3N were) able to evolve the persona/scenario set and design/study of future interventions. In other words, GDD methods do not make somebody into a designer; rather, they provide ways for researchers and designers to become more effective teammates.

### Conclusions

Increasing calls for a learning health system highlight the urgent need to translate this concept into reality. New personal health technologies, growing data repositories, and innovative analytic approaches yield clues to some tools that could be useful in creating a learning health system. Specific technologies, tools, and methods, however, are unlikely to form a cohesive human system absent a deliberative design process. Meanwhile, health care interventions are, for the most part, developed and designed by medical or public health researchers with limited, if any, software design experience or expertise. Methods developed for product design and marketing are now used widely in industries outside health care in order to gain a better understanding of users' attitudes, beliefs, behaviors, and values and to incorporate this information into the design of products and services prior to developing and diffusing them into the marketplace.

We found GDD helpful in elucidating the human context into which novel approaches could be introduced. Moreover, with its emphasis on the human scale of software-powered systems, GDD yielded actionable insights that could be used by designers, software developers, database engineers, physicians, nurses, and patients, and patient advocates alike to make C3N into a learning health care network that simultaneously improves care, promulgates novel clinical and self-care interventions, and discovery.

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### Authors' Contributions

DF designed the study, gathered the data, analyzed the data, and drafted the manuscript. LMG drafted the manuscript. PAM and MS designed the study and revised the manuscript critically for important intellectual content.

### Conflicts of Interest

None declared.



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## Multimedia Appendix 1

Other personas.

[PDF File (Adobe PDF File), 112KB - resprot_v2i2e43_app1.pdf ]

## Multimedia Appendix 2

Example scenario and design screenshots.

[PDF File (Adobe PDF File), 1MB - resprot_v2i2e43_app2.pdf ]

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## Abbreviations

**CCHMC:** Cincinnati Children's Hospital Medical Center
**C3N:** collaborative chronic care network
**GDD:** goal-directed design
**HCI:** human-computer interaction
**IBD:** inflammatory bowel disease
**IOM:** Institute of Medicine
**IRB:** institutional review board
**UC:** ulcerative colitis
**UCD:** user-centered design

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Original Paper

# Using Risk Group Profiles as a Lightweight Qualitative Approach for Intervention Development: An Example of Prevention of Tick Bites and Lyme Disease

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## Abstract

**Background:** Many public health campaigns use a one-size-fits-all strategy to achieve their desired effect. Public health campaigns for tick bites and Lyme disease (LD) in many countries convey all relevant preventive measures to all members of the public. Although preventing tick bites (eg, by wearing protective clothing or using repellants) and checking for tick bites after visiting a risk area are effective and cost-efficient methods to prevent an individual from contracting a tick-borne disease, public compliance to these methods is low.

**Objective:** We aimed to identify the group of individuals within the general Dutch population that are at high risk of being bitten by a tick or developing LD and to describe their characteristics, knowledge, and perceptions. The incidence of patients visiting their general practitioner for tick bites and erythema migrans (the first sign of LD) has increased tremendously in the last decades in the Netherlands and other European countries; therefore, our efforts can be used to counter this troubling trend.

**Methods:** We conducted in-depth semi-structured interviews to identify individuals belonging to the average risk group. Participants were recruited in two ways. Patients who visited two municipal health services travel health clinics (one in a high-endemic area and one in a low-endemic area) were asked to participate. This resulted in 18 interviews. Further, parents were recruited using the convenience sampling method, which resulted in 7 interviews. We discontinued interviewing when the point of data saturation was reached. We analyzed the results immediately after each interview to identify the point of data saturation. Data saturation is when the new interviews provided no new information compared to the previous interviews. The interviews were transcribed and analyzed using inductive thematic analysis.

**Results:** We identified four groups at risk of being bitten by ticks and developing LD among the general Dutch population. The groups were as follows: (1) outdoor people that check for tick bites, (2) outdoor people that do not check for tick bites, (3) parents that check their children for tick bites, and (4) parents that do not check their children for tick bites. Previous experience with ticks or LD was the main denominator between the groups. Checking for tick bites is a more easily adopted measure than preventing tick bites. Therefore, for all groups, public health efforts in the future should primarily emphasize on the importance of checking for tick bites.

**Conclusions:** The lightweight qualitative approach presented in this paper is highly relevant in tailoring public health efforts toward specific groups. The profiles of members in each risk group and the motivations underlying the behaviors of the members in each risk group can be used to determine the features and content of a targeted communication strategy about ticks and LD.



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**KEYWORDS**

ticks; Lyme disease; prevention; audience segmentation

## Introduction

Many public health campaigns use a one-size-fits-all strategy to achieve their desired effect. In the context of controlling infectious diseases, a single mode of communication (eg, a leaflet or a television commercial) is often used to convey all relevant evidence-based precautions for a single disease. For example, a Dutch leaflet on preventing food-borne infections advices people to wash their hands with soap before preparing food, after touching raw meat, before eating, and after visiting the toilet or changing diapers; to use a separate cutting board for raw meat and vegetables; to use clean knives for different products; to keep salads and meat cooled during barbeques; not to drink raw milk, etc. Dividing a heterogeneous audience into homogeneous audience segments and subsequently targeting health communication toward these audience segments is a more fruitful approach than distributing a one-size-fits-all message [1]. In the past, many audiences have been successfully segmented for health campaigns such as healthy eating campaigns [2] and promoting physical activity [3]. Segmentation is often based upon demographic, behavioral, and/or psychosocial data and involves the analysis of very large volumes of quantitative data [4].

Lyme disease (LD) is the most common tick-borne disease in the United States and in Europe. In the Netherlands, 564 per 100,000 inhabitants consulted their general practitioner (GP) about tick bites [5]. In 1994, about 39 per 100,000 inhabitants visited their GP for erythema migrans (EM, an associated symptom of LD). This number increased to 134 per 100,000 inhabitants in 2009 [5]. In humans, LD develops in three stages, starting with a circular red skin rash (EM) with fever, headache, fatigue, and depression to a chronic stage that can affect a wide range of body parts, including the brain, nerves, joints, and heart.

Public campaigns in many countries aimed at preventing tick bites and LD use the strategy of providing every member of the public with all the relevant preventive measures [6]. Although preventing tick bites (eg, by wearing protective clothing or using repellants) and checking for tick bites after visiting a risk area are effective and cost-efficient methods to prevent an individual from contracting a tick-borne disease [7], public compliance to these methods is low. According to Marcu et al [8] and Beaujean et al [9], people do not comply with precautions because of the following reasons: people believe that these precautions interfere with how they want to enjoy nature (eg, they refuse to wear long clothes on a hot day), people assume that the risk of tick bites is low, people do not believe that the precautions are effective (eg, they refuse to apply insect repellent products), and people do not know how to identify a tick bite (eg, recognizing and removing a tick). Although it is not impossible to change the knowledge and perceptions of the people about precautions, Mowbray et al [10] recently reported a finding for segmenting the general audience in relation to tick bites and LD. They claim that communication about preventive measures should be tailored toward the knowledge and perceptions of an audience segment about the disease and possible precautions. Thus, it will be more rewarding to provide an audience segment with the advice that they are likely to adopt only. For example, preventive measures that are realistic and fit within the perception of the audience (segment). The measures for preventing LD include checking for tick bites and removing them. Previous studies showed that to match the needs of the target users and to maintain their interest, user involvement is critical in planning and designing the intervention [11,12]. An assessment of mobile-based interventions for management and prevention of human immunodeficiency virus (HIV) infection showed that majority of the interventions failed to attract the attention of their users [13], and users criticized a computer-tailored program for chronic obstructive pulmonary disease (COPD) because the feedback was not tailored to the severity of the disease and could not be used for patients with severe COPD [14]. To develop an intervention that is likely to be used by its target users, it is crucial to gain insight into the perception of the audience segments.

To date, segmentation of the audience has not been performed for providing information about tick bites and LD. In this study, we identified the group of individuals among the general Dutch population that are at high risk of being bitten by ticks or developing LD, and we have described their characteristics, knowledge, and perceptions. The incidence of patients visiting their GP for tick bites and EM has increased tremendously in the last decades in the Netherlands and other European countries [5,15]; therefore, our efforts can be used to counter a troubling trend. Furthermore, to identify audience segments, we will use a lightweight qualitative approach that can be used whenever one does not have access to a large body of information about an audience, or is not in a position to create one, as is often the case in clinical practice. This is especially relevant within the sector of public health, because despite its importance at the societal level, the sector faces critical challenges, including substantial decreases in funding [16,17]. In recent years, public health organizations have been hit hard with cutbacks and layoffs, while more is expected of public health professionals [18,19]. In this study, we take a first step in identifying risk groups on the basis of the previous studies and attempt to understand the differences between the groups based on interview results. In the following sections, we describe the set-up of our methods and present the results for prevention of tick bites and LD. Finally, we discuss the risk groups that we identified and how our method can be used for targeting health communication about the prevention of tick bites and LD.

## Methods

### Overview

The approach of this study consists of two steps: (1) identification of a risk group on the basis of results from



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previous studies, and (2) in-depth interviews with members of the identified risk group(s) to describe the characteristics of the identified groups. We used a lightweight qualitative approach (small sample of respondents) as a first step in identifying risk groups among the general Dutch population.

### Risk Group Identification

The first step in targeting health communication is to identify groups at high risk for a condition. In the case of tick bites and LD, two high-risk groups are observed among the general Dutch population [20]. The first risk group consists of people that spend a lot of time outdoors (outdoor people), such as hikers, campers, and dog owners. The number of hours spent outdoors per week is related to the risk of tick bites; the greater the number of hours spent outdoors, the higher the incidence of tick bites [21,22]. The second risk group includes children aged from 5 to19 years because of their increased contact with tick habitats, for example, because they play outside [5,23,24]. Since parents are responsible for the health and tick checks of their children, we interviewed parents about their children and tick bites and LD.

### Profiling Risk Group Members: In-Depth Interviews

To profile the members belonging to an average risk group, conducting in-depth semi-structured interviews is an effective approach. These interviews allow for exploring a range of topics and subsequently pursuing a topic in-depth when it appears to be important [25]. This method was also suggested by Mowbray et al [9] to create a basis for designing targeted interventions against tick bites and LD.

Participants were recruited in two ways. People who visited two municipal health services (MHS) travel health clinics (one in a high-endemic area and one in a low-endemic area) for traveler's vaccination were asked to participate in an interview by a nurse in the infectious disease control department. We opted for this group, because they often recreate outdoors. This resulted in 15 interviews with people who spend time outdoors and 3 with parents. Further, we recruited parents via a convenience sampling method, which resulted in 7 interviews.

We created an interview scheme based on an overview of citizen characteristics that need to be taken into account when developing health interventions [26]. The interview scheme addressed (1) demographics, (2) frequency of visits to high-risk areas, (3) knowledge of ticks and LD (ie, using five statements about recognition of ticks, tick habitats, mode of transmission, and symptoms of LD), (4) experience with ticks and LD, (5) perception and behavior about LD prevention measures (eg, "How severe do you perceive LD?" and "What would you do in the case of a tick bite?"), and (6) tick- and LD-related information seeking behavior (eg, "Where would you seek for information on ticks and LD?"). Interview schemes can be found in Multimedia Appendix 1. An experienced qualitative researcher conducted all the interviews.

Each interview started with a short introduction of its goal, after which the interviewees were guaranteed anonymity. Then, the interviewees provided informed consent and permission for audio recording. Subsequently, the interviewees received a gift voucher as an incentive.

We stopped the interview when all pre-determined themes were discussed, and the interviewee added no new themes. We analyzed the results immediately after each interview to identify the point of data saturation. Data saturation occurred when the interviewer concluded that, compared to the previous interviews, the new interviews provided no new information.

### Analyses

The interviews were transcribed and analyzed using inductive thematic analysis according to the six steps suggested by Braun and Clarke [27]. Inductive thematic analysis focuses on identification and description of themes both implicit and explicit ideas within the interview data. An experienced analyst of qualitative data analyzed the interviews. Step 1 was familiarizing with the data. This involved transcribing the data and reading and re-reading the data in an active manner; searching for meanings, patterns, and writing down initial ideas. This phase was time consuming, but is the bedrock for the rest of the analysis. The formal coding process began after completion of this step. Step 2 was generating initial codes from the data. Codes identify a feature of the data (semantic content or latent) that appears interesting for the analysis and refer to "the most basic element of the raw information that can be assessed in a meaningful manner about the phenomenon." In this phase, it was important to ensure that all actual information was coded. Step 3 began when all information was coded and a long list of the different codes was identified across the data set. Now, the codes require to be ordered into potential themes. Step 4 included reviewing and refining the themes. Some themes collapsed into each other and some themes were not really themes (the data were too diverse). At the end of this step, we had a good idea of what the different themes were, how they fit together, and the overall story they told about the data. In step 5, we defined and named the themes. Finally, step 6 involved the final analysis and writing up of the results. We will provide an example to make this process more transparent. One interviewee said when we asked him how quickly a tick that has bitten should be removed from the body "I don't know; I only know that it is in its saliva. So, you should never use detergent or alcohol. Because if it has contaminated saliva, it will spit." A second interviewee said, "I don't know. I don't think it matters because either the beast has Lyme or it does not." Finally, a third interviewee said, "I think directly." Initially, the interview segments were coded as "knowledge about how soon to remove ticks." Next, the first two interviewees were coded as "not knowing how quickly to remove a tick", and the third response was coded as "knowing when to remove a tick." An overview was finally made when all interviewees were coded according to whether or not they knew how soon to remove a tick.

## Results

### Profiles of Risk Group Members

The responses of the interviewees to the open question about checking for ticks led us primarily to divide both risk groups into the following two subgroups:

1. Outdoor people that do not care about being bitten by a tick and the risks involved (those that do not check) and people



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that do care and therefore check for ticks when they have visited a high-endemic area (those that check).

2. Parents that check their children for tick bites, and those that do not.

Each subgroup had its own view toward ticks, LD, and preventive behavior, and therefore, we analyzed their responses separately.

Outdoor people that do not check ("I never check for ticks after being outdoors") constituted a large group (men: 7/14, 50% and women: 7/14, 50%; mean age 43 years). People in this group are often in their backyards and frequently visit a forest. The group of those that check ("I sometimes or always check for ticks after being outdoors") is relatively small (women: 3/3, 100%; mean age 42 years), and people belonging to this group spend a lot of time in their backyard and can frequently be found in forests, heathland, dunes, and city parks.

Parents that check ("I sometimes or always check my child/children for ticks after they have been outdoors"; men: 2/8, 25% and women: 6/8, 75%; mean age 41 years) accounted for the majority of parents. Their children very often play in the backyards and some of the children of these parents regularly play in forests. Parents that do not check ("I never check my child/children after they have been outdoors"; men: 1/2, 50% and women: 1/2 50%; mean age 42 years) were a small group, whose children often play in the backyards.

## Outdoor People

### *Overview*

The main characteristics of the two subgroups within the outdoor people are shown in Table 1. The results indicate that experience with tick bites or LD is the great denominator between the groups and the main reason for a person to shift from checking to not checking for tick bites.

### *Knowledge of Ticks and Lyme Disease*

Outdoor people that do not check for tick bites had a widespread knowledge of ticks and LD. Most of them knew that a tick is a little animal. Almost all the participants thought they could get a tick bite in a forest and falsely believed that ticks let themselves fall from trees. About half of our participants also said that ticks can be found in high grass or shrubs. Only few people knew that ticks live in dunes.

> *I would say only in the forest. And, when you stand under a tree, that's what you hear often, that they fall out of the tree. That's all I know.* [Woman; age, 18 years]

Most interviewees did not think that a tick bite always resulted in LD. Some thought there were individual differences in terms of susceptibility. Most participants thought that a tick should be removed as soon as possible. When asked how they could know whether they have LD, about half of the people mentioned "the red spot" (referring to EM). The remaining participants had no idea. Participants who do check for tick bites had medium to high knowledge of ticks and LD. They knew the size of the ticks, but were not completely informed of their habitat, because they mainly mentioned grassland and forests, and the possibility of ticks falling from trees. According to this group, whether or not a tick bite leads to LD is dependent on the tick being infected or not or how long it is attached to the skin. Finally, they mentioned "the red spot" as a first sign of LD.

### *Experience With Ticks*

Several outdoor people that do not check for tick bites told us they had seen a tick mostly on pets. On the other hand, those who checked for tick bites had direct or indirect experience with ticks or LD; they had pets with ticks, friends with LD, or experienced a tick bite followed by an EM.

### *Dealing With Tick Bites*

About half of the people that "do not care" would remove a tick using (tick) pliers themselves. However, some erroneous strategies were mentioned, such as burning it off with a cigarette, waiting for the tick to grow big so it can be removed more easily, and twisting the tick when removing it. Some people foresaw negative consequences of using tick pliers, like pain, difficulty in removing the tick, not removing the tick's head, and finally, the unpleasant feeling of "operating" on yourself. The other half would go to their GP after encountering a tick bite, mostly because they thought they were unable to properly remove a tick by themselves. Participants who check were more confident about their abilities and said they would remove ticks themselves when bitten using (tick) pliers.

### *Preventive Measures*

Participants of the group that do not check did not take preventive measures against tick bites when visiting a high-endemic area. They regard staying on paths and using an insect repellent spray on their skin as a viable option to guard themselves against ticks. Several of these people did indicate, however, that if something caught their interest in the forest, they would stray from the paths. Wearing clothes that cover the body was not a viable option according to the respondents as it was uncomfortable or "looks stupid." After visiting a high-endemic area, people that "did not care" never checked for tick bites. They did not know that they were in a high-endemic area (like dunes), forgot to check, or expected a tick bite to itch. Those that check thought that staying on the paths in the forest could be a viable preventive measure, but they also indicated that they would not comply whenever they wanted to explore the forest off the beaten path. Normally, these participants did not consider wearing clothes that cover the body as a good preventive measure, especially in warm weather. However, the participants also indicated that when the risk of being bitten is high (eg, when being in a high-endemic area), they would comply with this measure.

> *When it's 35°C outside, you walk in short pants anyway. And then, you check yourself properly in the evening. But, when the number of ticks runs out of hand, you do put on long thin pants.* [Woman; age, 53 years]

Finally, for most interviewees, using an insect repellent skin spray was a reasonable measure; it allowed them to wear short pants. All of those that check, stated they checked themselves for tick bites when they were outdoors.



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### *Information Seeking Behavior*

Outdoor people that do not check for tick bites indicated they would consult a wide range of sources when seeking information on ticks or LD. Most popular resources when searching for information on how to prevent tick bites are the Internet and the MHS, or when bitten by a tick, their GP, the Internet, or the MHS. When searching on the Internet, practically all interviewees would start with a Google search. Those that check expected their MHS to provide them with information on ticks and LD. When searching for information on how to prevent tick bites, they mentioned pharmacies and an online Google search. For information on how to remove ticks, they would resort to their GP or the Internet (with no specific website in mind).

**Table 1.** Characteristics of outdoor people.

| | Those that do not check | Those that check |
|---|---|---|
| Age | widespread | widespread |
| Family situation | either living alone, living together without children, or living together with grown-up children | either living alone, living together without children, or living together with grown-up children |
| Education | widespread | widespread |
| Pet ownership | about half of the people has a pet | about half of the people has a pet |
| Direct experience with ticks / LD | the majority of people has not been bitten by a tick | most of the people have been bitten by a tick or noticed a tick on their body once. |
| Knowledge of ticks / LD | widespread; some people know nothing, some people know a lot | medium to high |

## Parents

### *Overview*

Checking for ticks is determined by previous experience with ticks and LD (Table 2). Children of parents that check spend more time in high-endemic areas.

### *Knowledge of Ticks and LD*

Parents that do not check had little knowledge of ticks and LD but thought that LD was a dangerous disease. The forest was the main location where they thought a child could be bitten. According to them, not all tick bites lead to LD. They did not know the first signs of LD or how fast a tick should be removed. Parents that check had medium knowledge of ticks and LD. They knew what a tick was and that they are very small. In addition, all of them knew about LD and thought it is a serious condition. All participants thought one could be bitten in a forest or in places with shrubs or grass. It was not clear to them that ticks also reside in dunes. None of the interviewees thought a tick bite always leads to LD. Most of them thought a tick should be removed within 24 hours after being bitten. Parents that check knew that EM occurs after an LD infection. A few also mentioned flu-like symptoms as a first sign of LD.

### *Experience With Ticks*

Parents that do not check their children for tick bites had no experience with ticks or LD, while all of the parents that check their children for tick bites had previous experience. The latter were once bitten themselves, had one or more children or pets were bitten at least once, or they knew someone with LD.

### *Dealing With Tick Bites*

Parents that do not check their children for tick bites have two strategies for removing ticks: using (tick) pliers or visiting their GP. They were unsure about their own abilities to remove ticks because they were afraid they could not remove the tick in its entirety. Most parents that check would remove a tick themselves if one of their children were bitten. However, they anticipated difficulties in the removal. They were afraid they would do it wrong, because they received different kinds of instructions (twisting when removing, pulling upward), or they were afraid that they would also remove the skin or would leave (a part of) the tick's head behind.

> *I think I will have it removed by the family doctor. I don't mind with my own cat… but, in the case of my own child, I want to have it done properly. It's not that I won't dare to do it, but I think I will notify the family doctor or will discuss with him what to do. I have one of those tick pliers. But, the last time the cat had a tick, it didn't go as I wanted it to. So, I would go to the family doctor.* [Woman; age, 32 years]

### *Preventive Measures*

All parents agreed about the issue of tick bite prevention. They knew they could prevent their children from being bitten by a tick by wearing the right kind of clothing. When prompted about the different precautions they could take, parents were not enthusiastic. They did not want to keep their child on paths in forests or parks, because they thought the children should be allowed to run freely. Wearing clothes that cover the body was not seen as a practical option when it was warm outside. Wearing a cap was not seen as an option, because the parents expected their child to remove it. Parents disliked the use of insect repellent sprays, because they contain diethyltoluamide (DEET), or the parents did not want to spray in their child or their clothes every day. Parents that do not check their children for tick bites do so because they think the chance of their child being bitten by a tick is very small or expect their child to notice a tick bite; they assumed that the children would "feel it." Parents that do check their children do this when they thought their child was at risk of tick bite, for example, by having spent time in the forest. When they check their children, they mostly look at their armpits, neck, ears, groin, back of the knee, or "warm creases."



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### *Information Seeking Behavior*

Parents that do not check indicated that they would search the Internet when they wanted information on how to prevent tick bites or how to remove ticks. Parents that do check expected the national government or the MHS to inform them about preventing tick bites and LD. When they need information on how to prevent tick bites, they would perform an Internet search using Google. To find information on how to remove ticks, they would perform a Google search or would consult their GP.

> *I think I would go to the family doctor if I don't trust the situation [a child with a tick bite]. I would Google. That would be the way for me. Just type in "tick bite" and see where it gets me.* [Woman; age, 47 years]

All children of the parents we interviewed went into high-endemic areas with clubs or schools. Both groups of parents thought that checking for tick bites was their own responsibility when possible although they would like to be reminded to do so. When children are away overnight, the parents thought that it was the responsibility of the club or school to control for tick bites.

**Table 2.** Characteristics of parents and their children.

| | Parents that do not check | Parents that check |
|---|---|---|
| Age | 30 to 50 years old | 30 to 50 years old |
| Family situation | married; 1 to 3 children | married; 1 to 3 children |
| Education | widespread | widespread |
| Pet ownership | low | about half of them has a pet |
| Direct experience with ticks/Lyme | none | all parents have experience with ticks or LD, either being bitten themselves, via a child, or via a pet |
| Knowledge of ticks/Lyme | low | medium |

## Discussion

### Overview

In this paper, we have shown a lightweight qualitative approach by identifying risk groups and conducting in-depth interviews to create risk group profiles that can be used as inputs for targeting health communication. Such health communication is geared toward the characteristics and contexts of specific groups within a population and is generally more effective than one-size-fits-all communication [1]. To our knowledge, this is the first study in which this approach has been used providing information about tick bites and LD to the general Dutch population.

### Identifying Risk Groups

We identified four groups at a risk of being bitten by ticks bites and developing LD among the general Dutch population. The four groups were as follows: (1) outdoor people that check for tick bites, (2) outdoor people that do not check for tick bites, (3) parents that check their children for tick bites, (4) and parents that do not check their children for tick bites. Previous experience with tick bites or LD appeared to be the main denominator between the groups. Herrington [28] also identified previous experience with tick bites as one of the main factors governing compliance with preventive measures. The willingness to adopt measures that prevent tick bites (eg, wearing protective clothing) was low for all risk groups.

### Communicating Targeted Precautions

Our results were consistent with those reported by Gould et al [29], Marcu et al [7], and Beaujean et al [8], in that we found that checking for tick bites is a measure that is more easily adopted than preventing tick bites. Therefore, for all groups, the advice should primarily stress the importance of checking for tick bites. Moreover, we identified differences among groups, and therefore, health organizations should shift their focus from communicating expert-driven guidelines (promoting all precautions that can help) to communicating targeted precautions (those that members of a risk group are likely to adopt and/or fit with their perceptions). Using the profile of each risk group (Tables 1 and 2) and the motivations behind their behavior, health organizations can attune their informative and persuasive communication efforts. For example, outdoor people that do not check need to be educated about ticks and LD from scratch; they must be encouraged to check for tick bites after visiting a risk area; and they must be encouraged to remove ticks themselves instead of visiting their GP. However, outdoor people that do check already know the basics about ticks and LD and will remove ticks. These people should be provided with detailed information about the habitat of ticks. An approach similar to that mentioned above should be used in the case of parents. Parents that do not check their children for tick bites should be educated about the topic and should be motivated to check their children for tick bites and to independently remove the ticks that have bitten their children. Parents that do check are more willing to remove ticks that have bitten their child themselves but are afraid to do this wrong. Therefore, they do not need to be persuaded to remove the tick, but they require appropriate instructions.

### A Targeted Communication Strategy

Currently, we are developing a mobile app for ticks and LD as an example of a targeted communication strategy using a multidisciplinary requirements development approach [30]. We are using the profiles of each risk group (Tables 1 and 2) and the motivations underlying the behavior of the members of each risk group to determine the features and content of the app. A mobile app provides real-time up-to-date instructions and



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information and can be targeted to specific groups. Van Velsen et al showed that users need a video with information on how to remove a tick, a tick radar that indicates the actual tick activity on the basis of location and seasonality, and an alert that reminds people to check for tick bites at the end of the day when they have been in an endemic area. Finally, users expressed the need to document tick bites. A mobile app can provide these requirements identified by the users [31]. The app will offer only the selected information that is required according to the risk group. For example, for people that do not check (themselves or their children), information encouraging these people to check for tick bites after visiting a risk area will be included in the app. For people that do check, instructions on how to properly remove ticks will be added. Thus, the communication about ticks and LD will be targeted to great extent. Further studies are required to determine whether this method of communication is a more fruitful approach than communicating a one-size-fits-all message.

### Limitations

The main limitation of our study is the small sample size inherent to qualitative research and the approach used. Our study is a first step in identifying risk groups and understanding the differences between the risk groups used for the development of an intervention for the prevention of tick bites and LD. A larger number of respondents are required to draw more definite conclusions, for example, about the size of certain risk groups. However, the aim of this study and of creating a basis for targeted health communication is not to quantify conclusions (eg, give a certain percentage) that hold for a total population (and for which a quantitative study with a large sample would be most suited) but to identify risk groups, and most importantly, to understand the differences between the risk groups. Because we reached the point of data saturation, we were confident that we understand the differences between the risk groups (without actually quantifying these risk groups, which was not the aim of this study). Furthermore, we have presented an approach toward targeting health communication for situations in which access to large sets of data about a population is not available. When one wants to understand people's behavior, or when large sets of data about a population are not available (as is often the case in public health), qualitative research is the only feasible means to elicit the necessary information (with limited budgets).

Another limitation relates to the defined risk groups. The distinction between outdoor people and parents with children might be somewhat confusing because some people might belong to both, for example, outdoor people with children. For these people, both targeted strategies would apply; one strategy for checking themselves and one strategy for checking their children. Although children can also be outdoor people, they do not belong to the outdoors group because they cannot be held responsible for checking themselves for ticks; this is the responsibility of parents.

### Conclusions

Finally, the extreme form of targeting is tailoring, that is, tuning health communication toward the characteristics and context of the individual. This holds the potential to increase a person's attention or motivation about a specific health issue or healthy behavior [32,33]. Further, with the development of new technologies in the last decade, health organizations have gained a wide range of possibilities for gearing messages toward the individual user. However, although often effective [34], tailoring is not always preferred over targeting, because this choice depends on the complexity of the targeted behavior, the available budget, the variability of behavioral determinants among individuals, and the availability of mechanisms for assessing an individual's characteristics and context [35]. Moreover, in many cases, a combination of a targeted and tailored approach is the optimal health communication strategy [35]. Therefore, identifying differences among risk groups is and remains an important facet of tailoring health advice be it toward groups or individuals. The lightweight qualitative approach presented in this paper is highly relevant in achieving this objective.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Interview guide.

[PDF File (Adobe PDF File), 115KB - resprot_v2i2e45_app1.pdf ]

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## Abbreviations

**COPD:** chronic obstructive pulmonary disease
**DEET:** diethyltoluamide
**EM:** erythema migrans
**GP:** general practitioner
**HIV:** human immunodeficiency virus
**LD:** Lyme disease
**MHS:** municipal health services


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Original Paper

# An Interactive, Bilingual Touch Screen Program to Promote Breastfeeding Among Hispanic Rural Women: Usability Study

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## Abstract

**Background:** Computer technology can be effectively used to educate patients and improve knowledge and attitudes, leading to healthier behavior. Among rural women, breastfeeding outcomes seem to be worst compared to women living in urban areas. The implementation of a bilingual computer mediated health education program to disseminate information and improve outcomes among users with low literacy levels has proven to be successful.

**Objective:** The objective of this pilot study was to examine the usability of an interactive, bilingual touch screen computer-based educational program to promote breastfeeding practices among Hispanic women living in rural settings.

**Methods:** A convenience sample of 10 Hispanic rural women at the Regional West Medical Center (RWMC), Scottsbluff was enrolled during May 2013. Information about this cross-sectional study was made available through the flyers at the RWMC. A brief introduction of the prototype was given and study subjects were then asked to complete a predefined set of tasks by interacting with the prototype. Users were assigned 6 tasks and information was gathered about the time taken to complete the tasks, number of attempts, and if assistance was needed. Notes and test sessions were audiotaped. Usability assessment was performed using the System Usability Scale (SUS).

**Results:** The mean age of the study participants was 28 years (SD 3.6), the majority of them had 12 or more years of education (90%, 9/10), and 60% (6/10) had breastfed less than 6 months. There were 90% (9/10) of the study participants that had no prior history of taking prenatal classes and 80% (8/10) that did not intend to take any prenatal classes in the future. The average SUS scores were 90 and SD was 10.5. There were three participants that had average SUS scores of 100, followed by scores of 97.5 (1/10), 95 (1/10), 87.5 (1/10), 85 (2/10), 82.5 (1/10), and one participant had a score of 67.5 (1/10). No assistance was needed to complete any of the tasks.

**Conclusions:** The study participants were able to navigate through the multimedia program with ease and obtain relevant breastfeeding related health information. The interactive, touch screen computer-based breastfeeding program had high acceptance among 10 Hispanic women living in rural settings.

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**KEYWORDS**

usability; breastfeeding; education; evaluation; computer



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## Introduction

### Children and Breastfeeding

Breastfeeding is essential for children to have a healthy and regular development. The American Association of Pediatrics advises women to breastfeed exclusively for the first six months of the child's life [1]. Internationally, the World Health Organization also recommends that infants should be exclusively breastfed for the first six months of life, to achieve optimal growth, development, and health [2]. Breast milk provides the best nutritional source for the healthy growth and development of children and it is protective against a variety of diseases [3,4]. Rates of breastfeeding continue below the goals proposed by Healthy People 2020 [5,6].

Among rural women, breastfeeding outcomes seem to be worst compared to women living in urban areas [7]. Research has shown that breastfeeding practices depend on a multitude of factors including knowledge and perception of breastfeeding, socioeconomic status, cultural background, and family relationships [8,9]. Lower prevalence of breastfeeding initiation has been observed among Hispanics living in western states compared to non-Hispanic whites [10]. Many challenges exist to improve breastfeeding practices. Family and friends may provide inaccurate information about breastfeeding, and mothers often perceive social disapproval [11]. Information presented should be tailored, culturally appropriate, and relevant to improve breastfeeding related knowledge, change behaviors, and practices related to breastfeeding initiation and duration [12].

### Computer Technology and Breastfeeding

Computer technology can be effectively used to educate patients and improve knowledge and attitudes, leading to healthier behavior [13]. Prior research has shown successful interventions that facilitate behavior modification and health promotion through use of Information and Communication Technologies (ICT) [14]. Health information tailored through use of ICT has proven to be more effective and efficient [15-17]. Computer-based tailoring is a process of creating individualized communication and is an assessment-based approach in which individuals provide personal data related to a given health outcome [18]. Those data are then used to determine the most appropriate information or strategies to meet each individual's unique need. An important theoretical basis for tailoring comes from the Elaboration Likelihood Model [19], which states that people are more likely to actively and thoughtfully process information if they perceive it to be personally relevant. Messages processed in this way tend to be retained for a longer period of time and are more likely to lead to permanent attitudinal change.

### Usability Testing

Usability testing is a key component of product evaluation, and focuses on measuring a product's ability to meet its intended purpose by providing evidence on how real users interact with it [20]. Additional methods of usability testing include expert evaluators to be able to identify problems and determine whether the user conforms to established usability principles in a heuristic evaluation. Expert evaluation can identify errors in a systematic process, and accurately diagnose them within the system design [21]. Usability problems are important to be evaluated such as: (1) revision of instructions and functionality, (2) better introductory instructions, (3) elimination of instructional messages, and (4) simplified representation and improved labeling [21]. Several interactive health care applications often have been hampered by their poor design, making these systems difficult to learn and complicated to use [22]. The systems designed without taking into account the target users can result in poor adoption of these systems. Tailoring the design of the systems helps meet the specific needs of the users and results in increased productivity, reduced errors, reduced need of user training and user support, and improved acceptance [22]. This will allow the users to operate the system effectively rather than struggling with the computer's functions and user interface, enhancing users' productivity [23]. The implementation of a bilingual computer mediated health education program to disseminate information and improve outcomes among users with low literacy levels has proved to be successful [24]. Usability testing is an important process in the design and implementation of programs to allow for further development and better adoption of technologies in populations. Usability testing can be conducted among target populations, and can help identify key issues before full implementation.

The purpose of this pilot study was to examine the usability of an interactive, bilingual, touch screen enabled standalone and Internet based breastfeeding educational program among Hispanic women living in rural settings and in this case Scottsbluff, Nebraska.

## Methods

### The Convenience Sample

We enrolled a convenience sample of 10 Hispanic rural women at the Regional West Medical Center (RWMC), Scottsbluff, Nebraska during May 2013. Information about this cross-sectional study was made available through the flyers at the RWMC. The optimum number of participants for in-depth interviews is typically 6-10 people with similar backgrounds who participate in the interview for one to two hours, however interview times may vary [25]. Prior literature has suggested that smaller groups of a sample between 6 to 10 participants show greater potential and large enough to gain a variety of perspectives, and small enough not to become disorderly or fragmented [25]. After a brief introduction to the system, study subjects were asked to complete a predefined set of tasks by interacting with the system and the duration of this interaction was around 30 minutes. The study participants used a think aloud protocol involving participants thinking aloud as they used the program, and were asked to say whatever they were looking at, thinking, doing, and feeling. Then, users were assigned 6 tasks including: (1) entering age, (2) moving forward to the next question, (3) ability to pause the program, (4) replay, (5) use of help module, and (6) ability to change the settings. Tasks were chosen based on varied complexity. Information was gathered about the time taken to complete the task, task completion (yes or no), number of attempts taken to complete



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the task, and whether or not assistance was sought during the completion of the task. Notes and test sessions were audiotaped of everything that users said. Usability scores were recorded among the 10 study participants, where vast amounts of usability problems and issues can be identified with only a small number of test subjects, as few as 8 to 10 participants [26]. The UNMC Institutional Review Board (IRB protocol#430-12-EP) approved the study.

## Variables Description

### *Sociodemographics*

Information gathered included age (years), years of education, income, marital status, and employment status. Information was also gathered about the history of previous pregnancies, duration of breastfeeding, prior history of prenatal breastfeeding classes, or any intend to take these classes in the future. Information was also gathered about the sources of health information utilized by the study participants. Further information gathered included prior use of computers and Internet and the frequency of use.

### *Think Aloud Analysis*

Users were asked to navigate through the program when they were assigned tasks. Qualitative data were generated as they were asked to say whatever they were looking at, thinking, doing, and feeling as they go about their task, enabling observers to see first-hand the process of task completion. Audios were recorded and notes were taken.

### *Task Assessments*

The study participants were assigned 6 tasks to complete and information recorded included the task completion time, number of attempts an individual made to complete the task, and whether or not assistance was taken to complete that task.

The tasks chosen are the most common tasks that users would be using to interact with the system. Tasks were chosen based on varied levels of complexity. Notes were taken and audios were recorded.

### *System Usability Scale*

A Likert scale survey System Usability Scale (SUS) was used to assess user acceptance with an interactive, computer-based breastfeeding educational program and any recommendations that the study subjects might have to improve the system. SUS is a 10-item questionnaire with 5 response options ranging from strong agreement to strong disagreement. Possible scores are 0, 1, 2, 3, or 4 for each question. To minimize bias based on agreement or disagreement, odd items of the SUS questionnaire are given more points for strong agreement, and even numbered items are given more points for strong disagreement. The total score is calculated from adding up the converted responses for each user and multiplying that total by 2.5. This converts the range of possible values from 0 to 100 instead of from 0 to 40.

### *User Acceptance*

We adapted and used previously published questionnaires used to assess acceptance of a computer-based asthma educational program [27]. Feedback was gathered on ease of use of program, navigation patterns, future use of the program, and if others would be recommended to use the program.

### *Statistical Analysis*

Descriptive analysis was performed to report means and standard deviations of the continuous variables and frequency distribution of the categorical variables. Analysis of the qualitative data was performed on the data collected through written notes and recorded spoken language. A thematic approach was used from the narratives of research participants gathered during the think aloud approach to identify themes or patterns, organize data into coherent categories, and then interpret the findings of the data. Qualitative data were analyzed based on grounded theory. All quantitative analysis was performed using SAS version 9.1.

## Patient Education and Motivation Tool

### *The Patient Education and Motivation Tool Program*

Patient Education and Motivation Tool (PEMT) is a touch screen computer-based interactive health education program designed integrating a variety of cognitive-behavioral theories. PEMT facilitates health information and messages to be adapted depending on the psychosocial elements including attitude, self-efficacy, expectations, personal norms, and social influences (Table 1). PEMT has 3 key components. Screening is the first component, which gathers individual sociodemographics, knowledge, attitudes, and practice through a series of questions. Second, the learning component delivers educational material in a structured format. The entire educational material is broken down into a series of modules, each module into submodules and each submodule into a series of educational messages. Each message is then presented using various multimedia formats (such as audio, video, text, and images. Third, the evaluation component gauges effectiveness of the program by assessing change in knowledge, attitudes, and practices of the individuals. The main objective of the PEMT is to present health information in an interactive tailored manner considering multiple factors influencing health status and health behaviors.

The existing PEMT was modified to develop an interactive, tailored, computer-based breastfeeding educational support program to educate Hispanic women living in rural settings. The computer-based Breastfeeding Educational Support program aims to provide modular, culturally relevant, bilingual (English/Spanish) breastfeeding education tailored to the needs of the mothers. Content tailoring was performed based on the needs of the Hispanic women living in rural settings and guided the development of the breastfeeding educational modules. The modules of the finalized breastfeeding educational content were made available both in Spanish and English so that the study participant can use either language to navigate through the program. The modules included: (1) basics of breastfeeding, (2) how to breastfeed?, (3) benefits of breastfeeding to mother and child, (4) normal feeding signs, (5) problems during breastfeeding, (6) formula feeding, (7) coping with breastfeeding, and (8) ability to get pregnant while breastfeeding. The entire finalized breastfeeding educational content will be broken down into a series of modules, each module into submodules and each submodule into a series of educational messages. The computer-based program will have



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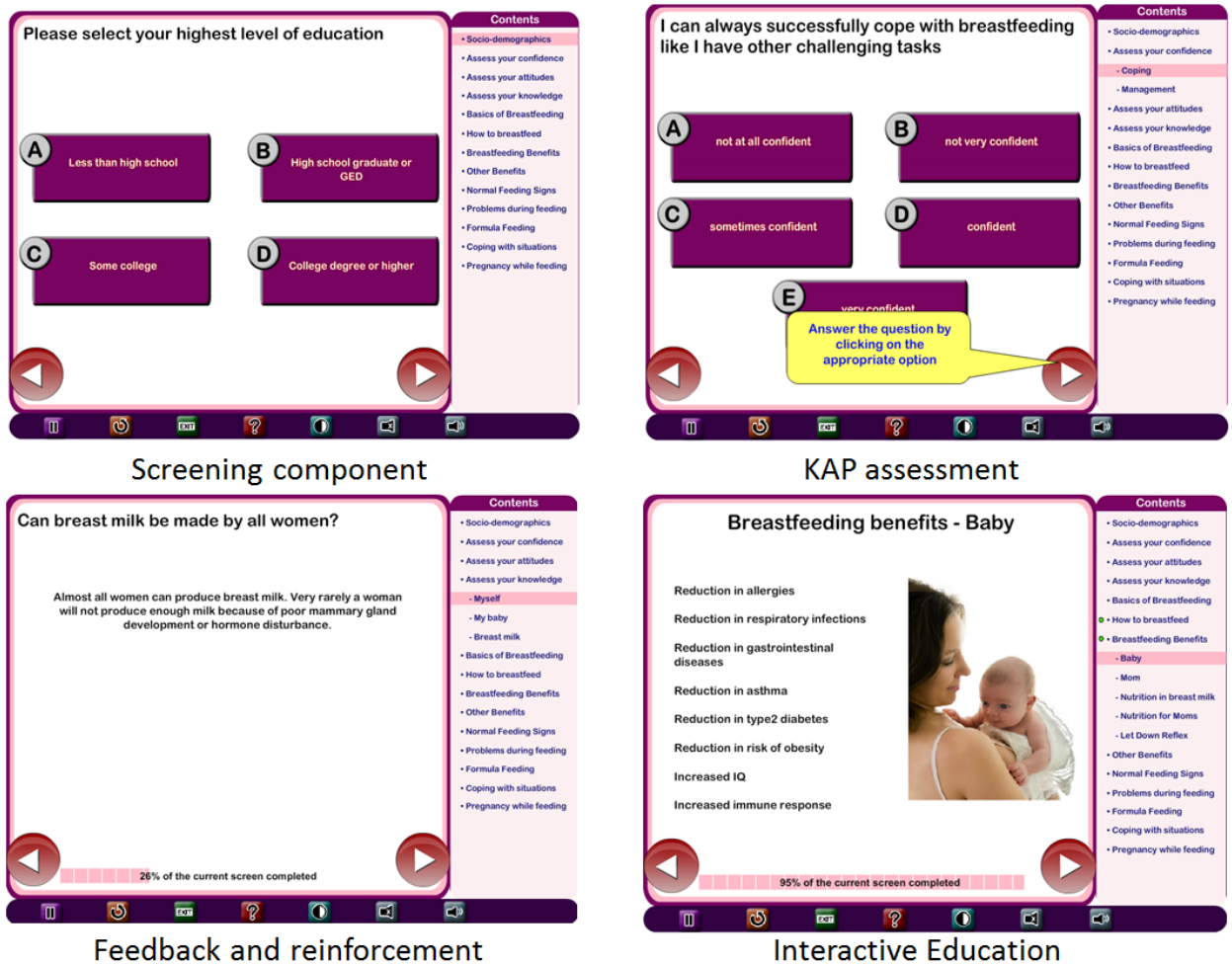
the ability to deliver breastfeeding education in varied learning styles such as text-only, audio and text, or text, audio, and images to account for health literacy of the individuals. The program will simplify the design and create multiple tailored versions of printed materials instead of using a single standardized version. Figure 1 shows the components of the computer-based education program.

**Table 1.** Modify PEMT to adapt to computer mediated breastfeeding educational program.

| Theory | Purpose | PEMT learning component |
|---|---|---|
| Information processing theory [28] | Present information as a meaningful unit and limited to 5-9 pieces of information | Each slide includes limited educational content |
| Constructivist theory [29] | Present information in a structured format simple to understand | The content presented on each screen is in a series of short messages |
| Cognitive flexibility theory [30] | Information presented should be highly interconnected and relevant to the learner | The educational material is related to each other |
| Cognitive flexibility theory [30] | Multiple content formats | Content is available as audio, images, and text |
| Cognitive load theory [31] | Minimize working memory load | Information is presented as a series of short educational messages |
| Behavioral theory and Operant conditioning [32] | Feedback given based on responses and positive reinforcement for healthy behaviors | Based on individual correct or incorrect response feedback is provided |

**Figure 1.** Components of computer based education program.




### *PEMT Tailoring Algorithm*

The PEMT tailoring algorithm involves several components including: (1) multifactor assessment that helps to gather information about several variables, (2) mapping module involves generating individual user profile, (3) decision logic involving data processing and interpretation, (4) knowledge module involves having library of educational messages and various formats in which these can be delivered, (5) evaluation module involves a series of assessments, (6) feedback module



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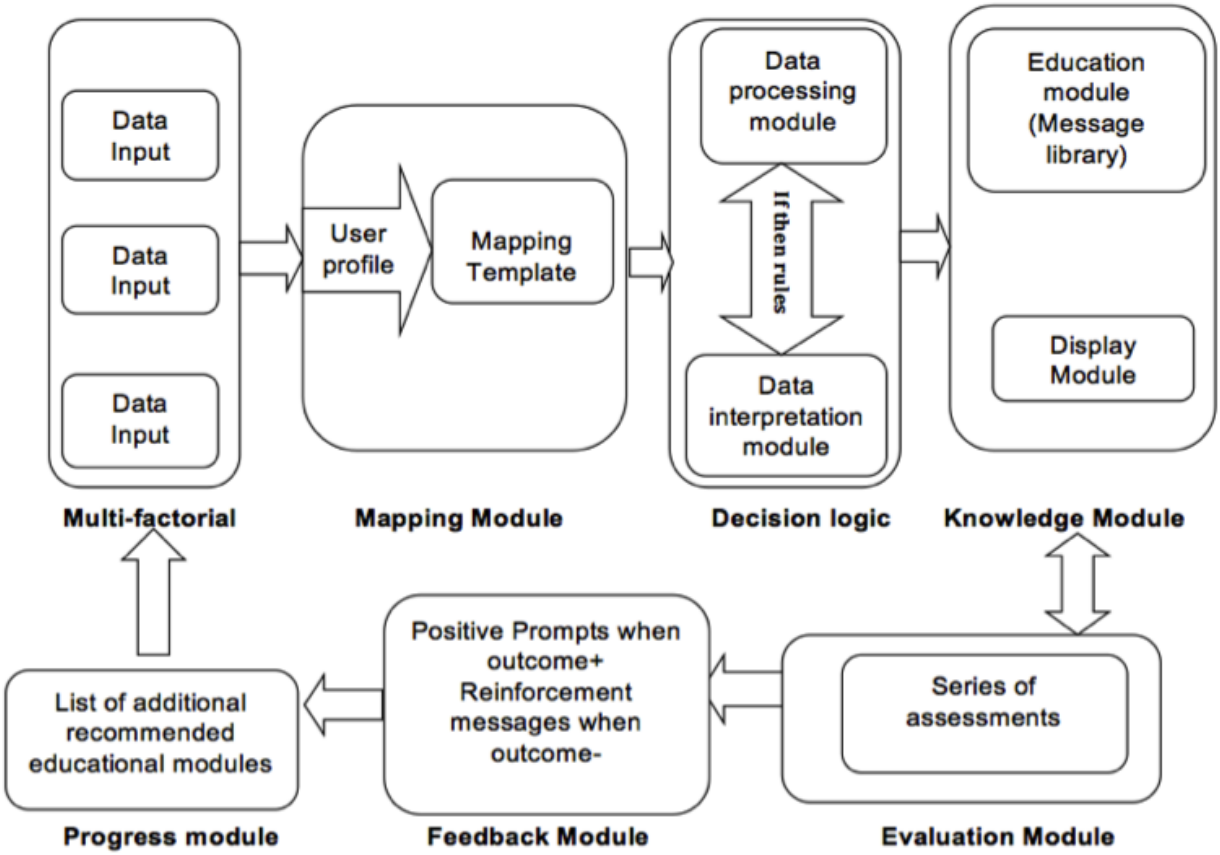
involves reinforcement based on the responses, and (7) progress module involves the topics covered (Figure 2 shows this tailoring algorithm). For example, sociodemographics and breastfeeding knowledge and attitude towards breastfeeding practices are gathered through a series of questions. For example, if a person had poor breastfeeding knowledge on certain topics; educational messages were tailored to address those gaps in the knowledge. Messages were also tailored for participants with poor breastfeeding skills and appropriate feedback was provided through reinforcement and use of motivational prompts. The program aims to deliver specific messages as computers provide a medium to adopt tailoring with no time lag and multimedia capabilities.

**Figure 2.** PEMT tailoring algorithm.




## Results

### The Participants and Their Sociodemographic Characteristics

Results showed the mean age of the study participants to be 28 years (SD 3.6), the majority of them had 12 or more years of education (90%, 9/10), half of them were married (50%, 5/10), 60% (6/10) had breastfed less than 6 months. The majority of the participants received a low income with one (10%, 1/10) participant's annual incomes less than $10,000, one (10%, 1/10) between $10,000-19,000, two (20%, 2/10) between $20,000-29,000, two (20%, 2/10) between $30,000-39,000, three (30%, 3/10) between $40,000-49,000, and one (10%, 1/10) was greater than $50,000. The majority of the study participants had either no prior history of taking prenatal classes (90%, 9/10) or did not intend to take any prenatal classes in the future (80%, 8/10) (Table 2).



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**Table 2.** Study population characteristics (N=10).

| Variables | Responses n (%) or mean (SD; range) |
|---|---|
| Age, years | 28.0 (3.6; 23-35) |
| Education ≥12 years | 9 (90) |
| Marital status, married | 5 (50) |
| Employment, full time | 8 (80) |
| Income status, $40,000-49,000 | 3 (30) |
| Smoking status, never smoked | 9 (90) |
| # of children, mean (SD; range) | 2 (1; 0-4) |
| Previous history of pregnancies | 2 (1; 0-4) |
| **Breastfeeding history** | |
| Breastfeeding duration | None=3; 1-5 months=4; 6-12months=1; >12months=2 |
| Number of children breastfed | 1.44 (1; 0-3) |
| Previous history of taking prenatal classes; no | 9 (90) |
| Intent to take prenatal classes in the future; no | 8 (80) |

## Familiarity With Use of Technology and Internet Enabled Breastfeeding Information

### *Participants and Computers*

Results showed that the majority of the study participants had household computers (80%, 8/10) and all of them were using the Internet (100%, 10/10). The frequency of using computers daily was 90% (9/10) compared to 10% (1/10) who used computers once a week. The frequency of using the Internet daily was 100% (10/10). More than half of them were using the Internet to find breastfeeding related information (60%, 6/10) compared to the 40% (4/10) that never used the Internet. Of those who used the Internet, 40% (4/10) used it rarely, compared to those who either used it once a week (10%, 1/10) or once a month (10%, 1/10). Only 20% (2/10) of the study participants agreed that they always found relevant breastfeeding information on the Internet compared to the other 20% (2/10) who would sometimes find relevant information related to breastfeeding. There were 20% (2/10) of the study participants that rarely found relevant breastfeeding information on the Internet (Figure 3 shows familiarity with the use of technology and breastfeeding information).

### *Task Assessments*

There were 6 tasks assigned to each study participant. One hundred percent of the study participants did not need assistance to complete any of the tasks. The average total time taken to complete all the tasks was 17.4 seconds (SD 6.39). More time was taken to complete certain tasks (Table 3). There were three tasks that were completed during the first attempt, compared to the others that were completed during the second attempt. No assistance was needed to complete any of the tasks.

### *Thematic Analysis Using Think Aloud Data*

One hundred percent of the study participants agreed that the educational content enhanced with visual images was sufficient to meet their informational needs related to breastfeeding. However, one participant suggested of “having more information about milk storage and pumping breast milk.” Two participants agreed about having additional pictures and less text to enhance their understanding about the breastfeeding related information “I am a visual person, it helps me understand better.”

All study participants found this interactive, computer-based breastfeeding educational program easy to navigate (100%, 10/10). The majority of the participants found the program “self-explanatory, easy to figure out, and simplified.” Some of the participants thought that a drop-down menu function would be good to gather information about various variables (40%, 4/10). There were 30% (3/10) of the participants that thought that the ability to customize colors based on the gender of the baby would be useful. The various functions of the program including the play/pause button, audio, and images were extremely beneficial. The help function was very useful and one of the participants felt that “help section is informative to let me know how to proceed to the next section.”

The labeling of buttons, highlighting keywords, videos, able to make distinctions between two screens, and the ability to self select the choice of medium to acquire breastfeeding related information (audio or text) could be additional features that can be added to the existing program. There were two study participants that also felt that a progress monitor and a summary report at the end of the program would be useful to help them show how far they have to complete the tasks and how much more they still have to go.

### *Usability of the Program*

The average SUS scores were 90 and SD was 10.5. There were three participants that had average SUS scores of 100, followed by scores of 97.5 (1/10), 95 (1/10), 87.5 (1/10), 85 (2/10), 82.5 (1/10), and one participant had a score of 67.5 (1/10) (Table 4).



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**Figure 3.** Familiarity with the use of technology and breastfeeding information.

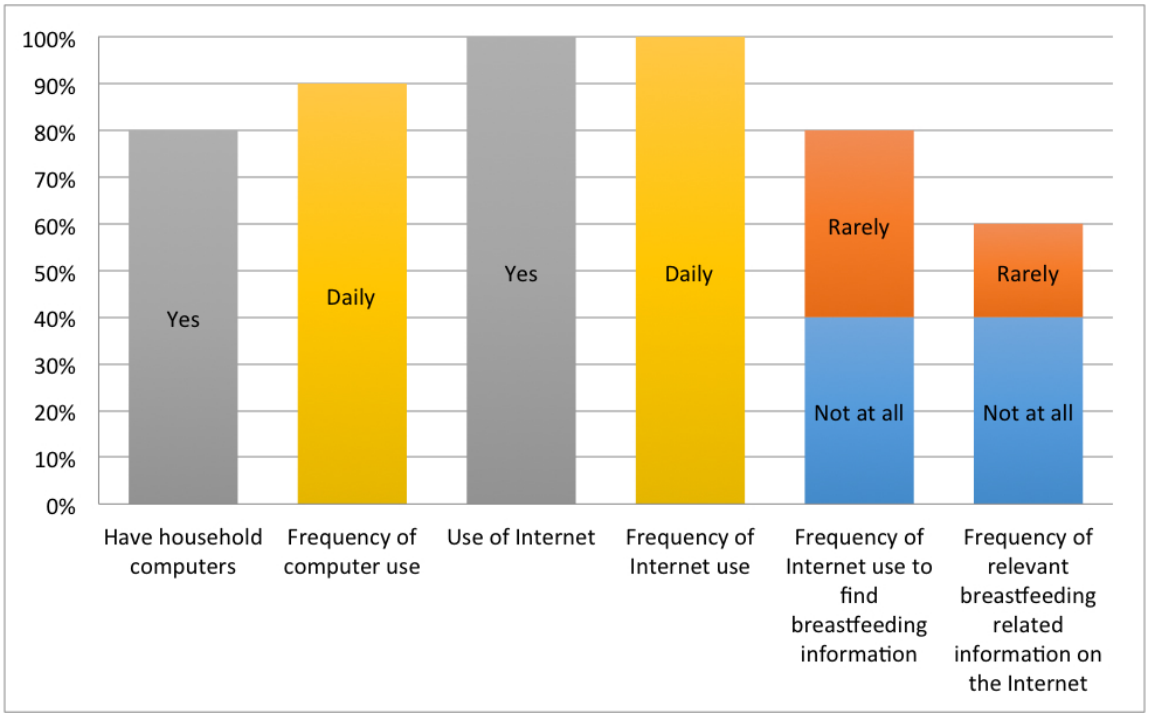


**Table 3.** Task completion times, attempts, and assistance needed to complete the tasks (N=10).

| Task types | Task completion time, mean; (SD) range | Tasks completion during the 1st attempt, n (%) | No assistance needed, n (%) |
|---|---|---|---|
| T1 select age | 3.94; (1.42) 2.30-6.80 | 10 (100) | 10 (100) |
| T2 move to next slide | 2.11; (2.4) 0.5-8.50 | 9 (90) | 10 (100) |
| T3 pause program | 2.48; (1.31) 0.5-5.30 | 10 (100) | 10 (100) |
| T4 replay | 2.23; (1.38) 0.9-5.80 | 7 (70) | 10 (100) |
| T5 using help | 2.75; (1.96) 1.0-7.50 | 10 (100) | 10 (100) |
| T6 change settings | 3.89; (5.55) 0.8-19.40 | 9 (90) | 10 (100) |

**Table 4.** Frequency distribution of the SUS.

| Variables | Frequency, n (%) | | | | |
|---|---|---|---|---|---|
| | 1 Strongly disagree | 2 | 3 | 4 | 5 Strongly agree |
| I think that I would like to use this system frequently. | | | 1 (10) | 3 (30) | 6 (60) |
| I found the system unnecessarily complex. | 10 (100) | | | | |
| I thought the system was easy to use. | | | | 1 (10) | 9 (90) |
| I think that I would need the support of a technical person to be able to use this system. | 10 (100) | | | | |
| I found the various functions in this system were well integrated. | | | | 4 (40) | 6 (60) |
| I thought there was too much inconsistency in this system. | 9 (90) | | | | 1 (10) |
| I would imagine that most people would learn to use this system very quickly. | 1 (10) | | | 2 (20) | 7 (70) |
| I found the system very cumbersome to use. | 5 (50) | 1 (10) | 1 (10) | | 3 (30) |
| I felt very confident using the system. | 1 (10) | | | 1 (10) | 8 (80) |
| I needed to learn a lot of things before I could get going with this system. | 10 (100) | | | | |



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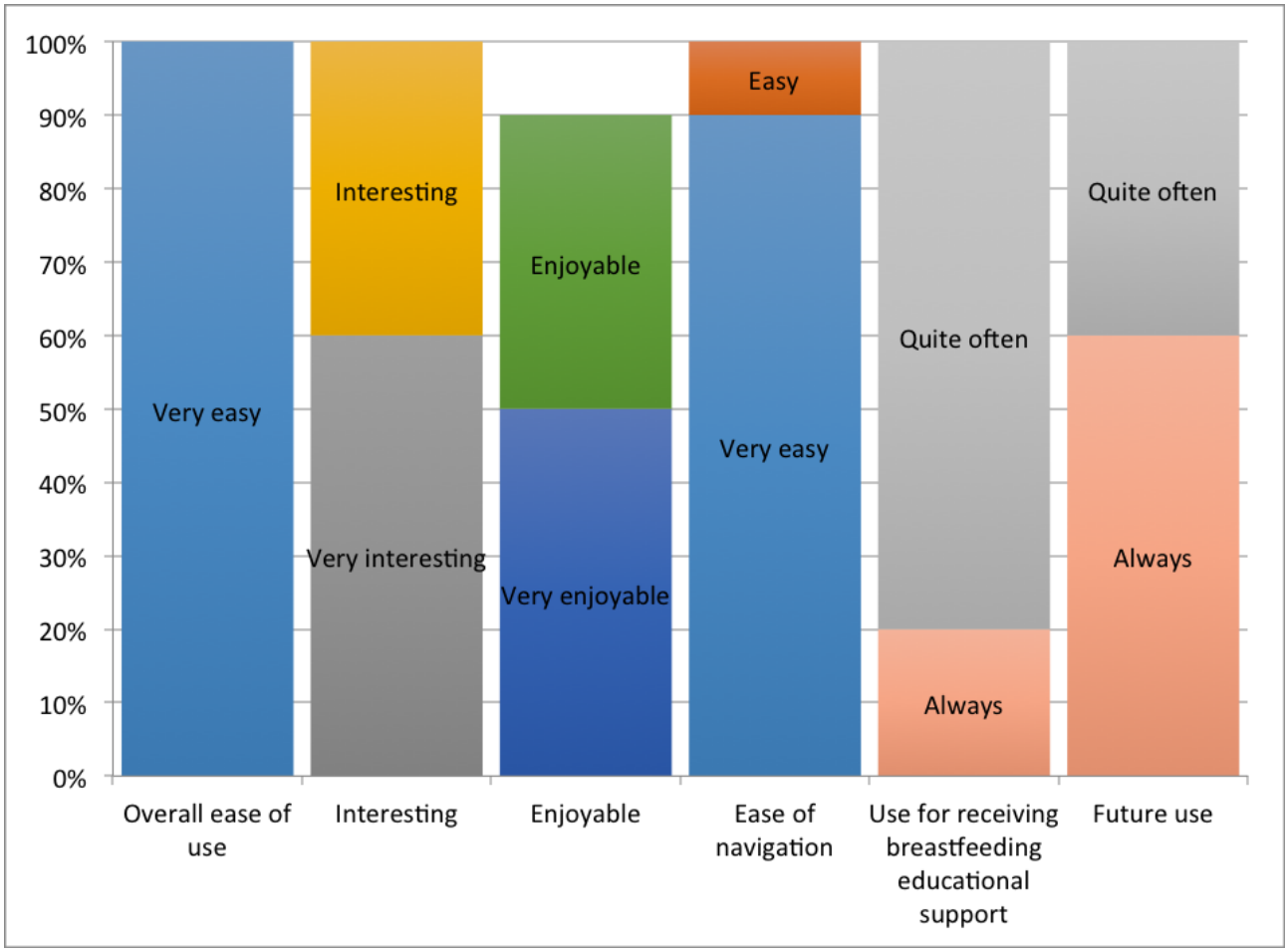
### High Program Acceptance Rate

Overall, the interactive, touch screen computer-based breastfeeding program had high acceptance. There were 100% (10/10) of the study participants that found the program very easy to use, 60% (6/10) of them found it very interesting, and more than half of them (80%, 8/10) would use it quite often for receiving breastfeeding educational support. More than half of them would always want to use the program in the future (60%, 6/10). Figure 4 shows the distribution of the program acceptance.

**Figure 4.** Frequency distribution of the program acceptance.




## Discussion

### Promoting Breastfeeding

Despite the clear benefits of breastfeeding to mother and infant, breastfeeding rates continue to remain below the recommendation levels in the United States, most notably among low income mothers living in rural settings. Modifiable factors such as maternal attitudes and self-efficacy demonstrate a positive relationship with continued breastfeeding. The promotion of breastfeeding is of utmost importance because of its role in many health related outcomes. There are many challenges that prevent Hispanic women from breastfeeding, these include embarrassment, pain, inconvenience, lack of breastfeeding support, and not being able to consume alcohol or smoke cigarettes [33,34]. These barriers need to be addressed in a culturally sensitive manner that focuses on how women can overcome them. The delivery of health information is challenging for non-English speaking populations due to well-known language, low literacy, and cultural barriers.

### SUS Scores

Research has translated the average SUS score to be easily interpreted by others where products that scored in the 90s are exceptional, products that score in the 80s are good, and products that score in the 70s were acceptable, and below 70 is concerned to have usability issues that cause concerns [35]. Results of this study among 10 low-income Hispanic women living in a rural setting suggest that an interactive, computer-based breastfeeding educational program is highly acceptable with an average SUS score of 90. The interactive program included a series of breastfeeding educational modules in English and Spanish. Each module was broken down into submodules and each submodule was further broken down into a series of short educational messages. The educational messages were enhanced using various formats of multimedia in the form of text, audio, and images.

### Participants' Computer Program Results

The majority of the participants had familiarity with the use of computers and had access to the Internet, however only 60% (6/10) of them used the Internet to find breastfeeding related information. Most of the participants did not find the



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breastfeeding related information on the Internet useful. Results of our study showed that all the participants were able to complete all the tasks unassisted during the use of the program. All the participants agreed that use of images and audio enhanced their understanding about the various breastfeeding educational modules. However, study participants believed that labeling of the buttons, highlighting keywords, and use of videos can further make the program interactive and useful. The system demonstrated high usability scores, reflecting its usefulness among rural Hispanic women. The usability testing of the program has helped to take into account the preferences of the target group.

### Health Information Technology Usability

Prior research suggests that technology is a promising way to change a person's health behavior. Usability factors are a major obstacle to health information technology (IT) adoption. Lack of attention to health IT evaluation may result in an inability to achieve system efficiency, effectiveness, and satisfaction. Consequences may include frustrated users, decreased efficiency coupled with increased cost, disruptions in workflow, and increases in health care errors [36]. It is essential to be attentive to health IT usability, keeping in mind its intended users, task to be performed, and environment. Further, the usability evaluation should not only be done through use of questionnaires that provide subjective information, but should also include objective assessments through task analysis. A longitudinal study is needed to explore the acceptance of the program after the program is used for a longer duration. Future studies are planned to determine the usability among a large longitudinal study. A longitudinal study will help identify further usability challenges and program acceptance among populations with varied characteristics.

Results of our study showed high acceptance with no assistance needed by the 10 Hispanic women living in rural settings. The study participants were able to navigate through the program with ease and obtain relevant breastfeeding related health information specific to meet their needs. An interactive, touch screen breastfeeding educational program using multimedia can help overcome these barriers by delivering health education among Hispanic rural women. The results add to the growing literature demonstrating the use of touch screen technology for health education in Hispanic populations living in rural settings. Delivering interactive breastfeeding educational material in a culturally relevant manner can help facilitate change in the knowledge, attitude, and practices related to breastfeeding.

## Acknowledgments

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## Conflicts of Interest

None declared.

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## Abbreviations

**ICT:** Information and Communication Technologies
**IT:** information technology
**PEMT:** Patient Education and Motivation Tool
**RWMC:** Regional West Medical Center
**SUS:** System Usability Scale

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Original Paper

# Adult Willingness to Use Email and Social Media for Peer-to-Peer Cancer Screening Communication: Quantitative Interview Study

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## Abstract

**Background:** Adults over age 40 are increasing their use of email and social media, raising interest in use of peer-to-peer Internet-based messaging to promote cancer screening.

**Objective:** The objective of our study was to assess current practices and attitudes toward use of email and other e-communication for peer-to-peer dialogues on cancer screening.

**Methods:** We conducted in-person interviews with 438 insured adults ages 42-73 in Georgia, Hawaii, and Massachusetts. Participants reported on use of email and other e-communication including social media to discuss with peers routine health topics including breast and colorectal cancer (CRC). We ascertained willingness to share personal CRC screening experiences via conversation, postcard, email, or other e-communication. Health literacy scores were measured.

**Results:** Email had been used by one-third (33.8%, 148/438) to discuss routine health topics, by 14.6% (64/438) to discuss breast cancer screening, and by 12.6% (55/438) to discuss CRC screening. Other e-communication was used to discuss routine health topics (11.6%, 51/438), screening for breast cancer (3.9%, 17/438), and CRC (2.3%, 10/438). In the preceding week, 84.5% (370/438) of participants had used email, 55.9% (245/438) had used e-communication of some type; 44.3% (194/438) text, 32.9% (144/438) Facebook, 12.3% (54/438) instant message, 7.1% (31/438) video chat, and 4.8% (21/438) Twitter. Many participants were willing to share their CRC screening experiences via email (32.4%, 142/438 might be willing; 36.3%, 159/438 very willing) and via other e-communication (15.8%, 69/438 might be willing; 14.4%, 63/438 very willing). Individuals willing to send CRC screening emails scored significantly higher on tests of health literacy compared to those willing to send only postcards ($P$<.001).

**Conclusions:** Many adults are willing to use email and e-communication to promote cancer screening to peers. Optimal approaches for encouraging peer-to-peer transmission of accurate and appropriate cancer screening messages must be studied.

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**KEYWORDS**

colorectal neoplasms; electronic mail; social media; breast neoplasms; early detection of cancer; communication; health promotion; Internet; peer group; social support



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## Introduction

### Electronic Peer Communication

The rise in use of email and social media among Americans over age 40 presents a unique opportunity for the development of novel health care interventions [1-6]. Electronic peer communication has been shown to influence political [7], consumer [8], and health-related behavior [9,10]. Internet-based peer-to-peer communication has the potential to act via a number of mechanisms, including information exchange, social support (eg, emotional and instrumental), and establishment of group norms [11]. Encouraging peer-to-peer promotion of healthy lifestyles and of cancer screening may be an effective way to further cancer prevention efforts in today's rapidly changing and collaborative Web 2.0 environment [5,6,12,13].

### Web 2.0

Web 2.0 is a term used to describe the interactive experience of the Internet (in the form of blogs, wikis, Internet-based forums, etc.) [14], which has been made possible by technological advances that allow for and encourage open sharing of information. Increasingly, adults over age 50 share information using social media platforms that enable the interactive Web by engaging users who create content and communicate with their social network members (eg, Facebook, Twitter, and LinkedIn) [1,4,15]. Adults of all ages now go online to share their own experiences and to seek advice from friends and family on issues such as chronic disease caregiver roles and medical crises [12]. While medical illness may pose a more urgent prompt for peer-to-peer communication, a recent study indicates that several hundred breast cancer and colorectal cancer groups exist on Facebook and Twitter, and that cancer prevention is the main objective in over one-quarter of these groups [16]. We were interested in assessing the feasibility of a peer-to-peer intervention in which individuals who had completed cancer screening tests were invited to share their experiences with unscreened peers in order to promote completion of recommended screening behavior. We identified understanding current practices in Internet-based cancer screening discussion and gauging acceptability of such discussions as a necessary first step in developing our intervention.

In a diverse group of HMO-insured patients across three states (Georgia, Hawaii, and Massachusetts), we sought to document current practices and attitudes toward Internet-based email and social media cancer screening discussions. We also explored willingness to use these avenues for future peer communication and the association between health literacy and likely mode of communication.

## Methods

### Study Population and Setting

This study was conducted within the Cancer Research Network (CRN), a consortium of research organizations affiliated with 14 community-based nonprofit integrated health care delivery systems and the National Cancer Institute. Participants were recruited from three health plans–Kaiser Permanente Georgia (KPGA), Kaiser Permanente Hawaii (KPHI), and Fallon Community Health Plan (FCHP). This study was reviewed and approved by the Institutional Review Boards at each of the plans.

Participants in the present study had previously completed a two-hour study session for a larger study focused on communication of cancer information [17]. One CRN site—Kaiser Permanente Colorado—participated in the previous larger study, but not in the present study. All participants were 40-70 years of age at the time of recruitment for the larger study (some were 71 by the time the interviews occurred), all had been a member of one of the participating health plans for a minimum of 5 years, were able to understand English, and had no physical or mental limitation that would preclude participating in a two-hour in-person interview. We targeted this age range because these adults are most likely to face cancer screening decisions and to be at elevated risk for most cancers compared to younger adults. To optimize sampling across educational levels, at FCHP, KPGA and KPHI, sampling was stratified by United States Census-based estimates of educational level defined by the percentage of residents with a high school education or less in the census tract in which participants lived. At KPGA, sampling was further stratified according to the percent of African-American residents, to ensure that African-American and white members were invited in equal numbers within each educational strata. A variety of recruitment techniques were used, including mailings, telephone follow-up, and offering sessions at multiple locations. Interested participants were screened to confirm ability to communicate in English, adequate corrected hearing and vision, and the absence of physical or psychological limitations that would preclude participation. Study sessions lasted approximately 2 hours, and were conducted in-person by a trained research assistant. All items (except reading items) were administered orally. A total of 1074 participants completed interviews between June 22, 2009 and April 19, 2010.

For the present study, 3 sites participated (KPGA, KPHI, and FCHP). There were 789 participants from the initial study that were contacted by mail; approximately one week later, individuals who did not respond were contacted via telephone to again extend the invitation to participate. There were 438 (56% of the 789 people invited) people who agreed to participate. For budgetary reasons, participants from FCHP were recruited more aggressively and made up a higher proportion of this current study population (46.3%, 203/438 of the present study sample was from FCHP as compared to 28.86%, 310/1074 of the previous larger study). This higher proportion of FCHP participants resulted in a higher proportion of white participants. There were no significant differences in age, educational level, health literacy scores, numeracy scores, or self-reported health status for current study participants from the 3 sites as compared to previous participants at these 3 sites.

Interviews were conducted for the present study between August 4, 2011 and January 27, 2012. Sessions lasted approximately 1 to 1.5 hours (see Multimedia Appendix 1).



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## Data Collection

Health literacy assessments were conducted during the previous study's sessions. Comprehension of spoken health messages (sometimes referred to as verbal health literacy) was assessed using the Cancer Message Literacy Test-Listening (CMLT-Listening). This test is administered via computer and requires no reading. Development of this test is described in further detail elsewhere [18]; results of reliability and validity studies are described by Mazor et al [17]. Print literacy was assessed using the Cancer Message Literacy Test-Reading (CMLT-Reading) [17,18]. Numeracy was assessed using the Lipkus numeracy scale [19]. Self-efficacy was assessed using the Perceived Efficacy in Patient-Physician Interactions (PEPPI) [20]. Aside from the CMLT-Reading, research staff administered the measures verbally.

During in-person interviews, 438 returning participants engaged in the current study reported on their recent use of email and other electronic communication. E-communication included texting, Facebook, instant messaging, Internet-based and video chatting, Twitter, and LinkedIn. We queried participants on their use of these media: (1) for any purpose, (2) to discuss routine health-related topics (including cancer screening, vaccines, diet, or exercise), and (3) for specific types of cancer screening; colorectal cancer (CRC) and breast cancer. Participants were also questioned regarding their willingness to communicate about such topics using email and other forms of e-communication.

In order to explore the role of user-generated content, participants were provided with the following hypothetical situation–"Imagine that you completed colon cancer screening. Everything went OK and your results were fine. The doctor asked you to help educate friends and family members over age 50 about colon cancer screening. We are trying to design a message to be sent out by people who have completed colonoscopies, so that they can explain to friends and family why screening is important. Please help us design a message you'd be willing to pass along to friends and family members over age 50."

We then provided participants with a sample message in which the sender shares the fact that he or she has completed a colonoscopy and urges readers to discuss CRC screening with their doctor (Figure 1 shows the sample message). We encouraged participants to edit the message as they wished, then asked whether they would be willing to send the edited message to friends and family by either email or postcard. No messages were actually sent. Those who indicated they would not be willing to pass along their message ("nonsenders") were asked to explain why and their answers were transcribed and categorized.

Participants who indicated that they would be willing to pass along messages were asked to estimate the number of emails or postcards they would send. To facilitate this estimation, participants were offered a worksheet (Figure 2 shows this worksheet) and encouraged to circle stick figures in each of 10 social group categories in order to visually designate members of their social network with whom they communicate about routine health topics and cancer screening.

**Figure 1.** Colorectal cancer screening message template with edits (example).

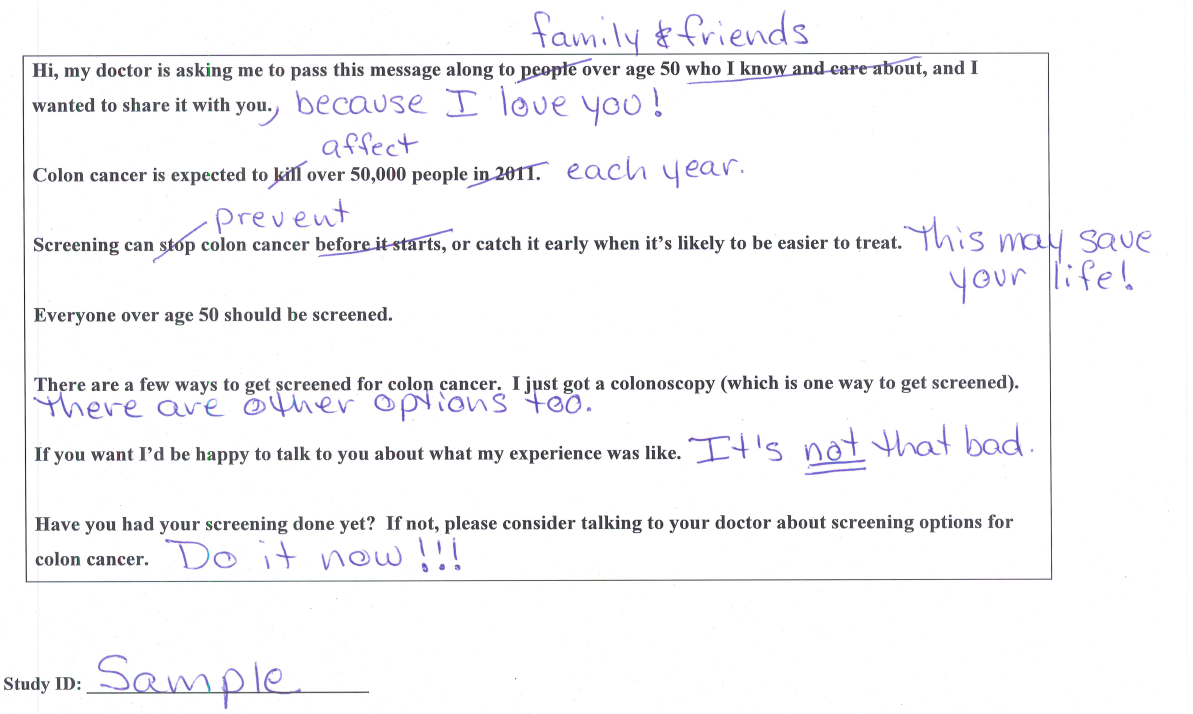




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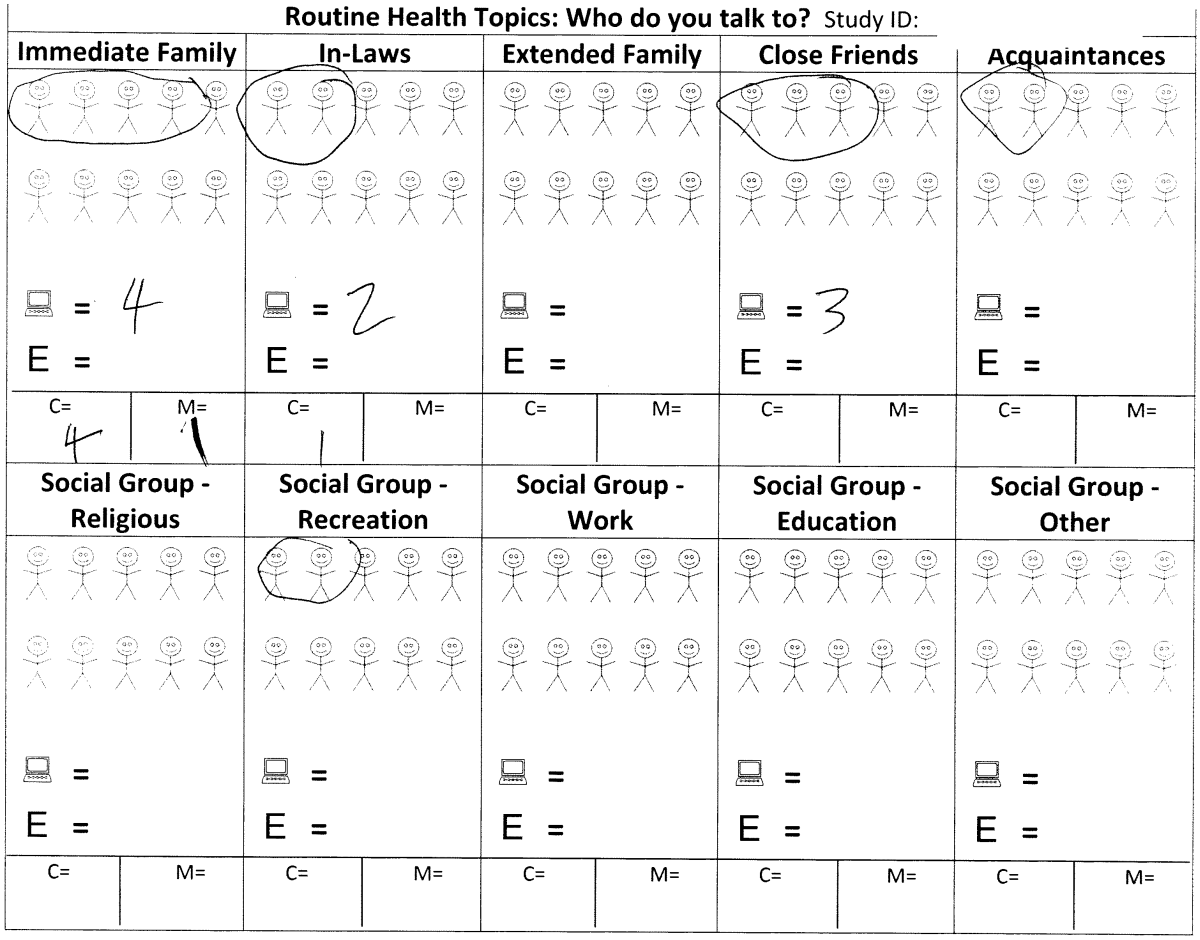
**Figure 2.** Health communication network tool. Study participants were provided with blank worksheets and asked: "Please mark one stick figure for each person you can think of that you communicate with about routine health topics…these are people you would communicate with about routine health topics like cancer screening, vaccine shots, diet, or exercise." The worksheet was used to facilitate the estimation of the number of emails or postcards promoting colorectal cancer screening that they would send to members of their social network.




### Analysis

We calculated the number of people who reported using email and e-communication for: (1) any use, and (2) discussion of routine health topics including cancer screening. We used $\chi^2$ to analyze bivariate associations between age group and use of email or e-communication. Then, focusing on CRC (since this screening is applicable to both men and women), we analyzed willingness to share CRC screening experience via various modes (through general conversation, email, or other e-communication; or through a specific self-edited message via email or postcard). For this analysis we again used $\chi^2$ to analyze bivariate associations between age and willingness to share via various modes. Finally, we sought to understand whether sociodemographic factors or measures of health literacy, numeracy, or self-efficacy were associated with willingness to share CRC screening experience via email or postcard. We conducted a multinomial logistic regression model (generalized logistic regression) using SAS 9.2 (SAS Institute, Inc, Cary, NC), modeling the odds of being: (1) an email sender, or (2) a postcard sender, as compared to (3) being a nonsender. We then conducted a logistic regression modeling the odds of being a sender of either email or postcard. We included in the model variables identified a priori as being of interest.

## Results

### Study Participants

The majority of our study participants (52.3%, 229/438) were 60 years or older and there were slightly more women (56.4%, 247/438) than men (See Table 1). There were three-quarters (75.6%, 331/438) reporting educational levels above a high school degree. Almost 90% (382/438) of all participants reported ever having completed any type of CRC screening and 72.6% (318/438) reported having had a colonoscopy.



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**Table 1.** Participant characteristics. $\chi^2$ used to derive *P* values shown for age, gender, race/ethnicity, education, marital status, ever had friends/family diagnosed with CRC, and ever had a colonoscopy. Analysis of variance–ANOVA used to derive *P* values for health literacy scores, numeracy, and self-efficacy.

| Characteristic | | n | % |
|---|---|---|---|
| Study sample | | 438 | 100.0 |
| **Study site** | | | |
| | Georgia | 130 | 29.7 |
| | Hawaii | 105 | 24.0 |
| | Massachusetts | 203 | 46.3 |
| **Race/ethnicity** | | | |
| | Black/African-American | 65 | 14.8 |
| | Asian/Pacific Islander | 45 | 10.3 |
| | White/Caucasian | 286 | 65.3 |
| | Other or not reported | 42 | 9.6 |
| **Language spoken at home** | | | |
| | English | 419 | 95.7 |
| | English and other | 9 | 2.1 |
| | Other | 7 | 1.6 |
| **Education** | | | |
| | High School degree or less (includes technical school) | 104 | 23.7 |
| | At least some college | 331 | 75.6 |
| **Age (in years)** | | | |
| | 40-49 | 52 | 11.9 |
| | 50-59 | 157 | 35.8 |
| | 60-73 | 229 | 52.3 |
| **Gender** | | | |
| | Male | 191 | 43.6 |
| | Female | 247 | 56.4 |
| **Marital status** | | | |
| | Married | 282 | 64.4 |
| | Unmarried | 153 | 34.9 |
| **Work status** | | | |
| | Working for pay | 260 | 59.4 |
| | Retired | 126 | 28.8 |
| | Disabled | 17 | 3.9 |
| | Other | 35 | 8.0 |
| **Self-reported health status** | | | |
| | Excellent/very good | 240 | 54.8 |
| | Good/fair/poor | 197 | 45.0 |
| **Number of comorbidities** | | | |
| | 0/1 | 336 | 76.7 |
| | 2+ | 99 | 22.6 |
| **Current smoking status** | | | |
| | Current smoker | 27 | 6.2 |



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| Characteristic | | n | % |
|---|---|---|---|
| | Current nonsmoker | 410 | 93.6 |
| **Has doctor ever recommended that you be screened for CRC cancer?** | | | |
| | Yes | 385 | 87.9 |
| | No | 48 | 11.0 |
| **Completed any type of CRC screening?** | | | |
| | Yes | 382 | 87.2 |
| | No | 50 | 11.4 |
| **Ever had a colonoscopy?** | | | |
| | Yes | 318 | 72.6 |
| | No | 114 | 26.0 |
| **Health literacy, numeracy, and efficacy measures, mean (SD)** | | | |
| | Verbal health literacy (CMLT-Listening) | 79.9 | (14.1) |
| | Print health literacy (CMLT-Reading) | 84.8 | (14.6) |
| | Numeracy | 78.5 | (21.9) |
| | Self-efficacy (PEPPI) | 8.1 | (1.3) |

### Use of Email for Discussions of Routine Health Topics and Cancer Screening

A high percentage of participants (84.5%, 370/438) had used email in the past week with no significant variation across age categories (Table 2). Only one-third of the participants (33.8%, 148/438) had ever used email to discuss routine health topics, and more than one in ten had used email to discuss CRC screening (12.6%, 55/438) or breast cancer screening (14.6%, 64/438). There was no significant variation by age category for these measures.

### Use of Electronic Communication for Discussions of Routine Health Topics and Cancer Screening

In the previous week, just over half of all participants (55.9%, 245/438) had used some other form of electronic communication (including texting, Facebook, instant messaging, Internet-based or video chatting, Twitter, LinkedIn, or other), there was significant variation by age with the youngest age group (40-49 year olds) being most likely to report use (Table 2). Approximately one in ten respondents (11.6%, 51/438) had ever used electronic communication (other than email) to discuss routine health topics, as expected from trends in overall use, youngest respondents were most likely to report such behavior. Similarly, close to one in ten participants under age 60 (8.6%, 18/209) had used electronic communication to discuss CRC screening or breast cancer screening. Texting and Facebook were the two most commonly mentioned forms of electronic communication across all age categories both for general use and specifically for discussion of routine health topics.



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**Table 2.** Use of email and social media to discuss health-related topics and to discuss cancer screening.

| | Total sample (N=438) | | Age 40-49 | | Age 50-59 | | Age 60-73 | | *P* |
|---|---|---|---|---|---|---|---|---|---|
| | n | % | n | % | n | % | n | % | |
| **Used email** | | | | | | | | | |
| Ever | 387 | 88.4 | 49 | 94.2 | 144 | 91.7 | 194 | 85.5 | .067 |
| In past week | 370 | 84.5 | 47 | 90.4 | 135 | 86.0 | 188 | 82.8 | .345 |
| For 5-7 days in past week | 303 | 69.2 | 39 | 75.0 | 120 | 76.4 | 144 | 63.4 | .016 |
| To discuss routine health topics | 148 | 33.8 | 14 | 26.9 | 62 | 39.5 | 72 | 31.4 | .180 |
| To discuss CRC screening[a] | 55 | 12.6 | 6 | 11.5 | 24 | 15.3 | 25 | 10.9 | .683 |
| To discuss breast cancer screening[a] | 64 | 14.6 | 9 | 17.3 | 26 | 16.6 | 29 | 12.7 | .176 |
| **Used other e-communication** [b] | | | | | | | | | |
| Ever | 247 | 56.4 | 43 | 82.7 | 107 | 68.2 | 97 | 42.4 | <.001 |
| In past week | 245 | 55.9 | 43 | 82.7 | 105 | 67.7 | 97 | 42.4 | <.001 |
| For 5-7 days in past week | 148 | 33.8 | 30 | 57.7 | 70 | 45.2 | 48 | 21.0 | <.001 |
| **Type of e-communication used** | | | | | | | | | |
| Texting | 194 | 44.3 | 41 | 78.8 | 88 | 56.1 | 65 | 28.4 | <.001 |
| Facebook | 144 | 32.9 | 24 | 46.2 | 59 | 37.6 | 61 | 26.6 | .008 |
| Instant messaging/Internet-based chatting | 54 | 12.3 | 10 | 19.2 | 28 | 17.8 | 16 | 7.0 | .002 |
| Video chatting | 31 | 7.1 | 5 | 9.6 | 16 | 10.2 | 10 | 4.4 | .068 |
| Twitter | 21 | 4.8 | 4 | 7.7 | 13 | 8.3 | 4 | 1.7 | .007 |
| LinkedIn | 3 | 0.6 | 0 | 0.0 | 3 | 1.9 | 0 | 0.0 | .067 |
| Other | 3 | 0.7 | 1 | 1.9 | 1 | 0.6 | 1 | 0.4 | .500 |
| Used other e-communication to discuss routine health topics | 51 | 11.6 | 16 | 30.8 | 25 | 15.9 | 10 | 4.4 | .000 |
| Used other e-communication to discuss CRC screening[c] | 10 | 2.3 | 3 | 5.8 | 7 | 4.5 | 0 | 0.0 | .168 |
| Used other e-communication to discuss breast cancer screening[c] | 17 | 3.9 | 7 | 13.5 | 9 | 5.7 | 1 | 0.4 | .244 |
| **Type of e-communication used to discuss routine health topics** | | | | | | | | | |
| Texting | 31 | 7.1 | 11 | 21.2 | 16 | 10.2 | 4 | 1.7 | .000 |
| Facebook | 21 | 4.8 | 5 | 9.6 | 10 | 6.4 | 6 | 2.6 | .053 |
| Instant messaging/ Internet-based chatting | 6 | 1.4 | 3 | 5.8 | 2 | 1.3 | 1 | 0.4 | .011 |
| Video chatting | 3 | 0.7 | 0 | 0.0 | 2 | 1.3 | 1 | 0.4 | .505 |
| Twitter | 1 | 0.2 | 0 | 0.0 | 1 | 0.6 | 0 | 0.0 | .408 |
| Other | 2 | 0.5 | 1 | 1.9 | 1 | 0.6 | 0 | 0.0 | .163 |
| Uses cell phone to access Internet | 122 | 27.9 | 23 | 44.2 | 55 | 35.3 | 44 | 19.2 | .000 |

[a]Only asked of those who use email to discuss routine health topics.

[b]Includes texting, Facebook, instant messaging, Internet-based or video chatting, Twitter, LinkedIn or other.

[c]Only asked of those who use e-communication to discuss routine health topics.

## Attitudes Toward Discussing CRC Screening via Email and Electronic Communication

When asked whether they would be willing to share their CRC screening experience with friends or family in order to educate and encourage screening, close to three-quarters of all participants (73.3%, 321/438) were “very willing” to share through conversation, with almost all of the remaining stating that they “might be willing” to share in this way (Table 3). Email and other electronic communication showed lower proportions of users who were “very willing” to share (41.3%, 159/385 email users; and 25.1%, 63/251 e-communication users), but over half of both user groups would at least consider sharing their CRC experience in this way (“might be willing” or “very



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willing" to share–78.2%, 301/385 of email users; and 52.6%, 132/251 of e-communication users).

When offered the opportunity to create their own content, adding, deleting, or rearranging text according to their own preferences (Figure 1), the vast majority of participants (85.4%, 374/438) were willing to send a message encouraging CRC screening; 68.5% (300/438) indicated that they would use either email or a combination of email and postcard (Table 3). Across all age groups, those who would send emails were in the majority and those who would send only postcards were the next largest group (Table 4). Older participants were least likely to send any message and men were more likely than women to indicate that they would not send. Those with a higher educational level were more likely to choose email, but education was not associated with overall willingness to send (Table 4).

**Table 3.** Willingness to share personal CRC screening experience with friends and family and preferred mode.

| Mode by which CRC screening experience would be shared | Total sample | | Age 40-49 | | Age 50-59 | | Age 60-73 | | *P* |
|---|---|---|---|---|---|---|---|---|---|
| | n=433 | % | n=52 | % | n=156 | % | n=225 | % | |
| **Through conversation asked of everyone (n=433)** | | | | | | | | | .620 |
| Not willing | 10 | 2.3 | 0 | 0.0 | 4 | 2.6 | 6 | 2.7 | |
| Might be willing | 102 | 23.6 | 13 | 25.0 | 32 | 20.5 | 57 | 25.3 | |
| Very willing | 321 | 74.1 | 39 | 75.0 | 120 | 76.9 | 162 | 72.0 | |
| **By email asked only of those who use email (n=385)** | | | | | | | | | .393 |
| Not willing | 84 | 21.8 | 8 | 16.3 | 30 | 21.1 | 46 | 23.7 | |
| Might be willing | 142 | 36.9 | 18 | 36.7 | 47 | 33.1 | 77 | 39.7 | |
| Very willing | 159 | 41.3 | 23 | 46.9 | 65 | 45.8 | 71 | 36.6 | |
| **By other electronic communication asked only of those who use e-communication (n=251)** | | | | | | | | | .029 |
| Not willing | 119 | 47.4 | 13 | 30.2 | 48 | 45.3 | 58 | 56.9 | |
| Might be willing | 69 | 27.5 | 18 | 41.9 | 27 | 25.5 | 24 | 23.5 | |
| Very willing | 63 | 25.1 | 12 | 27.9 | 31 | 29.2 | 20 | 19.6 | |



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**Table 4.** Characteristics of respondents who are willing to pass along self-edited email or postcard messages sharing CRC screening experience (n=432).

| | | Email[a] | | Postcard only | | Would not send | | *P* |
|---|---|---|---|---|---|---|---|---|
| | | n=300 | % | n=74 | % | n=58 | % | |
| **Age, n %** | | | | | | | | .010 |
| | 40-49 | 42 | 82.4 | 5 | 9.8 | 4 | 7.8 | |
| | 50-59 | 118 | 76.1 | 20 | 12.9 | 17 | 11.0 | |
| | 60-73 | 140 | 61.9 | 49 | 21.7 | 37 | 16.4 | |
| **Gender, n %** | | | | | | | | .010 |
| | Male | 117 | 62.2 | 37 | 19.7 | 34 | 18.1 | |
| | Female | 183 | 75.0 | 37 | 15.2 | 24 | 9.8 | |
| **Race/ethnicity, n %** | | | | | | | | .365 |
| | Black/African-American | 46 | 70.8 | 15 | 23.1 | 4 | 6.2 | |
| | Asian/Pacific Islander | 35 | 77.8 | 5 | 11.1 | 5 | 11.1 | |
| | White/Caucasian | 192 | 68.3 | 47 | 16.7 | 42 | 14.9 | |
| | Other or not reported | 27 | 65.9 | 7 | 17.1 | 7 | 17.1 | |
| **Education, n %** | | | | | | | | <.001 |
| | High School degree or less (includes technical school) | 55 | 53.9 | 33 | 32.4 | 14 | 13.7 | |
| | At least some college | 243 | 74.3 | 41 | 12.5 | 43 | 13.1 | |
| **Marital status, n %** | | | | | | | | .561 |
| | Married | 198 | 71.2 | 45 | 16.2 | 35 | 12.6 | |
| | Unmarried | 100 | 66.2 | 29 | 19.2 | 22 | 14.6 | |
| **Ever had friends/family diagnosed with CRC?, n %** | | | | | | | | .063 |
| | Yes | 103 | 76.9 | 19 | 14.2 | 12 | 9.0 | |
| | No | 196 | 66.0 | 55 | 18.5 | 46 | 15.5 | |
| **Ever had a colonoscopy?, n %** | | | | | | | | .039 |
| | Yes | 221 | 70.4 | 58 | 18.5 | 35 | 11.1 | |
| | No | 73 | 65.2 | 16 | 14.3 | 23 | 20.5 | |
| Verbal health literacy “CMLT-Listening”, mean (SD) | | 81.24 (13.50) | | 73.96 (15.11) | | 81.26 (13.46) | | <.001 |
| Print health literacy “CMLT-Reading”, mean (SD) | | 86.23 (13.72) | | 78.51 (15.60) | | 85.39 (15.85) | | <.001 |
| Numeracy, mean (SD) | | 79.72 (20.18) | | 71.62 (27.63) | | 80.82 (21.99) | | .012 |
| Self-efficacy “PEPPI”, mean (SD) | | 8.18 (1.21) | | 8.22 (1.51) | | 7.56 (1.67) | | .004 |

[a]Those indicated in the email column would send out either only emails or would send a mix of emails and postcards.

## CRC Screening Email Messages: Role of Health Literacy and Self-Efficacy

Using ANOVA tests, mean measures of health literacy (print and verbal) and numeracy were compared across email senders, postcard senders, and those who wouldn’t send (Table 4). We found a consistent pattern across these three categories, with postcard senders scoring significantly lower than the other 2 groups on all three measures. For measures of self-efficacy, senders (both email and postcard) scored significantly higher than those who wouldn’t send.

On multivariate analysis (Table 5, Model 1), those with lower education were significantly more likely to be postcard senders than to be nonsenders. When we modeled the odds of sending any message at all (Table 5, Model 2), neither education nor health literacy level was significant. Those with higher self-efficacy scores were more likely to send messages in both models.



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**Table 5.** Willingness to send messages sharing CRC screening experience with peers.

| | | Model 1[a] | | | | Model 2[b] | |
|---|---|---|---|---|---|---|---|
| | | Odds of being an email sender | | Odds of being a post-card sender | | Odds of sending either email or postcard | |
| | | OR | 95% CI | OR | 95% CI | OR | 95% CI |
| **Age** | | | | | | | |
| | 40-49 | 2.21 | 0.73-6.73 | 0.77 | 0.19-3.22 | 1.83 | 0.61-5.53 |
| | 50-59 | 1.72 | 0.89-3.29 | 1.06 | 0.47-2.41 | 1.57 | 0.83-2.97 |
| | 60 and up[c] | - | - | - | - | - | - |
| **Gender** | | | | | | | |
| | Male | 0.50 | 0.27-0.90 | 0.80 | 0.38-1.67 | 0.55 | 0.31-0.99 |
| | Female[c] | - | - | - | - | - | - |
| **Race/ethnicity** | | | | | | | |
| | Black/African American | 2.55 | 0.70-9.26 | 2.70 | 0.66-11.07 | 2.50 | 0.70-8.92 |
| | Asian/Pacific Islander | 1.19 | 0.46-3.12 | 0.59 | 0.15-2.32 | 1.05 | 0.41-2.72 |
| | Other or not reported | 0.85 | 0.31-2.30 | 0.93 | 0.28-3.14 | 0.84 | 0.32-2.20 |
| | White/Caucasian[c] | - | - | - | - | - | - |
| **Education** | | | | | | | |
| | High School degree or less (includes technical school) | 0.88 | 0.42-1.88 | 2.39 | 1.02-5.59 | 1.17 | 0.56-2.45 |
| | At least some college[c] | - | - | - | - | - | - |
| Print health literacy score[d] (CMLT-Reading) | | 1.01 | 0.99-1.03 | 0.99 | 0.96-1.01 | 1.00 | 0.98-1.03 |
| Self-efficacy (PEPPI)[d] | | 1.25 | 1.03-1.53 | 1.35 | 1.04-1.74 | 1.28 | 1.06-1.55 |

[a]Model 1–Odds of being an email sender or a postcard sender as compared to being a nonsender.

[b]Model 2–Odds of being a sender, either email or postcard, as compared to being a nonsender.

[c]reference

[d]per unit increase in score

### CRC Screening Email Messages: How Many Would Be Sent?

Those who indicated they would be willing to send emails estimated that they would send, on average, 15.9 emails per sender; those who indicated they would be willing to send postcards estimated they would send, on average 14.3 postcards per sender.

### CRC Screening Email Messages: Expected Impact

Close to three-quarters of all participants thought that the self-edited message could have a positive impact; 71.5% (313/438) thought receiving the edited message would make their friends and family more likely to discuss CRC screening with a health care provider, and 73.1% (320/438) would be more likely to discuss screening if they themselves received such a message.

### CRC Screening Email Messages: Reasons for Not Sending

While many participants in our study expressed willingness to share cancer-screening messages via email or e-communication, there are also important lessons to be learned from the 58/438 (13.2% of all participants) who were unwilling to send messages. Asked about their reasons for not sending this message, 43.1% (25/58) of those unwilling said they felt emails were inappropriate, 62.1% (36/58) expressed willingness to discuss the issue verbally. Additionally, 22.4% (13/58) cited their own limitations (lacked expertise) and 20.7% (12/58) felt their social network would not receive the message well (some felt their network members would be offended, while others said their network had already been screened). Equal percents (12.1%, 7/58) found the message unappealing and stated that they were already discussing this within their social network (and therefore didn't need to send such a message). (Participants could provide more than one reason for not sending messages).

## Discussion

### Study Participants and Electronic Communication

When given both a template and an opportunity to create their own content, most study participants expressed willingness to pass along a personalized CRC screening message to members of their social network, and most thought the message would



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have a positive impact. Adults in this 40-70 year old age group were willing to share their cancer screening experience with peers and to promote screening using a variety of modes. Approximately one in ten had already used either email or electronic communication to discuss a cancer screening test. Most were regular email users and over one-third had discussed routine health topics via email. The majority had used another form of electronic communication such as text messaging or social media in the preceding week, with one in ten having used these modes for communication about routine health topics. Many adults expressed a willingness to use email and electronic communication to share cancer screening experiences.

Our findings are consistent with recent surveys [1,2,4] that reflect already high rates of email use and rising rates of social media use among adults in this age group. Data from the 2007 Health Information National Trends Survey (HINTS) showed that approximately one-quarter of Internet users had used social networking sites in the preceding year, but that relatively few older adults had done so (5.5% of those 65 years and over) [3]. By 2012, a Pew Internet poll showed 57% of Internet users 50-64 years old and 38% of those 65 years and older using social networking sites [1].

Our findings also align with recent studies demonstrating use of electronic communication to discuss health topics. Cycle 1 of HINTS 4, collected in 2011-2012, asked specifically about visiting a social networking site such as Facebook or LinkedIn "to read and share about medical topics" and found that 17.0% of Internet users had done this (12.9% of Internet users 50-64 years old, and 7.6% of Internet users 65-74 years old, unpublished data) [21].

Recent work indicates that Internet users may be receptive to the use of narratives to promote CRC screening within an online community [22]. While participation in Facebook support groups for breast cancer has been described among younger users [23], there is little documentation in the literature of older adults using Facebook or Twitter to discuss cancer or cancer screening. Social groups for prevention as well as support in CRC and breast cancer have been described in a recent content analysis [16], which identified 216 breast cancer groups and 171 CRC groups on Facebook and Twitter, but did not provide information on the age of participants.

Our study addresses the intersection of two distinct evolutions. The first is the spread of innovative and Internet-based technologies among older adults who are becoming increasingly comfortable both with text messaging and with social media platforms. The second is patients' growing expectation that they will engage in collaborative and interactive dialogues around health.

### Adults Spreading the CRC Screening Message

As our next step, we plan to recruit insured patients 50-70 years old at the time of CRC screening completion, and invite them to spread messages promoting screening to network members via the pathway of their choice (eg, postcard, email, text messaging, and social media). We hypothesize that this approach would take advantage of new technologies [6], while remaining inclusive of motivated, but less technologically savvy adults. In addition to prompting Internet-based conversations, this approach might also encourage face-to-face or telephone discussions.

We found that adults with less education were just as willing to pass along a CRC screening message to friends and family members, but were more likely to favor postcards. Mean health literacy scores for those who would send messages via postcard were significantly lower than both email senders and those who chose not to send. Adults with less education and lower health literacy may have social networks with higher numbers of unscreened individuals; efforts to include this group in peer-recruiting interventions are therefore particularly important.

Exploring a participatory intervention with multiple choices for network communication might also allow for future adaptation as new technologies supersede those of today. Interventions should capitalize on increased connectivity among social network members, facilitating exchanges of support, and information around cancer screening. Caution must also be taken. At times, social network members may communicate unhelpful or even harmful information [24,25]; interventions encouraging user-generated health content must include provisions to address this issue.

### Potential Study Limitations

There are potential limitations to our study. Participants all had health insurance. Study participants may therefore not be representative of uninsured populations. Participants were asked to report whether they would be willing to forward messages to friends and family, but since they were not actually requested to send messages, it is possible that they overestimated their willingness to do so. Future studies are needed to assess whether these results are generalizable to the population at large, and whether people are in fact willing to forward personalized messages.

## Conclusions

In conclusion, the majority of adults 42-73 years old in our study were willing to promote cancer screening to peers, and many were willing to use email and e-communication to do so. As the use of Web 2.0 participative technologies continues to rise in this age group, email, text messaging, and social media may offer cost-effective ways to disseminate peer-to-peer cancer screening messages. Our study indicates, however, that interventions relying exclusively on newer technologies may miss adults with lower education and lower health literacy levels who would otherwise be willing to engage in peer-to-peer screening promotion. This is a critical moment for further research.



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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Willingness to use email and social media for peer-to-peer cancer screening communication.

[PDF File (Adobe PDF File), 144KB - resprot_v2i2e52_app1.pdf ]

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## Abbreviations

**ANOVA:** analysis of variance
**CMLT-Listening:** Cancer Message Literacy Test-Listening
**CMLT-Reading:** Cancer Message Literacy Test-Reading
**CRC:** colorectal cancer
**CRN:** Cancer Research Network
**FCHP:** Fallon Community Health Plan
**HINTS:** Health Information National Trends Survey
**KPGA:** Kaiser Permanente Georgia
**KPHI:** Kaiser Permanente Hawaii
**PEPPI:** Perceived Efficacy in Patient-Physician Interactions

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Original Paper

# Evaluation of the Compliance, Acceptance, and Usability of a Web-Based eHealth Intervention for Parents of Children With Infantile Hemangiomas: Usability Study

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## Abstract

**Background:** Infantile hemangiomas (IH) are common benign vascular tumors in children. Recognition and timely referral of high risk IH to specialized centers is important. This might be achieved by involving parents in the care for IH by means of an eHealth intervention.

**Objective:** The objective of our study was to evaluate parent compliance, acceptance, and usability of an open access, Web-based eHealth intervention (including e-learning and e-consult) designed to increase parents' knowledge and (risk) evaluation of IH.

**Methods:** A cross-sectional study of parents who completed the eHealth intervention between October 2010 and November 2012 was carried out. All parents were sent a study questionnaire. Questions to evaluate compliance (to the advice given by a dermatologist during e-consultation) were asked. Acceptance and usability were evaluated by using the modified Technology Acceptance Model.

**Results:** A total of 224 parents completed the eHealth intervention and received the questionnaire, 135/224 parents responded (response rate was 60.3%). There were 128/135 questionnaires that were completed and included. A total of 110/128 (85.9%) parents were compliant to the advice of the dermatologist. There were 116.8/128 (91.3%) that perceived the eHealth intervention as useful and almost all parents (98.4%, 126/128) found the information in the e-learning clear. There were 29/128 (22.7%) that experienced technical problems. The majority of the parents (94.5%, 121/128) found the eHealth intervention reliable and most of them (98.4%, 126/128) would recommend the eHealth intervention to other parents. Noncompliant parents judged the eHealth intervention significantly less reliable compared to compliant parents (71%, 10/14 versus 97.3%, 107/110; *P*=.003).

**Conclusions:** Parents of children with an IH showed a high compliance (85.9%, 110/128) to the advice of the dermatologist given via our Web-based eHealth intervention. This high compliance might be positively influenced by the good acceptance and usability of the eHealth intervention and might result in timely presentation and treatment of children with high risk IH in specialized centers.

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**KEYWORDS**

eHealth; e-learning; Internet; compliance; acceptance; usability; dermatology; optimizing care; infantile hemangioma; child

## Introduction

### Infantile Hemangiomas

Infantile hemangiomas (IH) are common benign vascular tumors with a unique growth pattern [1-3]. Although most IH have an uncomplicated course, 24% of the patients experience complications, such as ulceration, bleeding, functional impairment, life-threatening risk, or cosmetic risk of which 38% need treatment [4]. Also, a segmental IH can be associated with congenital malformations and requires diagnostic evaluation [4]. Currently, complicated IH can be treated with beta blockers, like propranolol [5,6]. Correct initial diagnosis and timely referral of patients at risk of complications is important since early intervention may prevent complications [4,7].

### Parents and E-Learning

In order to ensure timely referral of high-risk IH, it is imperative for parents and health care professionals to have knowledge about IH and risk factors for developing complications. e-learning is widely used to increase knowledge, including the field of dermatology [8-14]. Parents use the Internet as an information source for the disease of their child, and the use of an educational e-learning module to increase patients' knowledge has also been reported [15-18].

To increase parents' knowledge about IH and its complications, we have developed an open access Web-based eHealth intervention [19,20]. This eHealth intervention consisted of an e-learning module and an e-consult (including a teledermatology consultation). Advice on diagnosis, risk of complications, and need to be seen by a medical specialist was given. If parents follow this advice (compliance to the advice) it might contribute to timely referral of high-risk patients to a medical specialist.

### Parent Compliance

Patient/parent-compliance ("the extent to which the parent's behavior coincides with the advice of the dermatologist") is essential for the success of this eHealth intervention. Compliance to medication has been extensively described in the literature. However, little is known about compliance to advice given via eHealth.

The goal of this study was to evaluate the compliance of the parents to the advice given by the dermatologist via the e-consult. Second, the acceptance and usability of this eHealth intervention were determined.

## Methods

### Design and Participants

A cross-sectional study was carried out after participation in the open access Web-based eHealth intervention [19], consisting of an e-learning module and e-consult (Figure 1 shows illustrative screenshots).

The Dutch patient support group for Hemangiomas and Vascular Anomalies (HEVAS) and the University Medical Center Utrecht (UMCU) supported the eHealth intervention, and their logos were displayed on the home page. Parents were referred to the eHealth intervention by a link on the home page of HEVAS [21], by their child's youth or primary health care provider, or by surfing the Internet. Participation was voluntary and free of charge.

After registration on the website, parents received a password to start the e-learning module and e-consult. By using a password, safe uploading of personal information on the website was guaranteed. During the e-learning module parents were informed about IH and its complications and two illustrative cases were presented. During the e-consult parents were asked to provide one photograph of the skin lesion of their child and to give information regarding its growth pattern. A dermatologist of the Center for Congenital Vascular Anomalies Utrecht (CAVU) judged this photograph. In case the dermatologist was unable to make a proper diagnosis, due to lack of quality of the photograph, parents were asked for a new photograph or referred to their general practitioner (GP). Advice on diagnosis, risk of complications, and need to be seen by a medical specialist was given within 5 working days by email [20]. Parents were advised whether or not to go to a medical specialist and whether there was urgency. All parents of a child with a suspected IH, who fully went through the e-learning and e-consult between October 2010 and November 2012, were eligible for study participation and received a study questionnaire by email. The time between participation in the eHealth intervention and completing the questionnaire was variable. Demographic information of the parents was obtained. The ethics committee of the University Medical Center Utrecht approved the study.



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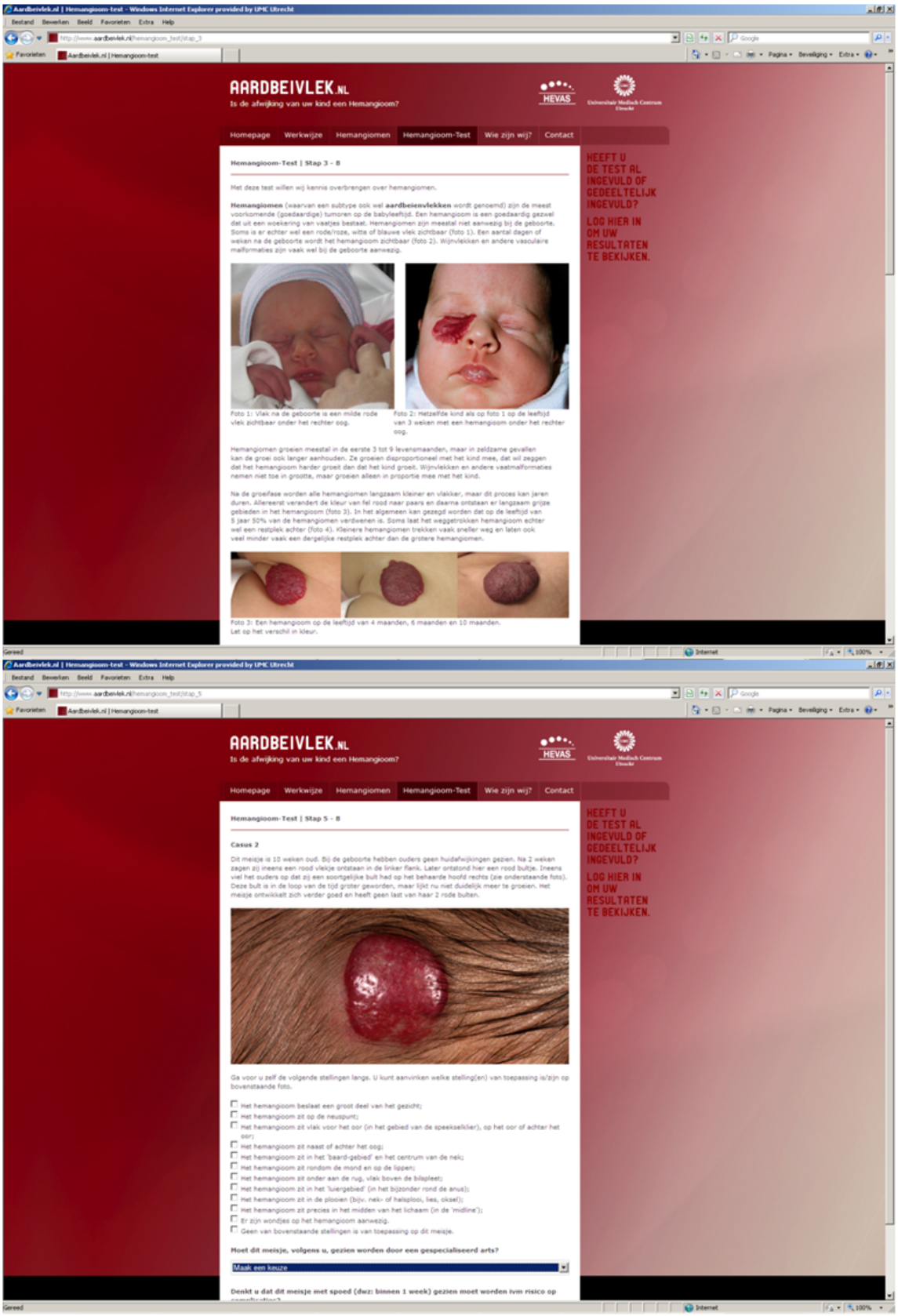
**Figure 1.** Illustrative screenshots of the e-learning module (in Dutch). The top image shows general information about infantile hemangiomas. The bottom image shows a case scenario of an infantile hemangioma on the scalp (Case 2).



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## Theoretical Framework and Study Questionnaire

### *Compliance, Acceptance, and Usability*

A questionnaire was developed to evaluate the variables–compliance, acceptance, and usability of the eHealth intervention.

### *Compliance*

Compliance was defined as the extent to which the parent's behavior coincides with the advice of the dermatologist. By means of the e-consult, parents were given an advice about the diagnosis of the skin lesion of their child (IH/no IH/uncertain) and about the need to visit a medical specialist (no need/need/urgent need). In case of "need to visit a specialist," parents were first referred to their GP because in the Netherlands a referral of the GP is required for visiting a medical specialist. In case of "no need to visit a specialist," parents were only advised to go to their GP if the IH was growing rapidly or became ulcerated. In all cases of "no IH" or "uncertain diagnosis" (in which the dermatologist was unable to diagnose the skin abnormality using the provided information by the parents), parents were advised to go to their GP. In order to determine the compliance, questions regarding visits to GP/medical specialists, additional diagnostics, and initiated treatment were asked. The time between the advice and the actual appointment with a specialist was also evaluated by asking the parents.

### *Acceptance and Usability*

The acceptance and usability of the eHealth intervention were evaluated by using a modified Technology Acceptance Model (TAM). The TAM is the most widely applied model to describe consumer acceptability [22,23]. Technology acceptance is defined as "an individual's psychological state with regard to his or her voluntary or intended use of a particular technology" [24]. The TAM theorizes that an individual's behavioral intention to use a technology is determined by two beliefs: (1) perceived usefulness (PU) and (2) perceived ease of use (PEU) [25]. It has proved to be suitable for different genders, age groups, cultures, levels of information technology competency, and in both obligatory and voluntary usage settings [26]. Health care professionals have tested the TAM for the prediction of adoption of telemedicine, and its reliability, robustness, and validity have been demonstrated [26-28]. To determine the acceptance and usability of our eHealth intervention, we have modified the TAM based on the Chau and Hu's model of telemedicine acceptance [29]. We have added the dimension "attitude towards use" to the original TAM, because behavioral intention is also determined by attitude, which is influenced by PU and PEU [29,30]. Attitude can be defined as "the perception by an individual of the positive or negative consequences related to adopting the technology." Questions to evaluate acceptance and usability were developed following the modified TAM.

### *Study Questionnaire*

The study questionnaire consisted of 24 questions, grouped into three variables (demographic information, compliance, acceptance and usability) (Table 1). Acceptance and usability was subdivided using the three dimensions of the TAM (PU, PEU, and attitude). There were 12 questions that were rated on a three-point scale (agree, no agreement/no disagreement, disagree). There were 7 questions that could be answered with "yes" or "no," and with the final question parents were asked to rate the eHealth intervention (including e-learning and e-consult) on a 0-10 scale (0=very bad, 10=excellent). At the end of the questionnaire there was an open field for comments and suggestions.

**Table 1.** Questions used to evaluate compliance, acceptance, and usability.

| Variable | Dimension | Related questions | Example |
|---|---|---|---|
| Demographic information | | 1-4 | Gender, age, relation to the patient, and education level |
| Compliance to advice | | 5-15 | Did you visit your general practitioner after our advice? |
| Acceptance and usability | Perceived usefulness | 16a-16e, 19a-19d | The e-learning module is useful to determine if my child is at risk for complications |
| | Perceived ease of use | 17, 20, 21a-21d, 23 | The information of the e-learning is understandable |
| | Attitude | 8, 18, 22, 24 | I would recommend the e-learning module to other people |

## Analyses

Only fully completed questionnaires were used for evaluation. Descriptive analyses were used to evaluate the compliance, acceptance, and usability.

Fisher's exact tests were used to evaluate the difference in acceptance, usability, and attitude between compliant parents and noncompliant parents.

# Results

## The Parent Questionnaire

A total of 224 parents completed the eHealth intervention and received the questionnaire, 135/224 parents responded (response rate, 60.3%). There were 128/135 questionnaires completed and included in this study. Reasons for not responding on the questionnaire are unknown. Parent characteristics are shown in Table 2.



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**Table 2.** Characteristics of the parents (N=128).

| Characteristic | | Frequency, n (%) |
|---|---|---|
| **Gender** | | |
| | Men | 10 (7.8) |
| | Women | 118 (92.2) |
| **Age** | | |
| | < 20 years | 0 (0) |
| | 20-29 years | 20 (15.6) |
| | 30-39 years | 85 (66.4) |
| | > 40 years | 21 (16.4) |
| | Unknown | 2 (1.6) |
| **Relation to the child** | | |
| | Parent | 127 (99.2) |
| | Caretaker (grandparent) | 1 (0.8) |
| **Highest educational level** | | |
| | Low | 6 (4.7) |
| | Moderate | 32 (25.0) |
| | High | 88 (68.8) |
| | Unknown | 2 (1.6) |
| **Previously received information** [a] | | |
| | None | 4 (3.1) |
| | Internet | 66 (51.6) |
| | Primary health care provider | 58 (45.3) |
| | Specialist | 6 (4.7) |
| | Unknown | 32 (25.0) |

[a]Some parents previously received information from multiple sources.

## Parent Compliance With Medical Advice

There were 119/128 (93.0%) skin lesions that were diagnosed as an IH of which 58/119 (48.7%) parents were advised not to visit the medical specialist, and 61/119 (51.3%) parents were advised to visit a medical specialist. In 9/119 cases (7.6%) the skin lesion was not an IH or the diagnosis was uncertain. A total of 110/128 (85.9%) parents followed the advice of the dermatologist. Figure 2 shows all patients who were advised not to visit a medical specialist. Figure 3 shows all patients, who were advised to visit a medical specialist. Figure 4 shows all patients with no IH or where it was not possible to make an accurate diagnosis.

There were 8/58 parents who were advised not to visit a specialist that did visit a medical specialist (for unknown reasons) (Figure 2). In four patients beta blocker treatment was initiated–one patient with a small, superficial, localized/nodular IH in the face was treated with oral propranolol; one patient with a superficial, localized/nodular IH on the lower arm was treated with topical timolol; and two patients with a small, superficial, localized/nodular IH in the face/neck area were treated with topical timolol. There were 3/61 parents who were advised to visit a specialist and did not–one small, superficial, localized/nodular IH close to the eye spontaneously went into regression; and two parents saw no need to visit a specialist (one patient with a big superficial IH on the arm, because of no functional impairment, and one patient with a small superficial IH on the tip of the nose whose parents did not want treatment). In three cases of “no IH/uncertain diagnosis” the advice of the dermatologist was not followed because the parents saw no need to visit a specialist (Figure 4).

The time between the advice and the actual appointment with a medical specialist, sorted by referral indication, are shown in Table 3. These data were available for 33/71 cases.



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**Figure 2.** Flowchart of the compliance of the parents who were advised not to visit a medical specialist by the dermatologist via e-consultation. The flowchart shows which doctor the parents visited and to what actions (eg, diagnostic evaluation and/or treatment) it has led. The figures indicate the number of patients. Infantile hemangioma(s) (IH); general practitioner (GP); and beta blocker (BB).

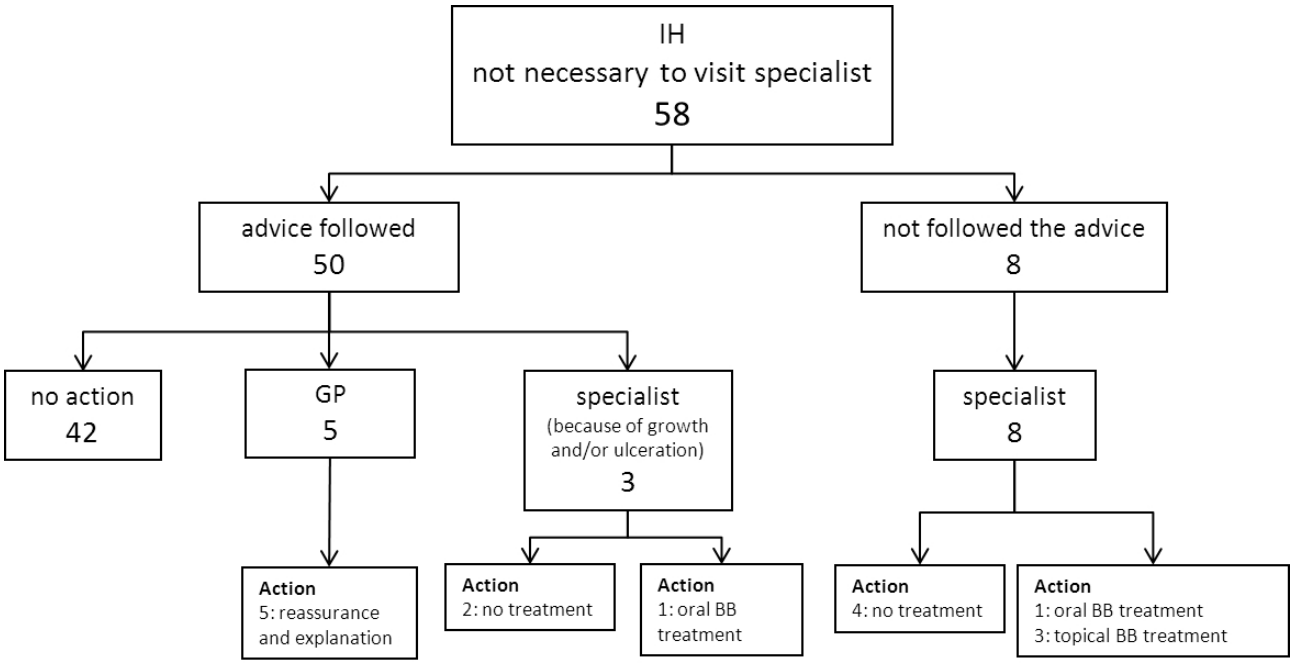


**Figure 3.** Flowchart of the compliance of the parents who were advised to visit a medical specialist by the dermatologist via e-consultation. The flowchart shows which doctor the parents visited and to what actions (eg, diagnostic evaluation and/or treatment) it has led. The figures indicate the number of patients. One patient, who followed the advice of the dermatologist and went to a specialist, underwent both diagnostic evaluation and topical beta blocker treatment was initiated. Infantile hemangioma(s) (IH); general practitioner (GP); and beta blocker (BB).

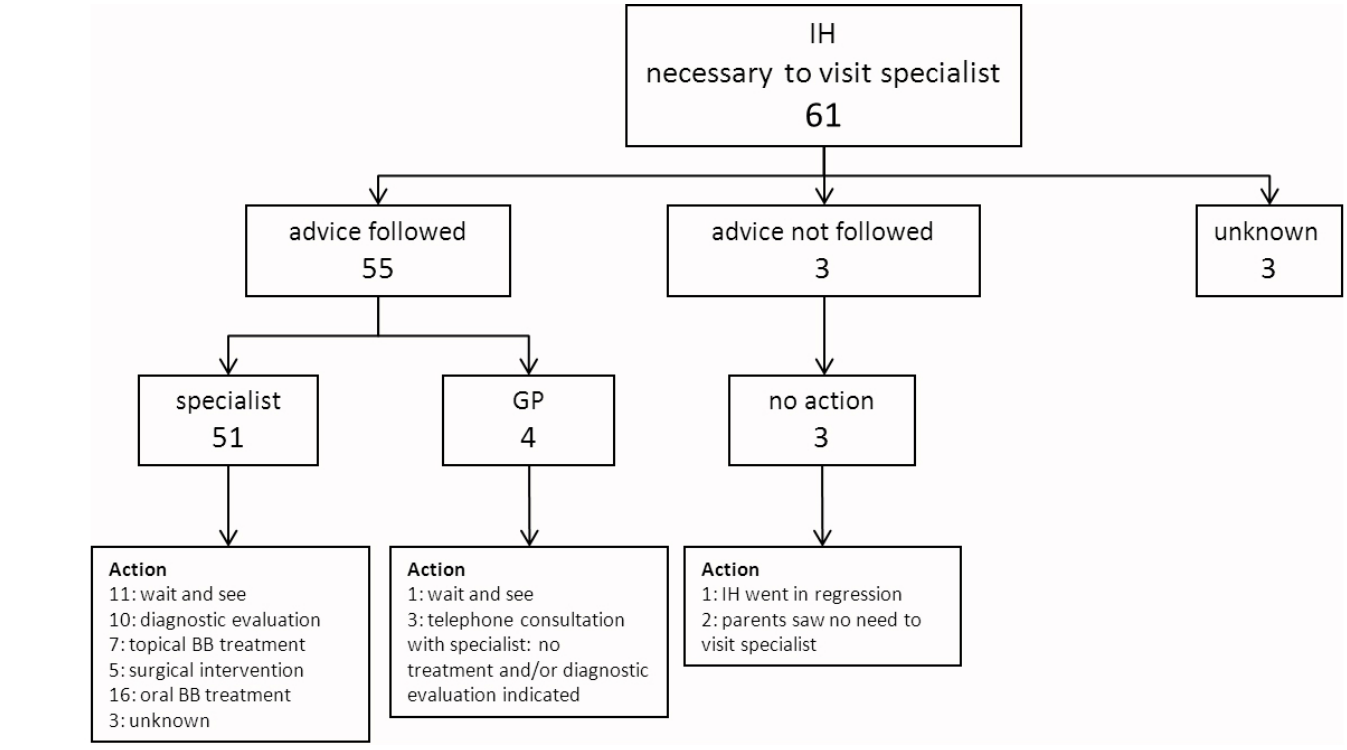




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**Figure 4.** Flowchart of the compliance of the parents of a child with no Infantile hemangioma (IH) or where it was not possible to make an accurate diagnosis by the dermatologist via e-consultation. The flowchart shows which doctor the parents visited and to what actions (eg, diagnostic evaluation and/or treatment) it has led. The figures indicate the number of patients. General practitioner (GP).

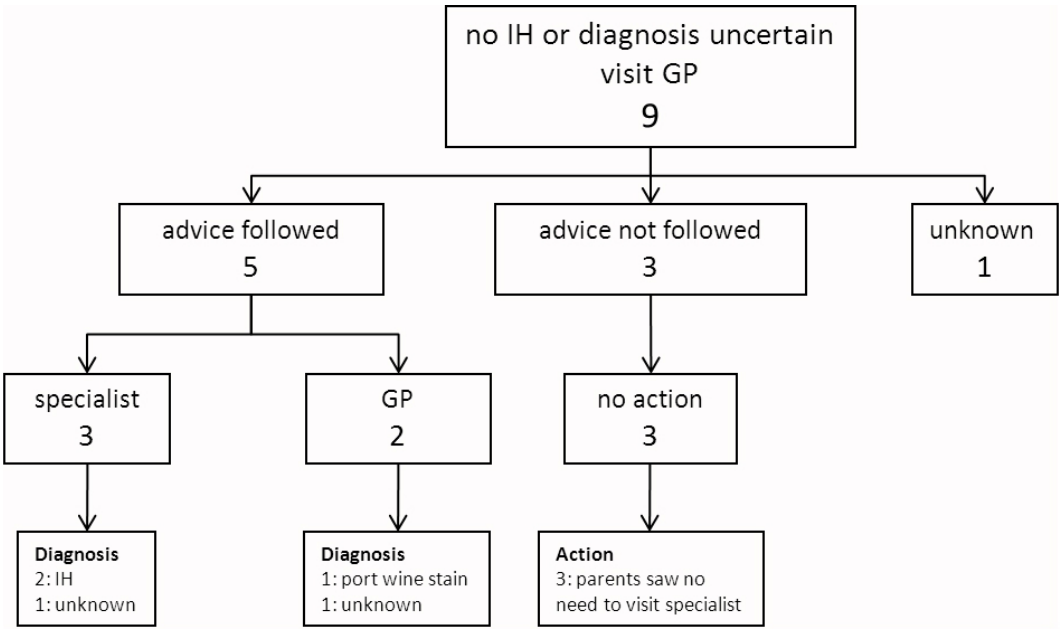


**Table 3.** Compliance, time between the advice and the actual appointment with a specialist, and average age of the patient, sorted by referral indication.

| Referral indication | n[a] | Compliance, n (%) | Average time to appointment in weeks, (SD[b]) | Average age of the child weeks, (SD) |
|---|---|---|---|---|
| (Imminent) functional impairment | 19 | 18 (94.7) | 2.6 (2.5) | 12.6 (9.1) |
| Ulceration | 19 | 18 (94.7) | 3.4 (2.6) | 13.5 (9.4) |
| Cosmetic impairment | 18 | 17 (94.4) | 3.9 (5.0) | 55.5 (143.4[c]) |
| Diagnostic | 15 | 14 (93.3) | 2.8 (3.1) | 9.3 (5.3) |

[a]n=number of patients

[b]Based on available data in 33/71 cases.

[c]One patient with cosmetic impairment was 12 years. Excluding this patient the average age was 22.1 SD 21.8 weeks.

## Acceptance and Usability

On all questions concerning PU an average of 91.3% (116.8/128) (range 86.7%, 111/128-98.5%, 126/128) of the parents agreed. This means that the PU was high.

Almost all parents (98.4%, 126/128) found the information of the e-learning understandable and clear, and 92.2% (118/128) of them found the eHealth intervention easy to use. There were 3/128 parents (2.3%) that experienced technical problems with logging in, 3/128 (2.3%) with filling in the questionnaire, and 29/128 parents (22.6%) experienced technical problems with uploading the photograph of their child.

The majority of the parents (94.8%, 121/128) found the eHealth intervention reliable and most of them (98.4%, 126/128) would recommend the eHealth intervention to other parents. There were 97.7% (125/128) of them that think the time investment was worth the effort (average time of completing the e-learning module, excluding e-consult, was 12.54 minutes). The average rate parents gave the eHealth intervention on a 0-10 scale was 8.4 (SD 1.1).

Comments and suggestions were evaluated. Positive comments were given about the reassurance parents experienced, the added value of the e-learning module for primary health care providers, and timely and adequate care due to the eHealth intervention. Negative comments were given about “shocking” photographs used in the e-learning module and difficulties in uploading photographs from an iPad.

An evaluation of difference in acceptance, usability, and attitude between compliant parents and noncompliant parents showed that noncompliant parents judged the eHealth intervention significantly less reliable compared to the compliant parents (71.4%, 10/14 versus 97.3%, 107/110), *P*=.003). There was no statistically significant difference between the percentage of highly educated parents in the compliant group (68.2%, 75/110) and the noncompliant group (85.7%, 12/14) (*P*=.23). All parents with a low education level (n=6) found the eHealth intervention easy to use.



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## Discussion

### Parent Compliance With Advice

This study shows that parents are highly compliant (85.9%, 110/128) to the advice of the dermatologist given via the described eHealth intervention for IH. Overall parents very positively judged the PU and PEU and they had a positive attitude towards the eHealth intervention.

The compliance rate is high compared to patient compliance with telephone triage recommendations in emergency care (62%), compliance to advice given via Web-based triage in primary care (57%), and family compliance to travel advice (≥80%) [31-33]. The high compliance of the eHealth intervention might have been positively influenced by its perceived reliability. Our eHealth intervention addresses the need of parents to get complementary information regarding diagnosis and treatment, to get a second opinion, to complement the information already provided by their doctor, or to confirm what they are already thinking [8,34]. It was developed in cooperation with the HEVAS and parents could find it by means of a link on their home page [21]. On the home page of the open access eHealth intervention the logos of HEVAS and UMCU were shown, as well as the names of the specialists of the CAVU team. All this might have contributed to the reliability of our eHealth intervention and might have increased the compliance of the parents. This is confirmed by the fact that noncompliant parents judged the eHealth intervention significantly less reliable.

Little is known about (non) compliance to advice given via eHealth. Compliance is a multifaceted process that is influenced by multiple factors (eg, social and economic circumstances, particularly health literacy, patient belief systems and patient education) [35,36]. Noncompliance to the advice may reflect ignorance or misunderstanding of the clinical situation and might result from the parents' inability to cope emotionally with the stresses surrounding the advice [37]. The advice, given by e-consultation, might have been in conflict with previously obtained advice by the parents from, for example, other health care takers, family, friends, media sources and health-related websites. Parents who encountered conflicting information might have been less compliant to the advice [38]. Principles to improve compliance to medication have been described and mostly apply in the case of a face-to-face contact between doctor and patient/parent [35]. Therefore most of these principles do not apply to compliance to the advice given via our eHealth intervention. Further studies are necessary to evaluate the factors influencing (non) compliance to advice given via eHealth.

The advice given via the eHealth intervention was based on criteria used in the literature [4,39-41] and in line with a recently published consensus about the treatment of IH with propranolol [6]. However, treatment was initiated in four children who were advised not to visit a medical specialist (Figure 2) and in 15 children visiting a GP/medical specialist has not led to action (Figure 3). A possible explanation is that in some cases our advice was inadequate because of the lack of information given by the parents (eg, photograph of the IH did not reflect the real situation). Another explanation might be that not all GPs and medical specialists are familiar with the most recent recommendations for the management of IH.

### Parental Education Levels and the Internet

In accordance with findings about parental Internet use for health-related information in the literature, the population of this study consisted of highly educated woman in the age group 30-35 [10,42,43]. This higher education is associated via higher eHealth literacy [9,44]. Possibly, low educated parents did not find the eHealth intervention on the Internet or dropped out of the e-learning module before finishing because they were not able to locate, evaluate, integrate, and apply the medical information (low eHealth literacy) [44], or had other needs and/or expectations. The small number of low educated parents in this study thought the eHealth intervention was easy to use and they were compliant to the advice. Our results show no significant difference in results between (the small number of) low educated and highly educated parents. Parents with a low socioeconomic status have access to the Internet and their Internet use is high [9,42,45]. The pressure to use the Internet to empower patients and exchange information is increasing and therefore the Internet might still provide an opportunity to reach low educated parents and may prompt them to consult their doctor [9,45]. Eventually this might contribute to timely presentation of high-risk IH, also for children of low educated parents.

Chang et al showed that the mean age of the first visit of IH patients to a specialist is 5 months [39]. The average age at the time of referral of IH leading to functional impairment (12.6 weeks) and the average time to appointment (2.6 weeks) suggest that this eHealth intervention might contribute to earlier presentation of patients with high-risk IH in specialized centers. More studies are necessary to confirm this.

### eHealth Intervention Positively Judged by Parents

The parents positively judged the acceptance and usability of the eHealth intervention. A positive attitude leads to intentions to follow the advice [33], and this might have influenced the compliance to the advice in our study. Although 71.8% (92/128) of the parents (Table 2) previously received information via Internet and/or from their primary health care provider/medical specialist, this eHealth intervention seems to have added value. However, there is still progress to be made. Almost a quarter (22.7%, 29/128) of the parents experienced technical problems with uploading of the photograph. Mostly, because uploading via a tablet was not supported by our website. This problem was temporally solved by giving parents the opportunity to send the photograph via email and is now completely resolved. Furthermore, parents commented on the lack of knowledge among primary health care providers. Initially, we have developed the eHealth intervention for both parents and health care providers. Until now, mostly parents participated in the eHealth intervention. To stimulate usage among health care providers, the link to our eHealth intervention has been since 2013 included in the IH guideline for youth health care providers in the Netherlands. It might be interesting to investigate whether this will improve the usage by health care providers.



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## Conclusions

Parents of children with an IH show a high compliance (85.9, 110/128) to the advice (about risk of complications and need to be seen by a medical specialist) given by the dermatologist via the described Web-based eHealth intervention. This high compliance might be positively influenced by the good acceptance and usability of the eHealth intervention. Our results implicate that increasing parents' knowledge and involving them in the care for IH might result in timely presentation and treatment of children with high-risk IH in specialized centers.

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## Conflicts of Interest

None declared.

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## Abbreviations

**CAVU:** Center for Congenital Vascular Anomalies Utrecht
**GP:** general practitioner
**HEVAS:** Dutch patient support group for Hemangiomas and Vascular Anomalies
**IH:** infantile hemangiomas
**PEU:** perceived ease of use
**PU:** perceived usefulness
**TAM:** Technology Acceptance Model
**UMCU:** University Medical Center Utrecht


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Protocol

# Psychosocial Interventions for Alcohol Use Among Problem Drug Users: Protocol for a Feasibility Study in Primary Care

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## Abstract

**Background:** Alcohol use is an important issue among problem drug users. Although screening and brief intervention (SBI) are effective in reducing problem alcohol use in primary care, no research has examined this issue among problem drug users.

**Objective:** The objective of this study is to determine if a complex intervention including SBI for problem alcohol use among problem drug users is feasible and acceptable in practice. This study also aims to evaluate the effectiveness of the intervention in reducing the proportion of patients with problem alcohol use.

**Methods:** Psychosocial intervention for alcohol use among problem drug users (PINTA) is a pilot feasibility study of a complex intervention comprising SBI for problem alcohol use among problem drug users with cluster randomization at the level of general practice, integrated qualitative process evaluation, and involving general practices in two socioeconomically deprived regions. Practices (N=16) will be eligible to participate if they are registered to prescribe methadone and/or at least 10 patients of the practice are currently receiving addiction treatment. Patient must meet the following inclusion criteria to participate in this study: 18 years of age or older, receiving addiction treatment/care (eg, methadone), or known to be a problem drug user. This study is based on a complex intervention supporting SBI for problem alcohol use among problem drug users (experimental group) compared to an “assessment-only” control group. Control practices will be provided with a delayed intervention after follow-up. Primary



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outcomes of the study are feasibility and acceptability of the intervention to patients and practitioners. Secondary outcome includes the effectiveness of the intervention on care process (documented rates of SBI) and outcome (proportion of patients with problem alcohol use at the follow-up). A stratified random sampling method will be used to select general practices based on the level of training for providing addiction-related care and geographical area. In this study, general practitioners and practice staff, researchers, and trainers will not be blinded to treatment, but patients and remote randomizers will be unaware of the treatment.

**Results:** This study is ongoing and a protocol system is being developed for the study. This study may inform future research among the high-risk population of problem drug users by providing initial indications as to whether psychosocial interventions for problem alcohol use are feasible, acceptable, and also effective among problem drug users attending primary care.

**Conclusions:** This is the first study to examine the feasibility and acceptability of complex intervention in primary care to enhance alcohol SBI among problem drug users. Results of this study will inform future research among this high-risk population and guide policy and service development locally and internationally.

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**KEYWORDS**

complex intervention; screening; brief intervention; alcohol; methadone maintenance; primary health care; general practice; substance-related disorders

## Introduction

### Overview

Problem alcohol use is associated with adverse health and economic outcomes, all the more so among problem drug users (eg, individuals currently using illicit drugs or trying to abstain from other illicit drugs such as benzodiazepines, cocaine, or heroin) [1,2]. Such alcohol use may decrease in response to psychosocial interventions whose benefits have been demonstrated in general adult populations. For example, a comprehensive review by Raistrick et al presented data on the effectiveness of many such interventions, including screening, further assessment, brief interventions, and alcohol-focused specialist treatment [3].

Primary care may have an important role in addressing problem alcohol use among problem drug users. Its potential impact on screening for alcohol problems and providing appropriate interventions in the general population has been described [4], although a recently published randomized trial indicates that more intensive primary-care-based interventions provide little by way of additional benefit to patient information alone [5]. Internationally, screening and brief interventions (SBI) are recommended as a treatment of choice for reducing alcohol use among problem drinkers in primary care [6,7], but these have not been tested in people who are addicted to other substances and who attend primary care [8]. It is important to address this issue because of the serious complications associated with problem alcohol use in this population, that is, the potential to increase the likelihood of a relapse to problem drug use, medical/psychological complications, liver disease, and so on [1,2].

Similar to other evidence-based interventions, the evidence on SBIs translates slowly into practice [9-11], and the findings from implementation studies are contradictory. For example, while a systematic review of interventions focused on increasing the use of SBI for hazardous alcohol consumption in primary care recommended complex, multicomponent strategies [12], a recent trial concluded that such a "tailored, multifaceted program aimed at improving general practitioner (GP) management of alcohol consumption" failed to show an effect and proved difficult to implement [13]. This also contradicts the conclusions of a recent paper, "real world evidence supports theory" of SBIs [14].

More impetus to this contradictory debate has been added by recent implementation studies and a controlled trial among problem drug users in secondary care that demonstrated feasibility of implementing SBIs among problem drug users in secondary care but suggested a controlled pilot study was necessary to establish key parameters for a similar evaluation in primary care [15-17]. The present study is designed to evaluate these issues.

### Previous Work in Ireland and Its Relation to Complex Intervention Theory

This protocol builds on our ongoing program of research that indicates (opiate) addiction treatment should also incorporate interventions that address problem use of alcohol and other illicit substances. For example, a national cross-sectional study reported that 35% of 196 patients attending GPs for methadone treatment also had problem alcohol use [18], while findings from a subsequent qualitative study highlight the need for a complex intervention to address this problem in primary care [19].

The UK Medical Research Council (MRC)'s "Framework for the Development and Evaluation of Complex Interventions for Randomized Controlled Trials (RCTs)" [20], which suggests following core phases to the development of complex health service interventions, informed the development of the intervention under study.

#### *Preclinical Phase: Theory and Problem Identification*

A national prevalence study showed problem alcohol use among patients attending general practice for methadone maintenance was high (35%) [18]. A review of scientific evidence found no studies examining this issue in primary care, but research in secondary or community care settings suggests that this type of intervention can be effective among problem drug users [21].



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### *Phase 1: Modeling*

The development of the complex intervention and clinical guidelines is informed by Cochrane Systematic review, qualitative interviews with health care providers and patients, and clinical guidelines.

Cochrane Systematic review was used to assess "psychosocial interventions for problem alcohol use in illicit drug users" [8]. Qualitative interviews with health care providers and patients that showed that barriers to implementation of alcohol intervention for drug users in primary care include patient factors, health care professional factors, and structural issues. The implementation strategies should utilize educational and support systems [19]. Clinical guidelines—informed by the findings of qualitative interviews, expert opinion through a Delphi-facilitated expert consensus process, and a Cochrane Systematic Review [8]—advocate SBI for problem alcohol use among problem drug users.

### *Phase 2: Exploratory Study*

A pilot study in addiction clinics showed that SBIs are effective in reducing alcohol consumption among opiate-dependent patients [16]. There is a current proposal to establish the acceptability and effectiveness of the intervention by conducting a feasibility study in primary care.

This protocol reflects the development and piloting phases of the MRC's "Framework for the design and evaluation of complex interventions to improve health" [20,22]. The present study will provide key parameters regarding the feasibility and acceptability of the intervention to patients and practitioners. As such, this research is essential to inform the design and conduct of a larger cluster randomized controlled trial (RCT).

The specific objectives of the study are as follows. First, this study aims to develop a complex intervention that will enhance SBI for problem alcohol use among problem drug users in primary care. This study will help to establish the practical feasibility and acceptability of complex intervention (1) by conducting a pilot study (with randomization at the level of practice), (2) exploring the feasibility and acceptability of the intervention under study and related research procedures to GPs, practice nurses, and patients, and (3) exploring the fidelity of the interventions as delivered in practice. Finally, we can decide to inform the subsequent design of a definitive cluster RCT by describing the optimum configuration of the complex intervention and by estimating the key parameters in such a trial (ie, practice/patient recruitment and retention rates, intraclass correlation coefficient for primary outcome measures, and the likely effect of intervention under study on these measures).

## Methods

### Overview of Study Design

Psychosocial intervention for alcohol use among problem drug users (PINTA) is a pilot feasibility study of a complex intervention to promote SBI for problem alcohol use among problem drug users, with cluster randomization at the level of general practice, and integrated qualitative process evaluation, involving general practice in two regions.

### Study Population

#### *Recruitment and Random Selection of Practices*

The following practices will be invited to participate, given written information on the study and their interest in participating:

- All practices in two regions—Health Services Executive (HSE) Midwest and Dublin Mid-Leinster regions
- All practices that have been involved in previous related research with our group [18,23-29]
- General practices in the study regions that are affiliated with two of the Ireland's six medical schools [30,31]

Practices will be eligible to participate if they are registered to prescribe methadone and/or have at least 10 patients currently receiving addiction-related care.

Of those who confirm their *interest* in the study and who are eligible to participate, a stratified random sampling technique will be used to select 16 practices.

Sampled GPs will be contacted about their participation, given further information on the study (eg, what their involvement will entail) and consulted about patient recruitment. The research team will telephone those not replying. Each practice will be visited by the principal investigator or lead researcher and provided with the information about the research program.

To ensure comparability between intervention and control groups for key practice characteristics, a restricted allocation involving stratified approach to randomization will be adopted. Prior to randomization, GPs who express their interest in participating will be grouped according to the level of training in providing addiction-related care (level 1 and 2), geographical location (Dublin/Midwest), with 16 randomly selected GPs using an independent remote randomization service.

To prescribe methadone, GPs are subject to clinical audit and must complete special training, while GPs providing methadone treatment for 15 or more patients are subject to more regular audit and advanced training. GPs who prescribe methadone for less than 15 patients are referred to as "level 1 GPs," and those prescribing for 15 or more as "level 2 GPs." Initiation of methadone therapy, treatment of patients with more complex medical and psychosocial needs (including alcohol dependence), and unstable drug use are only permitted by specialist addiction treatment services or by "level 2 GPs." A more complex, difficult cohort of patients is attended by level 2 GPs and this might have implications for the success of the intervention. Therefore, it will be introduced in the data analysis as a potential confounder.

#### *Identification and Recruitment of Patients*

Before introducing the complex intervention, each participating practice will engage in an intensive, 2-week period of patient recruitment, an approach we found most effective in previous qualitative work with this population [19]. This 2-week period will be supported by a member of the research team and will aim to: (1) establish a "disease" register of patients, (2) obtain contact details for and informed consent from eligible patients, (3) review the clinical records of patients who consent to



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participate in the study, and (4) collect baseline data, including patient demographics and current care process/outcome measures from clinical records.

Patients will be eligible to participate if they are 18 years of age or older, receiving addiction treatment/care (eg, methadone), or known problem drug user, and attending a participating general practice for general medical care. They will be excluded from the study if they have language difficulties (ie, unable to speak, read, and write English well enough to complete study questionnaires), are acutely intoxicated, and/or are cognitively impaired (including severe mental health illness) to the extent that they are unable to provide informed consent to participate.

Systematic random sampling of patients in participating practices is difficult in studies among this population [25]. Hence, a standardized nonprobability sampling framework will be used to identify *consecutive* patients from each practice on whom data will be collected for the purpose of the study. Potential patient selection bias will be assessed in the exploratory data analysis, by comparing the sociodemographics of the included patients with all patients, who were identified as problem drug users, in each practice.

Patients who consult a GP taking part in the study, and who in the clinical opinion of the GP are eligible to participate in the study (see inclusion criteria above), will be given written information on the study. Those interested in participating will be invited to meet a researcher who will be at the practice during the recruitment period. At this meeting, interested patients will be given further information on the study and will have an opportunity to ask questions from the researcher. If patients consent to participate, they will be asked to sign a consent form and complete a self-/interviewer-administered questionnaire that includes problem alcohol use and other outcome measures, if necessary with the assistance of the researcher at T1 (ie, Time 1, at baseline) and T2 (ie, Time 2, at 3 months follow-up). This applies to patients in both the intervention and control groups.

Following completion of the self-/interviewer-administered questionnaire with the researcher, patients in the intervention practices will be screened for problem alcohol use and delivered the brief intervention by their GP/practice team (at their earliest convenience). Patients in the control arm will receive the “Less is more” leaflet (a guide to rethinking your drinking, HSE, 2008) from the researcher. A “thank you” letter will be sent to all GPs and patients within 2 weeks of receiving completed study instruments/intervention. A reminder letter will be sent to all GPs and patients 5 weeks before the follow-up assessments, informing them of the anticipated time/date of their appraisal. Figure 1 presents the CONSORT diagram of participant flow and follow-up.

### *Power Calculations and Sample Size Estimates*

The goals of this study are to examine the feasibility, acceptability, and effectiveness of the complex intervention. As observed in previous studies, with respect to the feasibility component, the present study aims to achieve 20% recruitment/consent rate (ie, number of invited GPs who confirm their interest in the study) [19], 75% participation rate (ie, the number of participants allocated to the intervention arm who will receive/complete SBI) [5], and 75% retention or follow-up rate [5].

Based on the recommendations for good practice in pilot studies [32,33], we estimate that 160 patients (attending 16 general practices) will be adequate to calculate the actual recruitment and retention rates (ie, *feasibility*) for a sample of patients recruited in primary care and provide data on *acceptability* of study processes and outcome measures, which will inform a future definitive trial. This pilot study is not powered to determine effectiveness of SBI on reduction of alcohol consumption among problem drug users. The proportion of patients who reduce their alcohol consumption will be used to predict the sample size and length of follow-up for a future definitive RCT.



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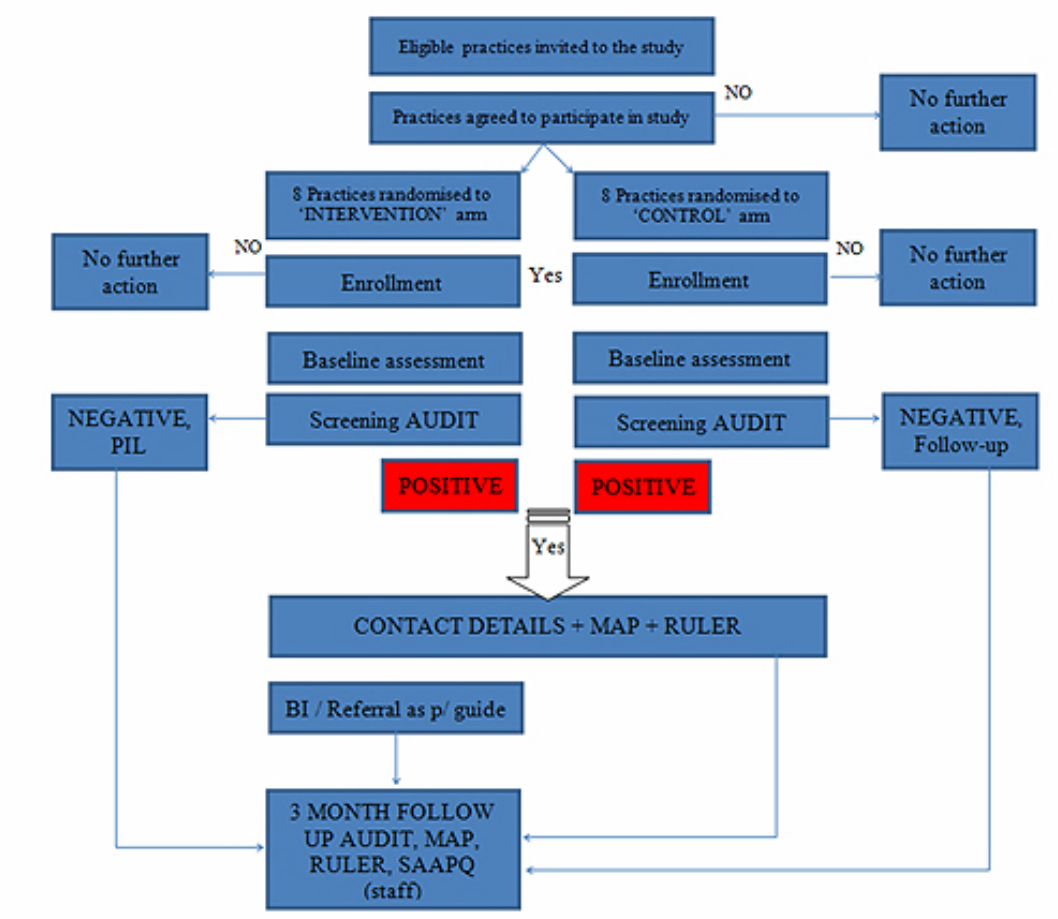
**Figure 1.** CONSORT diagram: participant flow and follow-up.




## Intervention

### *Overview*

A staggered intervention design will be adopted, whereby participating practices randomized to the intervention arm of the study will be provided with the complex intervention for the duration of the study period, while practices randomized to the control arm of the study will provide usual care to patients for the duration of the study and will be provided with the complex intervention thereafter (ie, delayed intervention). Such an approach was used successfully in our previous cluster randomized controlled study to improve screening for hepatitis C among problem drug users attending general practice in Ireland [25].

### *Control Intervention*

All practices (control and intervention arms) will be required to establish a "disease" register of "problem drug users" before the study onset. They will identify potential participants and recruit them for the study. At this stage, participants will be asked to sign an informed consent form. The research team will conduct interviews (telephonic or in person) to determine problem alcohol and other drug use and demographic details at baseline and at 3 months follow-up. Researchers will facilitate data collection (including morbidity and primary/secondary care utilization) from clinical records. Participating practices will be offered €50 per patient recruited to study upon receipt of completed data [34].

We consider the above engagement with practices as close to "usual care" as possible while still allowing evaluation of the complex intervention. To enable the development of a practice



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register of people with problem drug use, clinical records and prescribing information will be reviewed. For practices who use electronic patient records, an International Classification of Primary Care disease code (P19) will be assigned to patients who meet the criteria of European Monitoring Center for Drugs and Drug Addiction for problem drug use. For practices who use paper records, this register will be developed in a hard copy.

### *Experimental Intervention*

A complex intervention will be delivered to practices assigned to the intervention arm at two levels: (1) practice level and (2) patient level.

Interventions that are delivered at practice level include CME/CPD-accredited education delivered both internally (practice-based academic detailing) and externally (seminar), dissemination of clinical guidelines, other resources to facilitate implementation at practice level (eg, contact details/referral information for local services).

All practices will participate in the external education (seminar). Internal education (practice-based academic detailing) will be offered on as-needed basis, depending on practice resources and experience with SBI [35]. Academic detailing and support will be available to practices during the 3 months study period. The number and duration of these visits will be used to predict the level of support for a future definitive RCT.

At patient level, SBI (10-15 minutes) is delivered to patients.

## Data Collection

### *Timeline*

At baseline, demographic details and data on primary/secondary outcome measures will be collected by reviewing clinical records and by patients completing study instruments. At follow-up, data will again be collected by reviewing clinical records and by patients completing study instruments. Participants will be invited to complete a follow-up interview with a researcher to include primary/secondary outcome measures. A purposive sample of patients in the "intervention" arm will be interviewed regarding their experience in care for alcohol-related problem in the preceding 3 months.

Quantitative data will be collected at baseline (T1) and at 3 months follow-up (T2) using clinical records (T1, T2), self-/interviewer-administered questionnaires and semistructured interviews (patients, T1, T2), and self-administered questionnaires, including open-ended questions (practitioners, T2).

### *Outcome Measures*

Table 1 summarizes the key data being collected during the study.

#### Staff and Organization Measures

Health care professionals at participating practices will be asked to complete a self-administered questionnaire that will elicit data on practice/professional details, experience of training, intervention fidelity (The NIH "Behavior Change Framework" [36]), and Shortened Alcohol and Alcohol Problems Perceptions Questionnaire (SAAPPQ).

#### System Measures

System measures at the examination include the total number of patients screened for alcohol problems (and method of screening), the number of positive screening, and the number of patients receiving any alcohol intervention (including referral). Results of chemical tests for alcohol and drugs (eg, breathalyzer or urine tests) conducted by GPs will be also retrieved using the practice records (T2) to verify self-report measures.

#### Patient Measures

These measures include indirect examination and direct examination. At baseline and follow-up, the study battery will include the following: (1) Alcohol Use Disorders Identification Test (10 items) (AUDIT), (2) Maudsley Addiction Profile (MAP), and (3) Readiness Ruler.

AUDIT developed by the World Health Organization is used to identify a continuum of problem alcohol use [21,38].

MAP is a brief, structured questionnaire for treatment outcome research and measures problems specifically in four areas: substance use, health risk behavior, physical and psychological health, and personal/social functioning [18,39].

Readiness Ruler will assess patient's motivational state regarding changing their drinking behavior [41].

#### Financial Incentives

Participating practices will be offered €50 per patient to compensate for the extra administration work as in a similar trial [34]. We consider this a conservative level of remuneration given the additional work involved for participating practices [42].



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**Table 1.** Primary and secondary outcome measures to be used at the baseline and/or follow-up examinations.

| Aim/Target group | Patient measures | Staff and organization measures | System measures |
|---|---|---|---|
| Feasibility | Indirect (review of clinical records):<br>• Sociodemographic characteristics and general medical morbidity (ie, clinical records review using a structured instrument developed previously [24]) at baseline | Self-administered baseline questionnaire to include:<br>• Practice/professional details<br>• Experience of training<br>• Adherence to intervention guide/manual assessed with the NIH "Behavior Change Framework" [36] (includes five intervention adherence strategies: intervention design, training procedures, delivery of intervention, receipt of intervention, and enactment of SBI skills) at follow-up<br>• Shortened Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ) | Indirect (review of clinical records):<br>• Current and previous practice, with regards to screening and intervention for problem alcohol use among identified problem drug users<br>• Numbers of patients who were (1) screened for alcohol, (2) offered a brief intervention, (3) received the brief intervention, and (4) referred to a specialist at follow-up |
| Acceptability | • Patients' experience of intervention: semistructured interviews at follow-up (via telephone or in person) | Postal survey to include:<br>• SAAPPQ [37] at baseline and follow-up<br>• Health care professionals' experience of the intervention: free text in questionnaires at follow-up eliciting information on staff attitudes toward alcohol screening and brief intervention (SBI), previous practice of alcohol SBI, preparedness to undertake these activities, the training required to implement SBI, the suitability of each site to provide SBI [34] | Postal survey examining:<br>• perceived barriers or enablers of implementation of SBIs in Ireland |
| Effectiveness | Direct (interview at baseline and follow-up):<br>• AUDIT [38]<br>• Other drug use (eg, Maudsley Addiction Profile [39])<br>• Motivation to change risky behavior (eg, Readiness ruler [40]) | | Indirect (review of clinical records):<br>• Results of chemical tests for alcohol and drugs (eg, breathalyzer or urine tests) will be also retrieved using the practice records to verify self-report measures |

## Data Analysis

Descriptive statistics will be estimated with respect to key feasibility variables. At baseline, rates of practice and patient recruitment, prevalence of problem drug use at participating practices, and baseline prevalence of problem alcohol use among problem drug users will be estimated. Process and fidelity evaluation of pilot educational intervention will be explored. Practice/patient retention rates, prevalence of problem alcohol use among problem drug users, and confounding factors such as practice busyness or person who performed SBI will be analyzed for outcome measures.

SPSS v20 and R software will be used for analysis by the HRB Center for Support and Training in Analysis and Research.

## Qualitative Evaluation

A parallel qualitative evaluation will also be conducted with patients and health care professionals.

With regard to health care professionals, open-ended questions will be asked eliciting information on staff attitudes toward alcohol SBI, previous practice of alcohol SBI, preparedness to undertake these activities, the training required to implement SBI, the suitability of each site to provide SBI, and other barriers to effective implementation [34].

With regard to patients, among a 20% purposive sample (estimated N=16) of patients in the intervention practices, we will also explore patients' satisfaction with and experience of intervention and care related to problem alcohol use in the preceding 3-6 months. Interviews will be done by researcher via telephone, postal questionnaire, or in person. Prior to the interviews, the participant will be informed of the interview purpose, the interview procedure, and the use of the findings. The participant will then be invited to sign an additional consent form and the interview will commence.

Qualitative data analysis will be systematic and organized to easily locate information within the dataset when tracing results, providing examples in context [43]. The qualitative research software Nvivo v8 will be used to facilitate the coding. Thematic analysis will be used to analyze qualitative data. This approach has many benefits for such an interpretive study, as it is a "method for identifying, analyzing, and reporting patterns (themes) within data" [43].



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### Ethical Considerations

Ethical approval has been obtained from the Research Ethics Committee of the Irish College of General Practitioners (Protocol Reference: Cullen, 2012 Nov 29). Research carried out on humans in this study is in compliance with the Helsinki Declaration. The protocol follows the checklist of items to consider for inclusion in a report of a pilot studies [44], adopted from the CONSORT statement [45,46].

A two-stage procedure to obtain informed patient consent to participate in the study will be used during the study. Patients who consult a GP taking part in the study, and who in the clinical opinion of the GP are eligible for the study, will be given written information on the study (brief study information sheet). Those interested in participating will be invited to meet a researcher who will be at the practice during the recruitment period. At this meeting, interested patients will be given further information on the study and will have an opportunity to ask questions from the researcher. When all issues have been explained to patients' satisfaction, they will be asked to indicate consent to participate in the study by signing a consent form and this procedure will be witnessed by a third party. The standard patient consent form for participation in nonclinical trials, developed by the Research Ethics Committee of the Irish College of General Practitioners, will be used in the study. Participation in the study will be on a voluntary basis. No inducements to participate will be offered to patients, and refusal to participate will not compromise patient care.

Potential adverse effects of the intervention will be explored in the qualitative interviews with patients and practitioners.

## Results

This study is ongoing and a protocol system is being developed for the study. This feasibility study may inform future research among the high-risk population of problem drug users and guide policy and service development locally and internationally by providing initial indications as to whether psychosocial interventions for problem alcohol use are feasible, acceptable, and also effective among problem drug users attending primary care.

## Discussion

The PINTA is the first study to examine the feasibility and acceptability of alcohol SBI for problem alcohol use among problem drug users attending primary care. It will provide key data that will enhance scientific understanding of interventions that prevent risk behaviors, inform policy and service development, and contribute to health and social gain locally and internationally.

The project team involves academic, clinical, policy experts responsible for planning/delivery of addiction care/primary care, and international experts on optimum primary care delivery to at-risk populations/primary care alcohol treatment.

The proposed work will build on our recently completed project that has identified problem alcohol use as a common finding among patients on methadone and subsequent program of research, which has explored and documented existing practices with respect to alcohol interventions among this group. This information is used, in conjunction with scientific evidence, to develop clinical guidelines regarding screening and treatment for problem alcohol use, and then consult it with patients and health care professionals.

At the end of this research, the feasibility of a clinical intervention, informed by international best practice and local barriers, will be evaluated in areas of high need. This intervention is likely to consist of a training and support program and clinical guidelines. By involving service users and service providers in their development phase, acceptability and feasibility will be enhanced. The research methodology also gives a voice to a group of service users not normally at the center of how interventions are tested.

This feasibility study may inform clinical practice by providing initial indications as to whether psychosocial interventions for problem alcohol use are feasible, acceptable, and also effective among problem drug users attending primary care. It will also inform future research on the topic by providing key parameters for the design of a future cluster RCT. This study is ongoing and a protocol system is being developed for the study.

### Acknowledgments

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### Authors' Contributions

JK is lead researcher on the study. WC is principal investigator and conceived the study. JK and WC led preparation of the manuscript with a core group of authors. All authors read and approved the final manuscript.

### Conflicts of Interest

None declared.

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## Abbreviations

**AUDIT:** Alcohol Use Disorders Identification Test
**GP:** general practitioner
**HSE:** Health Services Executive
**MAP:** Maudsley Addiction Profile
**MRC:** Medical Research Council
**PINTA:** psychosocial intervention for alcohol use among problem drug users
**RCT:** randomized controlled trial
**SAAPPQ:** Shortened Alcohol and Alcohol Problems Perception Questionnaire
**SBI:** screening and brief intervention

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Protocol

# Processes and Outcomes of the Veterans Health Administration Safe Patient Handling Program: Study Protocol

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## Abstract

**Background:** Health care workers, such as nurses, nursing aides, orderlies, and attendants, who manually move patients, are consistently listed in the top professions for musculoskeletal injuries (MSIs) by the Bureau of Labor Statistics. These MSIs are typically caused by high-risk patient caregiving activities. In 2008, a safe patient handling (SPH) program was implemented in all 153 Veterans Administration Medical Centers (VAMCs) throughout the United States to reduce patient handling injuries.

**Objective:** The goal of the present study is to evaluate the effects associated with the national implementation of a comprehensive SPH program. The primary objectives of the research were to determine the effectiveness of the SPH program in improving direct care nursing outcomes and to provide a context for understanding variations in program results across sites over time. Secondary objectives of the present research were to evaluate the effectiveness of the program in reducing direct and indirect costs associated with patient handling, to explore the potential mediating and moderating mechanisms, and to identify unintended consequences of implementing the program.

**Methods:** This 3-year longitudinal study used mixed methods of data collection at 6- to 9-month intervals. The analyses will include data from surveys, administrative databases, individual and focus group interviews, and nonparticipant observations. For this study, a 3-tiered measurement plan was used. For Tier 1, the unit of analysis was the facility, the data source was the facility coordinator or administrative data, and all 153 VAMCs participated. For Tier 2, frontline caregivers and program peer leaders at 17 facilities each completed different surveys. For Tier 3, six facilities completed qualitative site visits, which included individual interviews, focus groups, and nonparticipant observations. Multiple regression models were proposed to test the effects of SPH components on nursing outcomes related to patient handling. Content analysis and constant comparative analysis were proposed for qualitative data analysis to understand the context of implementation and to triangulate quantitative data.

**Results:** All three tiers of data for this study have been collected. We are now in the analyses and writing phase of the project, with the possibility for extraction of additional administrative data. The focus of this paper is to describe the SPH program, its evaluation study design, and its data collection procedures. This study evaluates the effects associated with the national implementation of a comprehensive SPH program that was implemented in all 153 VAMCs throughout the United States to reduce patient handling injuries.

**Conclusions:** To our knowledge, this is the largest evaluation of an SPH program in the United States. A major strength of this observational study design is that all VAMCs implemented the program and were included in Tier 1 of the study; therefore,



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population sampling bias is not a concern. Although the design lacks a comparison group for testing program effects, this longitudinal field study design allows for capturing program dose-response effects within a naturalistic context. Implementation of the VA-wide SPH program afforded the opportunity for rigorous evaluation in a naturalistic context. Findings will guide VA operations for policy and decision making about resources, and will be useful for health care, in general, outside of the VA, in implementation and impact of an SPH program.

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**KEYWORDS**

back injuries; occupational injuries; moving and lifting patients; methods; program evaluation

## Introduction

### Background

Health care workers, such as nurses, nursing aides, orderlies, and attendants, who manually move patients, are listed in the top professions for musculoskeletal injuries (MSIs) by the Bureau of Labor Statistics [1]. MSIs are typically caused by high-risk patient caregiving activities that include turning and repositioning, lateral transfers, assisting to standing position, exiting the bed, and transferring from one surface to another, such as from a bed to chair. Manual patient handling has a deleterious effect on staff, patient safety, and organizational factors such as nursing staff turnover, job satisfaction, and cost due to workers compensation and lost work time. Indirect costs associated with MSIs include replacing employees (workforce attrition), injury investigation time, supervision time, training, staff morale, disruptions in teamwork and workflow, administrative time, and paid overtime [2,3].

Safe patient handling (SPH) programs consist of the following components: equipment, ergonomic assessment protocols, no-lift policies, and staff training. Recent studies have shown that SPH programs have a positive effect on MSIs [4-11]. In one study, it was observed that injury rates dropped as much as 73% after implementing a SPH program [10].

Given that the Veterans Health Administration (VHA) employs approximately 77,000 nurses, nursing assistants, health aids and technicians, and trainees [12], the effect of patient handling injuries on individuals and on the system is substantial. In 2008, the VA implemented a SPH program in all 153 Veterans Administration Medical Centers (VAMCs) throughout the United States. The implementation of the SPH program was financially supported by an investment of US $205 million. The National VA SPH program funded local equipment purchases, facility coordinators, and technical guidance from a VA expert in SPH and ergonomics. This paper reports on the study protocol for the mixed methods evaluation of the national implementation of the VHA SPH program. Many of the measures and evaluation procedures reported here were used in prior local and regional VHA studies [13,14].

### Objectives

The goal of the research was to assess the processes and outcomes associated with the implementation of a comprehensive SPH program across all 153 VAMCs. The primary objectives of the research were to: (1) determine the effectiveness of the SPH program in improving direct care nursing outcomes (eg, incidence and severity of injuries and job satisfaction) and patient outcomes (injuries associated with patient handling), and (2) provide a context for understanding variations in program results across multiple facilities over time including barriers and facilitators to implementation, local customization of the program, and organizational and individual factors that influenced implementation and program effects. Secondary objectives of the research were to: (1) evaluate the effectiveness of the program in reducing direct and indirect costs associated with patient handling, (2) explore the potential mediating and moderating mechanisms (eg, strength of program implementation and program uptake) by which SPH program exerts its effects on outcomes, and (3) identify unintended consequences of implementing the program. All data for this study have been collected. We are now in the analyses and writing phase of the project, with the possibility for extraction of additional administrative data. The intention of this paper is to describe the SPH program, its evaluation study design, and its data collection procedures.

### Theoretical Framing

Implementation of evidence-based practices is a function of multiple factors including the nature of the evidence, the transmission of knowledge to users, and context of implementation including the health system and organizational factors [15]. Theoretical and conceptual models commonly used to either guide implementation or account for these factors include Diffusion of Innovations [16], Stetler Model [17], Translating Research into Practice [18], and Promoting Action on Research Implementation in Health Services [19].

The SPH program was primarily conceptualized as an evidence-based health care safety program based on ergonomic principles and designed to improve both caregiver and patient outcomes. The key elements of SPH program include: (1) ergonomic risk assessment of each unit or area to evaluate and address conditions that may present injury risks related to patient handling, (2) selection and purchase of safe handling equipment, (3) training and continuing staff SPH competency evaluations, (4) ongoing evaluation and reporting of program outcomes, (5) peer leadership to implement at the unit level, (6) a multidisciplinary facility-level Safe Patient Handling Committee, representing all stakeholders of the program, (7) local policy mandating minimal patient lifting and moving, and (8) a part-time facility coordinator to assume leadership of the program implementation and serve as a bridge among administrators, managers, and caregivers.

The selection of indicators for measuring context, knowledge transmission, program, and outcomes was guided by theoretical



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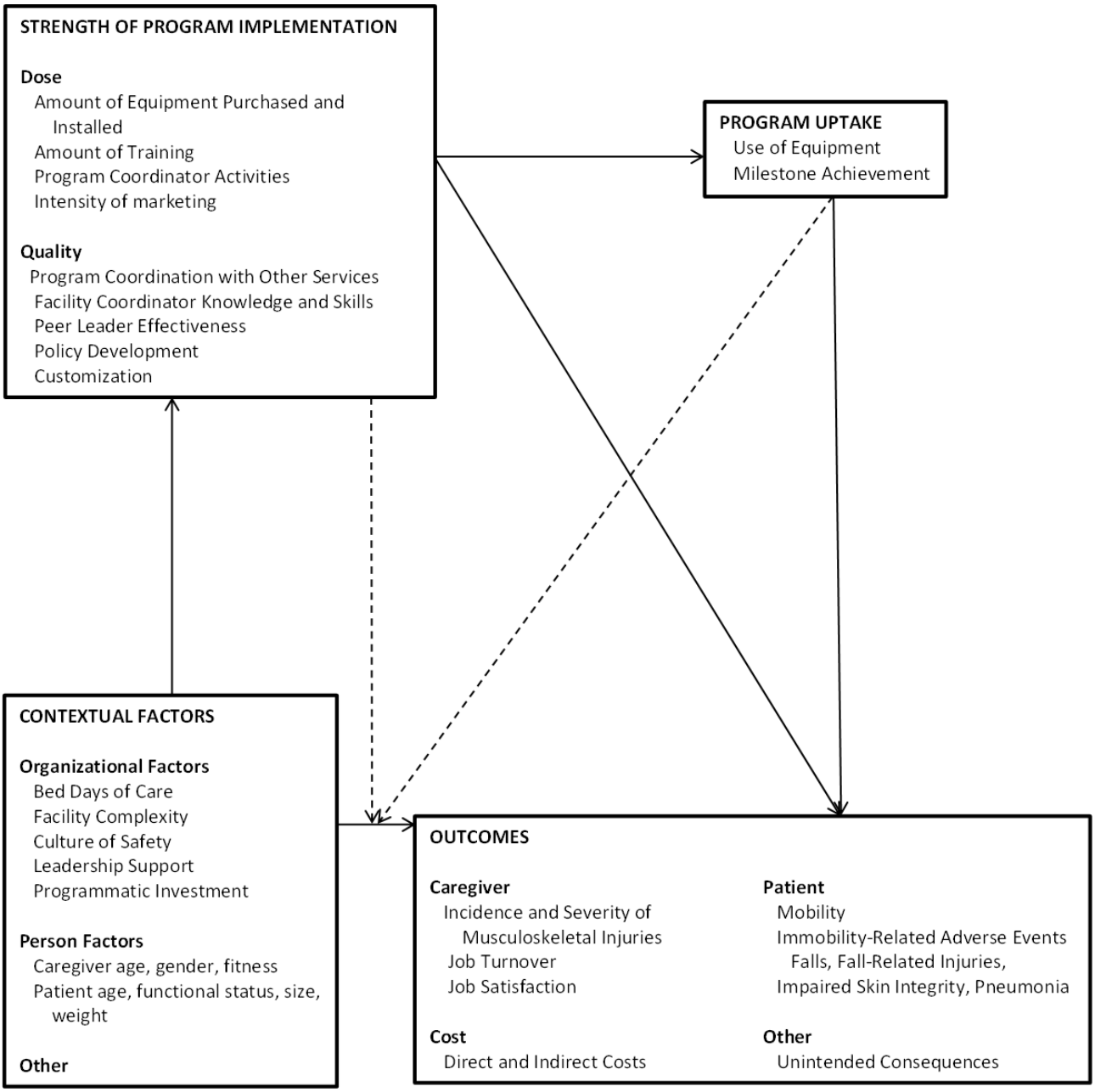
underpinnings of implementation, and all of these variables were grouped into relational categories in a quantitative conceptual model (see Figure 1). However, not all expected variables were measured due to limitations of the administrative data and availability of administrative data sets at the facility and patient levels. To set the framework for more specific hypotheses in subsequent sections, we specified four global hypotheses in general terms within the context of our quantitative conceptual model of patient-handling-related outcomes (eg, MSI incidence rates for nursing professions, job satisfaction, patient injury rates, and costs). The hypotheses are as follows: (H1) contextual factors will be used as significant risk factors (predictors) for the outcomes; (2) after accounting for contextual factors, higher strength levels of SPH program implementation and uptake will be significantly associated with the favorable outcomes; (3) the risk association between contextual factors and the outcomes will be moderated by the strength of SPH program implementation and uptake; and (4) higher strength of program implementation will increase program uptake that in turn will lead to favorable outcomes. More specific versions of each hypothesis are described later under appropriate sections.

**Figure 1.** Conceptual framework for the implementation and evaluation of the VA Safe Patient Handling Program.




## Methods

This 3-year longitudinal study used mixed methods of data collection at 6- to 9-month intervals: analysis of data from surveys, administrative databases, individual and focus group interviews, and nonparticipant observations. All measures of indicators and data sources are given in Table 1.



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**Table 1.** The measurement plan.

| Indicator | Data source |
|---|---|
| **Strength of program implementation** | |
| Number of equipment purchased and installed | Facility coordinator questionnaires |
| Amount of training | |
| Program coordinator activities | |
| Intensity of marketing | |
| Program coordination with other services | |
| Peer leader effectiveness | |
| Policy development | |
| Customization | |
| Management skills of facility coordinators | Observation and interviews during the site visits |
| **Program uptake** | |
| Use of equipment | Facility coordinator questionnaires<br>Interviews during site visits |
| Milestone achievement | Facility coordinator questionnaire |
| **Context of implementation: organizational factors** | |
| Bed days of care | VA administrative data (Bed Cube, VHA Support Service Center) |
| Facility complexity | |
| Culture of safety | Observation and interviews during site visits |
| Leadership and stakeholder support | Facility coordinator and peer leader questionnaires<br>Observation and interviews during site visits |
| Programmatic investment | Facility coordinator questionnaire |
| **Nursing outcomes** | |
| Incidence of injuries related to patient handling | VA Administrative Data (Veterans Affairs Nursing Outcomes Database/Automated Safety Incident Surveillance and Tracking System) |
| Job turnover | VA Administrative Data (VHA Support Service Center) |
| Job satisfaction | Staff survey |
| Patient immobility adverse events | Interviews during site visits |
| Unintended consequences | Interviews during site visits |

## Sample and Sampling

For the present study, a 3-tiered evaluation plan was used. For Tier 1, the data sources were facility coordinators and administrative data, and all 153 VAMCs participated. The coordinators at 12 facilities were responsible for 2 VAMCs. Therefore, the maximum number of surveys that could be collected was 141 (92.1%). Table 2 presents the sample size and data collection timeline. Data sources for Tiers 2 and 3 were VHA staff who implemented the SPH program and frontline caregivers, and included a sample of 17 and 6, respectively, of the total 153 VAMCs. For Tier 2, we originally planned to randomly select 1 VAMC from each of the 21 regional Veterans-Integrated Services Networks, but 11 Veterans-Integrated Services Networks or regions did not volunteer to participate. For all most non-participating regional Veterans-Integrated Services Networks, the reason was that no individual volunteered to serve as the local investigator. For the 11 nonparticipating regions, we were able to replace 7 regions with volunteer facilities. Of all the participating facilities, 10/17 (59%) were the original randomly selected facilities and 7/17 (41%) were replacement facilities. Table 3 presents sample sizes and data collection timeline for Tier 2.

Ethnography was used as the qualitative methodology of Tier 3. Ethnography is a qualitative research method that is used to engage with others and their practices to better understand their culture [20]. It does not test a formative theory to establish whether it is right or wrong but rather may expand a model, discover associations among domains or variables, or match expected results from the formative theory with those obtained during the data collection process [21]. Purposive sampling was used to identify Veterans Administration Medical Centers for Tier 3. We used data from the first wave of data collection to determine the degree of deployment of SPH program elements.



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One of these facilities withdrew and was replaced with another facility from the same region. All six participating facilities, also participated in tier 2 data collection. The summary of data collected in Tier 3 is presented in Table 4. Within each site visit, the goal was to capture a well-rounded view of the SPH program at the facility. The individual interviews and focus groups included participation from direct caregivers, SPH program peer leaders, nurse managers, the SPH committee, facility coordinator, and hospital administration. For the unit observations, facilities were asked to identify one stellar unit and one struggling unit. Photographs were taken of equipment and staff during the unit observations.

**Table 2.** Administration times and sample size of facility coordinator surveys for Tier 1.

| | December 2008 | June 2009 | December 2009 | June 2010 | December 2010 | June 2011 |
|---|---|---|---|---|---|---|
| Milestone Questionnaire | 141 | 141 | 141 | 139 | 135 | 128 |
| Program Dose Survey | 141 | 141 | 140 | 137 | 135 | 127 |
| Program Status Report | 141 | 141 | 140 | 137 | 135 | 127 |

**Table 3.** Tier 2 peer and staff surveys administration times and sample size.

| | February 2010 | | July 2010 | | February 2011 | | July 2011 | |
|---|---|---|---|---|---|---|---|---|
| | Number of sites | Number of surveys | Number of sites | Number of surveys | Number of sites | Number of surveys | Number of sites | Number of surveys |
| Staff Survey | 10 | 988 | 14 | 1382 | 17 | 1643 | 14 | 1294 |
| Peer Leader Survey | 10 | 133 | 14 | 173 | 17 | 242 | 15 | 272 |

**Table 4.** Sample size for Tier 3 site visits.

| | 2009 | 2010 | 2011 | Total[a] |
|---|---|---|---|---|
| Number of sites | 3 | 6 | 6 | 6 |
| Number of site visits | 4 | 7 | 4 | 15 |
| Number of participants | 71 | 124 | 91 | 286 |
| Number of individual interviews | 18 | 31 | 15 | 64 |
| Number of focus groups | 12 | 18 | 18 | 48 |
| Number of photographs | 86 | 132 | 85 | 303 |

[a]Several sites were visited more than once per year.

## Measures

### *Tier 1*

The Milestone Questionnaire was developed to track each facility's progress in meeting predetermined quarterly activities of the program. The milestones were developed by the VHA Occupational Health Program Office and covered patient care ergonomics, patient handling equipment, SPH policy, patient assessment forms, algorithms, and peer leader development. For each of 36 milestone items, the respondent could answer any of the following: did not start this task, started this task but did not complete it, or have completed this task. Furthermore, facility coordinators were asked if they had updated a list of 10 key stakeholders groups. They were also asked if they had made progress in developing their facility's SPH policy which should have included seven core program components.

The Program Dose Survey measured the degree of deployment of SPH program elements. The survey was developed by the research team and was composed of the following three sections: (1) percent of program elements deployed, (2) percent handling equipment installed, and (3) adequacy and usage of equipment. Section 1 contained 10 elements including ceiling lifts, policy, competency evaluations, peer leader program, staff involvement in equipment selection, after actions reviews, assessments forms, routine orientation of new clinical staff, marketing program, and bariatric program. For each element, patient care areas (acute care, ambulatory care, long-term care, diagnostic, morgue, and therapy) received percent implementation scores. In section 2, percent equipment coverage was recorded for each nursing unit (acute care, ambulatory care, long-term care, diagnostic, morgue, therapy, and spinal cord injury). Finally, for section 3, the facility coordinator was asked to rate the adequacy and usage of the equipment, number of patient handling devices, number of slings, use of devices by caregivers over manual handling, and how the facility was situated to implement the program from completely disagree to completely agree (5 points).

The Program Status Report was developed by the investigators to examine human factors associated with implementing the program, and was organized into five sections: (1) facility coordinator demographics, (2) caregiver training, (3) peer leader program, (4) marketing, and (5) program support. Each section contained at least one open-ended question generally related to



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effectiveness. The last portion of the survey contained open-ended questions about facilitators, barriers, and customization of program implementation.

In section 1 of the Program Status Report, the survey collected data on the demographic patterns and turnover of the facility coordinator. All coordinators were asked about the implementation of their position as the facility coordinators (with 0, 25, 50, 75, or 100% implemented as anchors). The position development questionnaire included questions about the status of the job description, maintenance of position, role expectations, succession planning, and role orientation. The coordinators were also asked to rate their own effectiveness in implementing the program from extremely effective to extremely ineffective (based on a 5-point Likert scale). In section 2, they rated the caregiver training for the five patient areas (acute care, ambulatory care, long-term care, diagnostic, morgue, and therapy) with 0, 25, 50, 75, or 100% implemented as anchors. In section 3, the coordinators completed a grid based on the number of peer leaders needed, trained, vacant positions, and the number who had received annual training for each of five patient care areas. Similar to their self-rating, the coordinators also rated peer leaders for two areas: (1) position development and maintenance such as job description, role expectations, succession planning, role orientation, and whether they have selected persons to cover each shift in all care clinical, and (2) overall effectiveness of peer leaders in implementing the program. The marketing section contained two questions about the development of a marketing plan and the implementation of the plan, with 0, 25, 50, 75, or 100% implemented as anchors. In the last section, the coordinators rated the support received from 12 individual persons or groups regarding the program, for example, facility senior leadership and peer leaders, using a 5-point Likert scale from extremely supportive to extremely unsupportive.

Injury data and staff demographics were collected from VA Nursing Outcomes database, Nurse Staff Injury database, along with reports on incident records from the Automated Safety Incident Surveillance Tracking [22]. The Automated Safety Incident Surveillance and Tracking System was created in 2003 to track work-related injuries and illnesses and to serve as a data collection repository for Occupational Safety and Health Administration, VA headquarters, regional directors, and facility safety managers. We collected the 2004 (first year available) through 2011 data on MSIs associated with lifting and repositioning patients among direct care nursing occupations (nurse, practical nurse, and nursing assistant).

Nurses have the highest number of injuries in the VA and make up the greatest percentage (31% as of 2011) of workers in the VA. MSI data extraction was restricted to direct care nursing occupations and the anatomical sites of back, abdomen, and trunk. MSI incidence rate, defined as the number of injuries and/or illnesses per 10,000 full-time nursing occupation employees, is calculated as follows: Incidence rate=(N/EH)×20,000,000. In this formula, N is the number of back, abdomen, or trunk injuries; EH is the total hours worked by nursing employees (nurse, practical nurse, and nursing assistant) during the fiscal year; and 20,000,000 resulted from 10,000 equivalent full-time nursing occupation employees (working 40 hours per week, 50 weeks per year).

Bed days of care data was extracted from the National Bed Control System file, which is available from the VHA Support Service Center [22]. This dataset is designed to assist facilities by monitoring their authorized, operating, and unavailable bed capacity at a specific point in time (eg, the last day of each month or fiscal year).

The VHA's 2011 Facility Complexity Model classification is based on seven standardized criteria [23]: (1) volume and patient case mix, (2) clinical services provided, (3) patient risk calculated from VA patient diagnosis, (4) total resident slots, (5) an index of multiple residency programs at a single facility, (6) total amount of research dollars, and (7) the number of specialized clinical services [23]. The 2011 model identified five ranking complexity levels: 1a, 1b, 1c, 2, and 3, where 1a is the most complex and 3 is the least complex.

### *Tier 2*

The Peer Leader Survey was developed by the investigators and distributed to all peer leaders at each of the 17 regions included in Tier 2. The survey contained 28 items organized into following four sections: (1) demographics, (2) perceived support for the program, (3) peer leader job activities, and (4) effectiveness ratings by peer leaders (of themselves and also their facility coordinators). The nine demographic questions concerned their work, such as employment duration at this hospital, area of specialty, and length of time as a peer leader. The peer leaders rated the support received from individual persons or groups (eg, VHA senior leaders, other peer leaders) regarding the program. They were asked to indicate the number of times they had done a specific job activity during the past week, for example, demonstrating the use of patient handling equipment or dealing with a problem that arose while operating the lifting device.

The staff survey was developed by the investigators to capture information on: (1) demographics, (2) culture of safety, (3) job satisfaction, and (4) personal injury severity. The same demographic questions used in the Peer Leader Survey were repeated in the staff survey also. Two of the eight components of the Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture [24] were used to capture the culture of safety; these included "nonpunitive response to error" and the "feedback and communication about error" dimensions. The survey has acceptable evidence for reliability and validity and is widely used in hospital settings [25].

The Stamps and Piedmont Index of Work Satisfaction Instrument was used to measure job satisfaction for nurses [26]. With permission of the instrument author, the investigators made a single modification to the survey to be inclusive of all caregiver positions and accomplished this by changing all "nursing" profession references to "in your profession" or other similar language. Past use of the Index of Work Satisfaction Instrument indicates that an SPH program resulted in increased job satisfaction for 5 of the 6 components (pay, professional status, task requirements, autonomy, and organizational policies)



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with statistically significant increases in both the professional status and the task requirements components [26].

To capture information on staff injury incident related to patient handling in the past 6 months, 12 questions were asked. Follow-up questions included: where they received treatment for the injury, what type of treatment they received, how many treatment visits were needed, how the treatment was paid for, how many days in total were taken off, and how many days the staff person worked on a restricted or modified duty basis. These questions were previously created for a prior study on the VA SPH program [14].

### *Tier 3*

Data was collected through site visits, which included individual interviews, focus groups, observations, and taking photographs. Data collection tools for this tier included: (1) previsit clinical coordinator phone call script, (2) interview guide (individual or focus group), and (3) unit observation walk-around checklist.

The previsit clinical coordinator phone call script was used to (1) collect data on the SPH policy of the facility, (2) identify key informants and others for interviews during the site visit, and (3) identify a unit that was doing well with implementing SPH and a unit that was struggling to implement SPH. During the call, coordinators were told to recruit key informants for the site visits, from the safety committee chair, industrial hygienist, occupational medicine physician, engineering service chief, peer leaders, the nurse executive, and nurse mangers. Altogether, they were asked to recruit 27-34 individuals for each site visit. A list of potential candidates was emailed to the facility coordinator. The interview guide for individuals and focus groups contained a general overview of procedures, ground rules, and confidentiality. Interview questions asked about roles in the program, what was working well and not, barriers and facilitators to program implementation, strategies to overcome barriers or customize the program, and surprises in implementation, sustainability, and support. Peer leaders, facility coordinators, managers, and administrators were further prompted to explain their roles and reasons for choosing those roles. Prompts and storytelling techniques were used to stimulate the discussion. For example, staff members were asked to describe a recent interaction with another staff member regarding the program.

The unit walk-around checklist included general questions for staff about their perceptions of the SPH program and targeted questions on the number of beds, number of ceiling lifts, method of equipment handling, training received, sling storage, equipment maintenance, and comfort in using equipment. Open-ended questions addressed the availability of equipment, supervisory support, protocols on the unit, and who would they go to for help regarding SPH and when.

## Data Collection Procedures

Data collection for Tier 1 included extractions from several VA extant databases including Veterans Affairs Nursing Outcomes database, Automated Safety Incident Surveillance and Tracking System, Bed Cube, and the Human Resources Employee Cube. Data were extracted using ProClarity Microsoft software [27] and exported into a spreadsheet and Statistical Analyses System [28] software for analysis. All three facility surveys (ie, Milestone Questionnaire, Program Dose Survey, and Program Status Report) were sent to each facility coordinator who then returned completed surveys using a traceable mail service, an exclusive fax, or an encrypted email within the VHA firewall.

The survey instructions to the facility coordinators explained that the hospital or regional director might want to see responses to the Milestone Questionnaire, but responses to the Program Status and Program Dose questionnaires should not be shared.

In Tier 2, the local site investigators sent emails to invite the peer leaders of their facilities asking them to participate in the survey. A separate email invitation was sent to the frontline staff to participate in the staff survey. All recruitment materials and survey instructions stated that the surveys were completely voluntary, that no rewards would be given for participation, and that the surveys would remain anonymous. Participants in both Peer Leader and Staff surveys were offered the options to fill out the survey either online or using paper-and-pencil version of the survey. The same security procedures were followed for either option as described in Tier 1.

For Tier 3, we collected data during previsit phone calls with facility coordinators, 1- to 2-day visits to facilities and during post-site visit activities. Using a scripted guide, during previsit phone calls, investigators planned site visits with the facility coordinator, requested SPH policies, and finalized logistics of the site visit. During the site visits, experienced investigators conducted 1-hour-long semistructured interviews with key informants (individuals and focus groups) using the interview guide. During the unit walk-arounds, the facility coordinator or other staff escorted investigators to selected units where they made observations, conducted informal interviews with caregivers, and photographed places and persons to capture activities illustrative of key concepts and local innovations. After the site visit, investigators conducted debriefings to note significant observations, identify preliminary conclusions and gaps in data, and determine if changes in approaches to data collection or in the use of data collection instruments were warranted. Post-site visit activity also included document review of the facility SPH policy.

## Data Quality: Missing Data

Missing data can be a potential problem in any large-scale longitudinal study, particularly those that rely, in part, on administrative data systems. To minimize missing data in Tier 1, the project manager maintained a database to track incoming data and followed up by phone calls and emails to increase response rates. The milestone survey was an administrative requirement associated with program funding; therefore, high response rate was expected.

All survey data were scanned into a database using Teleform [29]. Efforts were made to identify and correct errors in data collection, coding, and entry. Keystroke error rate computed on a 10% sample of the data was found to be less than 2%, which ensures accuracy. Data cleaning was initiated early during the data collection; this process allowed us to limit propagation of any systematic error during subsequent stages of data handling.



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To ensure data quality of interviews, experienced focus group facilitators and individual interviewers conducted all interviews. Data collection and analysis ran concurrently in the interviews, that is, feedback was obtained as conclusions were drawn; an assistant recorded notes of discussions during the focus groups; audio tape recordings of interviews were used to ensure no material was missed during analysis; and analysis was conducted by two investigators. The data record of Tier 3 included notes from the pre-site visit interviews and unit walk-around observations, field notes written by site visitors, transcripts of the interviews and focus groups, and photographs taken during the unit observations for all site visits.

## Statistical Analysis Plan

### *Overview*

The study used a prospective cohort of facilities, in observation design with up to five waves of data collection points over time. Because the SPH program was already implemented by all VAMC facilities before the evaluation study was established, there will be no intervention-control groups for testing comparative effects of the SPH program. Therefore, we propose a standard approach to investigating causal effects in designs without a control group. That is, our design can yield strong causal inferences mainly by reducing the plausibility of alternative explanations for the program effects [30]. Given the multicomponent nature of the SPH program coupled with a 3-tiered data collection process, we specified our hypotheses in general terms initially. Simplified and more specific version of each general hypothesis for each tier is described in the following text.

### *Tier 1*

Summary scores for each program component will be produced as a continuous measure for each facility at each data wave, and dose-response approach to analysis will be used. Where appropriate, the scores from Tier 1 survey data will be calculated as average over time to obtain a single score per facility before they are used as predictors in a model. To investigate our primary outcome (ie, injury incidence rate of caregiver patient handing), a more specific H2 is: after accounting for contextual factors (Bed Days of Care, Facility Complexity, and baseline MSI incidence rates), higher scores on SPH implementation, strength, and SPH uptake measures will be significantly associated with (1) lower 2011 MSI incidence rates and (2) greater decline of MSI incidence rates over the study period. The more specific H3 can be explained as follows: the effects of contextual factors on MSI incidence rates will be moderated by SPH implementation and SPH uptake. A multiple regression model of 2011 MSI incidence rates with contextual factors as predictors will test H1. For H2a, H2b, and H3, SPH components and contextual factors will be included as predictors, respectively, in (1) a multiple regression model of 2011 MSI incidence rates, (2) a growth curve model of repeated observations of MSI incidence rates over time, and (3) additional testing of two-way interactions between SPH components and contextual factors in the regression models. The models will evaluate the direct effects of the SPH program components on MSI rates, as well as moderation of the effects of contextual factors by program components. The growth model will facilitate a greater understanding of the individual facility differences in change in MSI incidence rates over time. Parallel hypotheses will be similarly tested for handling-related patients' injuries and costs outcomes.

To accommodate both linear and nonlinear relationships in the data, the Generalized Additive Model method available in the R package *mgcv* [31] will be used. A major strength of Generalized Additive Model is that it employs scatter plot smoothers which are nonparametric techniques that define data relationships in a flexible way, thereby relieving the user from the need to search for the appropriate transformation for each predictor [32-34]. The coefficients of each SPH program component and its interaction(s) will capture the magnitude and direction of that SPH program component effects, adjusted for other covariates in the model. For the overall SPH program effects, we will identify optimal subset of the components that significantly explains the greatest amount of unique variance (estimated as $R^2$) in the outcome in the most parsimonious way, that is, variation explained in addition to the proportion already explained by a base model containing only non-SPH program variables.

A two-level latent growth curve model will be specified (ie, time at level 1 nested within facility at level 2). The time trends of MSI incidence rates (level 1) will be characterized by estimated growth parameters for individual facilities. Simultaneously, the growth parameters will be modeled as dependent variables that are predicted by facility-level variables (level 2), for example, by contextual factors and SPH component scores. The estimated growth parameters including intercept, linear slope, and quadratic slope will, respectively, approximate initial MSI incidence rate, rate of decline of MSI incidence rate, and acceleration of decline of MSI incidence rate. Only the first two parameters need to be estimated and modeled if prior graphical examination reveals linear trends, or if the estimated quadratic parameter is not statistically significant. Within the structural equation model framework, the contextual factors will be added first to the model as plausible alternative explanatory variables for the growth factors, followed by SPH program components (eg, SPH uptake). This will allow SPH components to explain systematic patterns of MSI incidence rates over time across facilities while accounting for alternative sources of variation in these patterns. We will explore two options to incorporate SPH program scores in the growth model. The first option will use each program component score averaged over time per facility as a static (time-invariant) predictor variable. The second option will apply the repeated assessment scores of each component as a dynamic (time-varying) predictor variable having different values at different time points. To investigate the meditational process of SPH program effects, we will test a number of specific H4: for example, higher levels of Peer Leader effectiveness (predictor) will lead to increased use of equipment (mediator), which will cause reduction in MSI incidence rate (outcome); and the proportion of the total effects of predictor on outcome that is mediated can also be determined using a single mediator model [35]. The growth and mediation modeling will be performed using Mplus Version 6 statistical application [36].



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### *Tier 2*

Since individual facilities but not persons can be linked across the four assessment occasions at Tier 2, two approaches can be adopted to analyze both Staff and Peer Leader surveys: (1) choosing a single time point (eg, Feb 2011 job-satisfaction data to which all 17 facilities contributed; N=1643 staff), and (2) analyzing change over time using data aggregated at the facility level (N=17 facilities). Consistent with our global H2, here we hypothesize that after accounting for contextual factors, higher scores on SPH implementation strength and/or SPH uptake measures will be significantly associated with (1) higher staff job satisfaction and (2) steeper positive trend in staff job satisfaction over the study period. In keeping with H3, we also hypothesize that contextual factors (eg, culture of safety) will be significantly associated with SPH program implementation strength (eg, amount of training).

In the first approach, a multilevel analysis will be appropriate given the nested structure of the data (individuals are nested within facility). Therefore, to test a variable-specific H2(a), a two-level regression model will be used to examine Feb 2011 staff job satisfaction (individual level 1) as a function of predictors both at the individual level (eg, staff demographics, professional experience) and at the facility level (eg, SPH program implementation scores, Bed Days of Care). For another specific H2(b), a growth model will test the predictive effects of the scores of SPH program implementation (averaged over time) on the trajectory of staff job satisfaction as described by growth parameters including intercept (initial status) and linear slope (rate of change), while adjusting for other covariates. To test hypothesis H3, a regression model of program implementation strength (eg, policy development) will be fitted to include contextual factor (culture of safety) aggregated at facility level as a predictor. All modeling will be performed in Mplus [36].

### *Tier 3*

In the qualitative tier, all electronic interview and focus group files, field notes, documents, and photographs were transcribed verbatim or scanned and stored on a secure VA server with access only by the research team. All files were loaded into the qualitative computer analysis software program ATLAS.ti to systematically develop a code book that catalogued and organized defined codes. Qualitative data were analyzed using a content analysis approach that used memos, process mapping, and diagramming to describe, categorize, and connect the data to determine common themes. For this purpose, analysts (1) assigned first level codes to units of meaning, (2) synthesized codes into complex categories, (3) compared and contrasted the categories to identify relationships across categories, (4) grouped categories into a taxonomic structure that described the data set, and (5) linked representative sections of text to the categories to identify salient quotes that illustrated the codes and constructs and that supported the coding decisions. Multiple sites, interviews, focus groups, and observations allowed for methodological triangulation, thereby increasing likelihood of credible findings.

Logistically, Drs. Besterman-Dahan and Elnitsky led the qualitative data analysis and Dr. Powell-Cope provided consultation as needed. In later stages of the project, additional analysts joined the qualitative team. Initially, the team members compared and contrasted perceptions of key findings following interviews, focus groups and observations at individual sites. The analysis strategy of the project was as follows: (1) data analysts reviewed the first few transcripts and developed codes independently, (2) they reviewed their work together and through consensus agreed on codes and definitions, (3) they continued to double code transcripts making memos and including field notes where relevant, and (4) after 90% agreement was attained, they coded transcripts independently using the common codebook. Every fifth coded transcript they met to review randomly selected portions for agreement, and discrepancies were discussed and decisions were made jointly to determine whether new codes were needed. Data analysts met regularly to review ongoing coding results and resolve coding issues.

### Ethics Approval

Approval for the study was obtained by the VA Research and Development Committees and the associated Institutional Review Boards at the evaluation center facility and all facilities participating in Tiers 2 and 3. Approval for Tier 1 data collection, with a waiver of informed consent was sought and granted from the Department of Research and Development, James A Haley Veterans Hospital and from the Institutional Review Board, University of South Florida, in Tampa Florida. For Tiers 2 and 3 data collection, permission from each site respective VA Research and Development Department and Institutional Review Board were sought and obtained. To maintain anonymity, we received waivers of written informed consent for Tier 2 Peer Leader and Staff surveys. We obtained written informed consent for all interviews conducted and all photography of persons in Tier 3.

## Results

All three tiers of data for this study have been collected. We are now in the analyses and writing phase of the project, with the possibility for extraction of additional administrative data. This study evaluates the effects associated with the national implementation of a comprehensive SPH program that was implemented nationally in all 153 VAMCs to reduce patient handling injuries.

## Discussion

### Overview

To our knowledge, this is the largest evaluation of an SPH program in the United States. The direct cost of treating an average back injury case is US $19,000, with serious cases involving surgery costing as much as US $85,000 [37]. The large numbers of nursing professionals at risk of back injury in the VA system is the rationale for this research. With the data collected, as the administrative data, we have the opportunity to ascertain the impact of the program on nursing back injuries and other outcomes such as job satisfaction. This could result in a reduction of direct cost due to the potential reduction in the number of injuries. Another benefit of the research is the ability



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to examine program implementation and sustainability. The VA is continuously at the forefront of program implementation for patients and the health care workers. This study will look at links between the outcomes and the role of moderating variables, such as program dose and organizational factors on the outcome. The qualitative sections will answer contextual questions about barriers and sustainability of the program.

### Limitations

However, there are some potential limitations in this study. The lack of experimental groups for comparison is a limitation of the present design, particularly at Tiers 1 and 2. Another major concern is that the potential SPH program effects may be compounded with cohort effects (changes and variations occurring irrespective of intervention as the cohort of facilities moves through time). However, these limitations have been partially addressed by the adoption of dose-response approach and do not constitute a serious threat to the study design and inferences based on the results.

A major strength of this observational study design is that all existing 153 VAMCs implemented the program and are included in Tier 1. Therefore, population sampling bias in relation to tests of program effects is not a concern. Moreover, unlike the typical experimental and controlled designs, our nonexperimental one-cohort design in which repeated data points capture differential program implementation rates across all VAMC facilities and over time better approximates a "real-world" situation. Although designs without control groups make it difficult to know what would have happened without an intervention, the differential program implementation or intervention exposure rates (across facilities and over time) allow us to tap into some information about what might have happened to facilities had the SPH program not been implemented in terms of degree and timeliness. Also, the longitudinal setting for this study establishes a temporality critical for establishing a cause-and-effect relationship among key variables, while also accounting for competing time effects (eg, as intrafacility change at level 1 of the growth model). To enhance external validity of findings from Tier 2 data, some degree of control was instituted for the sample selection. In this part of the study, 17/21 (81%) regions were represented.

### Conclusions

In conclusion, VA-wide implementation of the SPH program afforded the opportunity for rigorous evaluation in a naturalistic context. In the process, we are posed to contribute to implementation science in health care by linking program dose and quality to outcomes. Outcomes will be useful for VA operations for policy and resourcing decision making, and to health care outside of the VA in decision making about SPH programming.

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### Conflicts of Interest

None declared.

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## Abbreviations

**MSI:** musculoskeletal injuries
**SPH:** safe patient handling
**VAMC:** Veterans Administration Medical Center
**VHA:** Veterans Health Affairs

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Original Paper

# Development and Validation of a Web-Based Survey on the Use of Personal Communication Devices by Hospital Registered Nurses: Pilot Study

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## Abstract

**Background:** The use of personal communication devices (such as basic cell phones, enhanced cell phones or smartphones, and tablet computers) in hospital units has risen dramatically in recent years. The use of these devices for personal and professional activities can be beneficial, but also has the potential to negatively affect patient care, as clinicians may become distracted by these devices.

**Objective:** No validated questionnaire examining the impact of the use of these devices on patient care exists; thus, we aim to develop and validate an online questionnaire for surveying the views of registered nurses with experience of working in hospitals regarding the impact of the use of personal communication devices on hospital units.

**Methods:** A 50-item, four-domain questionnaire on the views of registered nursing staff regarding the impact of personal communication devices on hospital units was developed based on a literature review and interviews with such nurses. A repeated measures pilot study was conducted to examine the psychometrics of a survey questionnaire and the feasibility of conducting a larger study. Psychometric testing of the questionnaire included examining internal consistency reliability and test-retest reliability in a sample of 50 registered nurses.

**Results:** The response rate for the repeated measures was 30%. Cronbach coefficient alpha was used to examine the internal consistency and reliability, and in three of the four question groups (utilization, impact, and opinions), the correlation was observed to be very high. This suggests that the questions were measuring a single underlying theme. The Cronbach alpha value for the questions in the performance group, describing the use of personal communication devices while working, was lower than those for the other question groups. These values may be an indication that the assumptions underlying the Cronbach alpha calculation may have been violated for this group of questions. A Spearman rho correlation was used to determine the test-retest reliability. There was a strong test-retest reliability between the two tests for the majority of the questions. The average test-retest percent of agreement for the Likert scale responses was 74% (range 43-100%). Accounting for responses within the 1 SD range on the Likert scale increased the agreement to 96% (range 87-100%). Missing data were in the range of 0 to 7%.

**Conclusions:** The psychometrics of the questionnaire showed good to fair levels of internal consistency and test-retest reliability. The pilot study demonstrated that our questionnaire may be useful in exploring registered nurses' perceptions of the impact of personal electronic devices on hospital units in a larger study.

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**KEYWORDS**

cellular phones; Internet; electronic mail; text messaging; nurses; distraction; medical staff/psychology; attitude of health personnel; survey methodology; questionnaire design

## Introduction

The use of personal communication devices including Internet surfing, text messaging, and emailing has increased in recent years. Electronic tools such as basic cell phones, enhanced cell phones (smartphones), and tablet computers are becoming mainstream, and numerous positive benefits of personal communication devices are cited in the literature. They provide clinicians with rapid access to medical references and patient information [1]. They are used for medical consultation [2], documentation [3], and patient education [4], and applications have been created for many clinical specialties [5-8].

There is much debate about whether online distractions, regardless of whether they are personal or professional in nature, can prove hazardous in medical settings, potentially distracting health care workers from patient care (termed "distracted nursing") [9]. For example, the Joint Commission for the Accreditation Organization [10] and the United States Pharmacopeia through MEDMARX analyzed medication error reports and found that 43% of medication errors in hospitals were attributable to workplace distractions [11]. The ECRI Institute, a nonprofit health care research organization, publishes an annual top 10 technology hazards list. The ninth hazard on this list for 2013 was "Caregiver distractions from smartphones and other mobile devices" [9]. Concern among surgeons about distraction caused by the use of cellular telephone technology in the operating room led the American College of Surgeons to issue a statement (ST-59). The statement says, "the undisciplined use of cellular devices in the [operating room]—whether for telephone, e-mail, or data communication, and whether by the surgeon or by other members of the surgical team—may pose a distraction and may compromise patient care" [12].

Rapidly increasing technology fosters multitasking because it promotes multiple sources of input. A key concern about such multitasking is that this increase in simultaneous media consumption decreases the amount of attention paid to each device [13,14].

Several studies have reported the effects of using personal communication devices while driving [15]. It has been reported that drivers react more slowly to brake lights and stop signs during phone conversations [16], and additional driving studies have shown that peripheral vision is reduced when using a cell phone [17]. These studies have led to numerous new state laws prohibiting the use of personal communication devices for calling, texting, or both while driving.

Based on this research and findings that interruptions to patient care are common in hospitals [18] and may contribute to errors in said care, we chose to initiate a study into how "distracted nursing" might affect patient care in a hospital setting. For the purpose of this research, we propose the development and validation of an online survey to identify the concerns and opinions of registered nurses who had experience of working in hospitals regarding the effects of using personal communication devices while on duty in hospital units. This paper sets out the process for the development and initial testing of an online survey. We hypothesize that, in the future, the information obtained from this survey could be used to determine policies for the use of personal communication devices on hospital units to minimize risks to patients.

## Methods

### Questionnaire Research and Development Process

#### *Domain Identification*

In our literature review, we searched the Cumulative Index to Nursing and Allied Health, PubMed, and Dissertation Abstractions International databases for relevant publications on distraction and communication devices related to health care workers in the 2003-2012 period. As the term "cellular phone" was first introduced as a MeSH keyword in 2003, we selected this year as the starting point. The search terms for the present research were as follows: "cellular phones", "Internet", "computers, portable", "electronic mail", "text messaging", "nurses", "healthcare workers", "distraction", "medical staff/psychology", and "attitude of health personnel".

#### *Item Development*

We reviewed previous questionnaires used in surveys related to distraction and personal communication devices and included the following as items in our survey: opinions about how cell phones impact team effectiveness [19], registered nurses' opinions about cell phone use and patient safety [20], and frequency of Internet use for personal activities at work [21].

A total of 64 potential survey items were identified based on criteria outlined by DeVellis [22]. These survey items were reformulated, assessed, refined, or rejected in collaboration with a nursing team with knowledge about questionnaire methodology, consisting of 3 faculty members at nursing schools, all of whom had worked as nurses for more than 20 years. The items were also discussed with a unit manager and 2 hospital nurses, all of whom were certified clinical nurse specialists and had worked for more than 10 years on their nursing units.

#### *Format of the Questionnaire*

The 50-item pilot questionnaire adhered to the recommendations of Bowling [23]. The first item in the questionnaire asked respondents to choose a 4-digit identification number that they would be asked to provide again in the second survey to assist us in matching their test-retest surveys while remaining anonymous.

A total of 10 survey items used a drop-down menu asking respondents to select one answer, including the demographics: gender, age, race/ethnicity, type of workplace setting, and primary nursing practice position. The demographic questions were developed in accordance with the Forum of State Nursing



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Workforce Centers for Standardizing Nursing Workforce Data [24].

There were 2 types of questions following the initial demographic questions. The first type aimed to gain straightforward numerical-type data through the use of three different 4-point Likert scales (1) “strongly disagree”, “disagree”, “agree”, and “strongly agree”; (2) “>5 times”, “2-5 times”, “once”, and “never”; and (3) “strongly negative”, “slightly negative”, “slightly positive”, and “strongly positive”. No scale had a “don’t know” option. The second type of question probed the reasoning behind why respondents had answered specific Likert-scale questions (“If yes, please describe”) or asked them to state recommendations.

The other 5 items using drop-down menus, where respondents were asked to select one answer, sought their opinion of personal communication device use while at work (2 items), hospital policy concerning the use of device in hospital units, how concerned their employer is about nonwork-related use of personal communication devices, and their awareness of their employer disciplining or terminating the employment of a nurse for excessive personal communication device use while working.

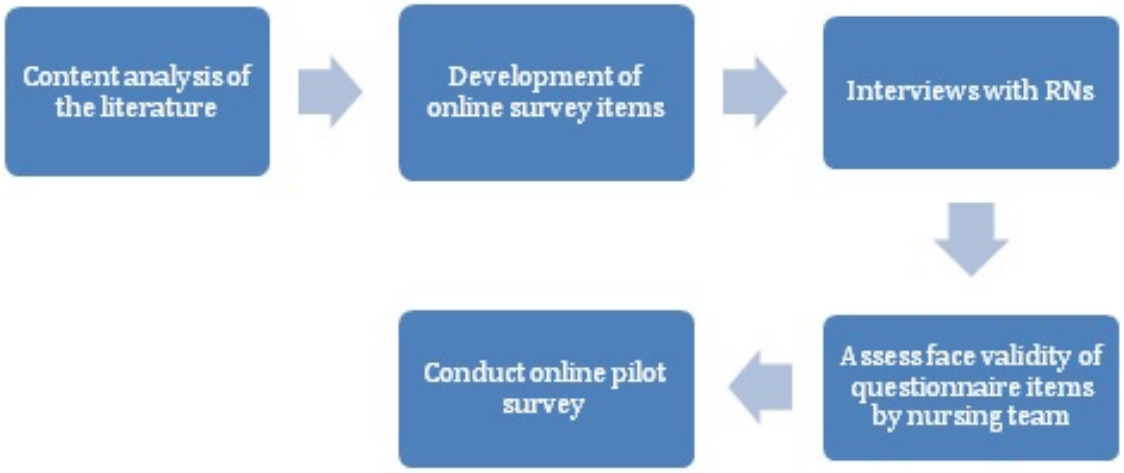
The survey then included a total of 32 Likert-type questions that consisted of: 14 questions on personal communication device use on hospital units; 9 questions on the effects of these devices on job performance, and specifically, how they affect patient care; 6 questions on how the devices influence coordination and teamwork; and 3 questions on how nurses think patients or other health care providers perceive a nurse using their personal communication device during work time.

Following the Likert-type questions, there were 7 open-ended questions. One question asked respondents to provide a description of their hospitals’ personal communication device policy. Another one queried respondents’ opinions about how these devices should be used in hospital units. Respondents were asked in another question to address the overall impact of these devices on nursing units. Two of the questions asked for examples of how personal communication devices had positively or negatively affected a nurse’s performance. One question queried respondents if they were aware of a situation where their employer had disciplined or terminated the employment of anyone for excessive use of a personal communication device at work and, if so, to describe the situation. The last question asked respondents for any additional comments about the use of personal communication device in hospital units.

## Validation Process

The validation process is set out in Figure 1, and was based on criteria proposed by Terwee et al [25]. First, the items for inclusion were developed from a content analysis of the literature as described above. Informal interviews with a small convenience sample of registered nurses using personal communication devices on general medical-surgical units took place to identify themes relevant to nurses working in clinical settings. A team of 3 nursing experts assessed the initial 64 items selected for face validity and content validity [26]. Finally, the number of items was reduced to 50 for the pilot online questionnaire.

**Figure 1.** The validation process for the development of the online survey.



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### Online Pilot Survey

Following the validity testing, an online pilot survey was conducted in November 2012, with 50 registered nurses associated with acute care settings in Honolulu, Hawaii and the San Francisco Bay area in California. Only registered nurses who had worked in a hospital unit for at least 5 months in the previous 2 years were eligible to participate in the survey.

For the pilot online survey, two versions of the same questionnaire were created with questions randomly arranged within blocks of grouped questions. The registered nurses were invited to participate in the survey and asked to complete two separate online questionnaires, accessed via a hyperlink email sent 1 week apart. The interval between the two questionnaires was set for 1 week because it limits the recall of responses but does not generally allow enough time for respondents to have altered their attitudes or behaviors [21,26]. The random arrangement of questions within each block was to check that there was no order effect bias [27].

No literature was found to have similar study settings to our pilot project. A sample size could not be calculated from power analysis, but a sample size of 12 per group is a useful principle based on experience, according to Julius [28]. A sample of 50 registered nurses was chosen for the pilot study considering a conservative 50% nonresponse rate. We planned to use data collected from the pilot study to determine power and sample size for a larger online survey.

### Data Analysis

The pilot online survey data were downloaded to Excel (version 14.2.5, Microsoft Corporation), and statistical analyses were performed using SPSS version 21 (SPSS Inc). Descriptive statistics were used to examine missing data and the floor and ceiling effects [26]. Spearman correlation coefficients were used to examine test-retest reliability for agreement with the level of significance set at $P<.05$. Cronbach alpha was used to examine the grouped question items for internal consistency reliability and kappa scores to measure reliability.

The online questionnaire comments were analyzed using the meaning condensation method introduced by Kvale and Brinkmann [29] in which the main sense of what is said is rephrased into more succinct formulations, and content analysis [30].

### Ethics

Based on the Code of Federal Regulations 45 CFR 46 (2), this online pilot study was exempt from institutional review board approval. Permission to conduct the exempt study was granted by the University of Hawaii Human Subjects Committee on September 13, 2012. All participants were informed in writing of the purpose of the study, that participation was voluntary, and that responses were anonymous.

## Results

### Respondents

The overall response rate for the pilot survey is shown in Table 1. Of the 50 invited respondents, 15 (30%) respondents completed both the test and retest online surveys. Table 1 also presents background information of the participants in the pilot surveys. The mean age of the 15 respondents answering both online surveys was 49.23 (SD 10.2) years. Respondents who completed both surveys were primarily female 13/15 (87%), and 35/50 (70%) participants were missing/nonresponders.

### Face and Content Validity

Based on the responses to the open-ended questions, the respondents in the pilot online survey understood the questions. Respondents considered the questions relevant, and none found areas lacking. In response to discussions with experienced colleagues in nursing research methodology, we made minor adjustments to phrasing and response options in multiple-response questions.

### Reliability and Agreement

In the pilot survey, 19/32 responses (59%) to the 4-point Likert-scale questions covered all response categories. However, the variability in answers was not spread evenly across all questions. Test-retest reliability for respondents who completed both questionnaires was determined by intrarespondent percent agreement for each of the Likert-type questions. The results indicate that 74% (range 43-100%) of the answers to the questions were the same for both questionnaires (Tables 2-5); accounting for responses within the 1 SD range on the Likert scale increased the agreement to 96% (range 87-100%).

Cohen's kappa was calculated for each Likert-scale question on the online test/retest pilot survey to assess the items' inter-rater agreement. Comparing the answers from the two versions of the questionnaire, the mean Cohen's kappa for the Likert-scale questions was .41 (41%, range .67 to −.057). A kappa of 1 indicates perfect agreement, whereas a kappa of 0 indicates agreement equivalent to chance [31].

The discrepancy between the relatively low kappa results and the high percent of agreement is most likely due to the sensitivity of kappa to small sample sizes (n=15). It is also possible that the registered nurses undergoing the survey changed their attitudes during the 1-week interval between the two questionnaires. Such a shift could have been subtle, but any difference results in a lower kappa value.



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**Table 1.** Respondent demographics in the first, second, or paired test-retest online surveys (N=50).

| | | First survey, n (%)[a] | Second survey, n (%)[a] | Paired surveys, n (%)[a] |
|---|---|---|---|---|
| **Gender** | | | | |
| | Total respondents | 39 (78) | 21 (42) | 15 (30) |
| | Male | 5 (10) | 2 (4) | 2 (4) |
| | Female | 34 (68) | 19 (38) | 13 (26) |
| | Missing; nonrespondents | 11 (22) | 29 (58) | 35 (70) |
| **Age, years** | | | | |
| | Total respondents | 39 (78) | 21 (42) | 15 (30) |
| | <30 | 1 (2) | 0 (0) | 0 (0) |
| | 30-40 | 5 (10) | 3 (6) | 3 (6) |
| | 40-50 | 8 (16) | 5 (10) | 4 (8) |
| | 50-60 | 12 (24) | 8 (16) | 6 (12) |
| | >60 | 13 (26) | 5 (10) | 2 (4) |
| | Missing; nonrespondents | 11 (22) | 29 (58) | 35 (70) |
| **Race/ethnicity** | | | | |
| | Total respondents | 38 (76) | 21 (42) | 15 (30) |
| | American Indian or Alaska Native | 0 (0) | 1 (2) | 1 (2) |
| | Asian | 1 (2) | 1 (2) | 1 (2) |
| | Black/African American | 0 (0) | 0 (0) | 0 (0) |
| | Native Hawaiian/Pacific Islander | 2 (4) | 0 (0) | 1 (2) |
| | White/Caucasian | 31 (62) | 19 (38) | 12 (24) |
| | Hispanic/Latino | 1 (2) | 0 (0) | 0 (0) |
| | Other | 3 (6) | 0 (0) | 0 (0) |
| | Missing; nonrespondents | 12 (24) | 29 (58) | 35 (70) |
| **Workplace setting** | | | | |
| | Total respondents | 39 (78) | 21 (42) | 15 (30) |
| | Hospital | 17 (34) | 9 (18) | 8 (16) |
| | Nursing home/extended care | 1 (2) | 1 (2) | 1 (2) |
| | Home health | 1 (2) | 0 (0) | 0 (0) |
| | Academic setting | 16 (32) | 6 (12) | 3 (6) |
| | Ambulatory care setting | 1 (2) | 0 (0) | 0 (0) |
| | Insurance claims/benefits | 1 (2) | 1 (2) | 1 (2) |
| | Other | 2 (4) | 3 (6) | 2 (4) |
| | Missing; nonrespondents | 11 (22) | 29 (58) | 35 (70) |
| **Position title** | | | | |
| | Total respondents | 39 (78) | 21 (42) | 15 (30) |
| | Consultant/nurse researcher | 1 (2) | 1 (2) | 1 (2) |
| | Nurse executive | 0 (0) | 2 (4) | 0 (0) |
| | Nurse unit manager | 3 (6) | 2 (4) | 1 (2) |
| | Nurse faculty | 17 (34) | 7 (14) | 4 (8) |
| | Advanced practice nurse | 2 (4) | 0 (0) | 1 (2) |
| | Staff nurse | 13 (26) | 7 (14) | 6 (12) |
| | Charge nurse | 1 (2) | 1 (2) | 1 (2) |



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| | | First survey, n (%)[a] | Second survey, n (%)[a] | Paired surveys, n (%)[a] |
|---|---|---|---|---|
| | Other—health related | 1 (2) | 1 (2) | 1 (2) |
| | Other—not health related | 1 (2) | 0 (0) | 0 (0) |
| | Missing; nonrespondents | 11 (22) | 29 (58) | 35 (70) |
| **Personal communication device (PCD)** | | | | |
| | Total respondents | 30 (60) | 19 (38) | 15 (30) |
| | Do not have a PCD | 2 (4) | 1 (2) | 1 (2) |
| | Basic PCD (cell phone only) | 4 (8) | 2 (4) | 2 (4) |
| | PCD (cell phone and texting) | 3 (6) | 3 (6) | 3 (6) |
| | PCD (cell phone/texting/Internet/email/apps) | 21 (42) | 13 (26) | 9 (18) |
| | Tablet computer | 0 (0) | 0 (0) | 0 (0) |
| | Missing; nonrespondents | 20 (40) | 31 (62) | 35 (70) |

[a]Percentages may not sum due to rounding.

**Table 2.** Respondents with the same answers to both online pilot surveys for Group 1: utilization scale.

| Please select the column that best describes your opinion about the use of personal communication devices by nurses at work. | Never, n (%) | Once per day, n (%) | 2-5 times per day, n (%) | >5 times per day, n (%) | Spearman rho | *P* |
|---|---|---|---|---|---|---|
| I access work-related drug references. | 8 (53) | 1 (7) | 0 (0) | 0 (0) | .862[b] | <.001 |
| I access work-related nursing/medical information. | 6 (40) | 3 (20) | 2 (13) | 0 (0) | .750[b] | .001 |
| I use the device as a calculator for nursing/medical formulas. | 4 (40) | 2 (13) | 0 (0) | 1 (7) | .858[b] | <.001 |
| I access work-related protocols. | 7 (47) | 3 (20) | 0 (0) | 0 (0) | .605[a] | .02 |
| I access work-related apps that assist patient care. | 9 (60) | 2 (13) | 1 (7) | 0 (0) | .603[a] | .02 |
| I access sites for professional education and development. | 6 (43) | 2 (14) | 0 (0) | 0 (0) | .603[a] | .02 |
| I access sites for patient handouts and teaching. | 10 (71) | 1 (7) | 0 (0) | 0 (0) | .994[b] | <.001 |
| I use it to communicate with other members of the health care team to coordinate patient care. | 7 (50) | 2 (14) | 2 (14) | 0 (0) | .914[b] | <.001 |
| I check/send personal text messages or emails to family or friends. | 4 (27) | 2 (13) | 2 (13) | 0 (0) | .638[a] | .01 |
| I shop on the Internet. | 13 (87) | 0 (0) | 0 (0) | 0 (0) | −.071 | .80 |
| I check/post on social networking sites (Facebook, Twitter, etc) (excluded from analysis because of lack of variation in responses). | 14 (93) | 0 (0) | 0 (0) | 0 (0) | -[c] | -[c] |
| I play online games. | 12 (86) | 0 (0) | 0 (0) | 0 (0) | .734[b] | .003 |
| I check/send nonwork-related text messages or emails to coworkers. | 6 (43) | 0 (0) | 0 (0) | 0 (0) | .386 | .17 |
| I conduct personal business online (eg, paying bills, banking). | 13 (87) | 1 (7) | 0 (0) | 0 (0) | .681[b] | .005 |

[a]Correlation is significant at the .05 level (2-tailed).

[b]Correlation is significant at the .01 level (2-tailed).

[c]Cannot be computed because at least one of the variables is constant.



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**Table 3.** Respondents with the same answers to both online pilot surveys for Group 2: performance scale.

| Please select the column that best describes use of your personal communication device while working (excluding breaks or meal times). | Never, n (%) | Once per shift, n (%) | 2-5 times per shift, n (%) | > 5 times per shift, n (%) | Spearman rho, n (%) | *P* |
|---|---|---|---|---|---|---|
| My personal communication device for nonwork-related activities has distracted me (reversed scale). | 8 (53) | 3 (20) | 0 (0) | 0 (0) | .443 | .11 |
| My personal communication device for nonwork-related activities has negatively affected my performance (reversed scale). | 10 (77) | 1 (7) | 0 (0) | 0 (0) | .362 | .22 |
| I have witnessed nurses whose personal communication devices have negatively affected their performance (reversed scale). | 4 (29) | 5 (36) | 0 (0) | 1 (7) | .704[a] | .005 |
| My personal communication device for nonwork-related activities has helped me focus on my work. | 6 (43) | 4 (29) | 0 (0) | 0 (0) | .463 | .10 |
| My personal communication device for nonwork-related activities has positively affected my performance. | 7 (50) | 5 (36) | 0 (0) | 0 (0) | .708[a] | .005 |
| I have witnessed nurses whose personal communication devices have positively affected their performance. | 6 (46) | 4 (31) | 1 (7) | 0 (0) | .750[a] | .003 |
| I have made a medical error that was a result of distraction caused by use of my personal communication device (excluded because of lack of variation in responses). | 13 (93) | 0 (0) | 0 (0) | 0 (0) | -[b] | -[b] |
| I have witnessed another nurse making a medical error that was the result of distraction caused by his/her use of a personal communication device (excluded to lack of variation in responses). | 14 (93) | 0 (0) | 0 (0) | 0 (0) | -[b] | -[b] |
| I am aware of a serious medical accident that was the result of a nurse being distracted while using his/her personal communication device (excluded because of lack of variation in response). | 14 (100) | 0 (0) | 0 (0) | 0 (0) | -[b] | -[b] |

[a]Correlation is significant at the .01 level (2-tailed).

[b]Cannot be computed because at least one of the variables is constant.

**Table 4.** Respondents with the same answers to both online pilot surveys for Group 3: impact scale.

| Please select the column that best describes your opinion about nurses' use of personal communication devices at work. | Strongly disagree, n (%) | Disagree, n (%) | Agree, n (%) | Strongly agree, n (%) | Spearman rho | *P* |
|---|---|---|---|---|---|---|
| Use of personal communication devices in nursing units has enabled better coordinated patient care among nursing/medical teams. | 3 (21) | 3 (21) | 4 (29) | 0 (0) | .411 | .15 |
| Use of personal communication devices in the nursing unit improves unit cohesion and teamwork. | 3 (21) | 3 (21) | 4 (29) | 0 (0) | .059[a] | .02 |
| Use of personal communication devices in the nursing unit improves patient safety. | 2 (14) | 2 (14) | 4 (29) | 0 (0) | .468 | .11 |
| Personal communication devices in the nursing unit are beneficial to patient care. | 1 (7) | 1 (7) | 4 (29) | 0 (0) | .161 | .60 |
| Use of personal communication devices at work helps me resolve personal issues quickly and improves my ability to focus on work. | 2 (14) | 2 (14) | 2 (14) | 0 (0) | .283 | .33 |
| Use of personal communication devices at work reduces work-related stress and improves patient care. | 2 (14) | 1 (7) | 3 (21) | 0 (0) | .489 | .09 |

[a]Correlation is significant at the .05 level (2-tailed).



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**Table 5.** Respondents with the same answers to both online pilot surveys for Group 4: opinion scale.

| Please select the column that best describes your opinion about nurses' use of personal communication devices at work. | Strongly negative, n (%) | Negative, n (%) | Positive, n (%) | Strongly positive, n (%) | Spearman rho | *P* |
|---|---|---|---|---|---|---|
| How do you feel about nurses when you see them using their personal communication devices on the unit? | 3 (21) | 4 (29) | 1 (7) | 0 (0) | .648[a] | .01 |
| How to you think patients feel when they see a nurse using his/her personal communication device on the unit? | 6 (43) | 5 (36) | 0 (0) | 0 (0) | .645[a] | .01 |
| How do you think other health care staff feel when they see a nurse using his/her personal communication device on the unit? | 4 (29) | 8 (57) | 0 (0) | 0 (0) | .073[b] | .003 |

[a]Correlation is significant at the .05 level (2-tailed).

[b]Correlation is significant at the .01 level (2-tailed).

## Internal Consistency

For the purposes of measuring survey reliability using Cronbach alpha, the survey was organized into 4 groups: (1) utilization of personal communication devices in nursing units, (2) effects of personal communication devices on registered nurses' performance, (3) registered nurses' opinions about personal communication device use and patient safety, and (4) registered nurses' knowledge about hospital policy concerning personal communication device use in hospital units.

Several modifications were required to Group 2 questions. The final 3 questions (see Table 3, Group 2 questions) were excluded from the reliability analysis because nearly all respondents gave a response of "Never" to these questions. This lack of variation in the responses made it impossible to calculate reliable statistics, so the analysis used only the 6 remaining questions from Group 2. Of the 6 remaining questions, 3 dealt with negative events, whereas the other 3 dealt with positive events. To ensure consistency in the interpretation of the responses, the response scale was reversed for the 3 negative questions so that when calculating reliability statistics for this group, a positive response to a negative question was counted the same way as a negative response to a positive question. The 7 open-ended questions were excluded from the reliability analysis, as they did not share a common scale with the other questions.

## Reliability of Grouped Questions

Cronbach alpha (ranging between 0 and 1) was selected as the most appropriate statistical analysis for testing the reliability of grouped questions because it can be used on ordinal data, such as the Likert scale. Higher alpha values imply a greater degree of correlation or inter-relatedness, with .7 generally considered a minimally acceptable value for reliability [31].

Table 6 shows the Cronbach alpha statistic for each of the four sets of grouped questions. For each survey, two analyses of the datasets were run: (1) inclusion of all survey respondents (ie, includes respondents who completed only one questionnaire), and (2) inclusion of only those respondents who completed both questionnaires. The unpaired alpha values make use of all of the available data to produce a reliability estimate based on as many responses as possible, but may be susceptible to selection bias if there is a systematic pattern in the types of respondents who completed both surveys. The paired values eliminate this concern by ensuring that the same set of respondents is included in both Week 1 and Week 2 calculations, but sacrifice sample size to achieve this. Before computing these reliability statistics, all the responses to these questions were converted to a simple number scale, assigning integer values to each response ("never", "strongly disagree", or "strongly negative" was converted to 1; "once a day", "disagree", or "slightly negative" was converted to 2; "2-5 times per day", "agree", or "slightly negative" was converted to 3; ">5 times per day", "strongly agree", or "strongly positive" was converted to 4). No attempt was made to quantify the answers or the gaps between them accurately; the scale was kept simple for convenience.

Table 6 shows that the measured reliability of 3 of the 4 question groups (utilization, impact, and opinions) was high, indicating that responses in these groups tended to be highly correlated. This suggests that the questions were measuring a single underlying theme. For these 3 groups, the reliability remained high in both weeks, and there was little variation based on whether all responses or only paired responses were included.

The Cronbach alpha value for Group 2 performance questions, describing use of personal communication devices by registered nurses while working, was notably lower than that for other question groups. The Week 2 values indicated that responses were fairly consistent, but the Week 1 responses displayed a very low Cronbach alpha value of .08, or −.35 if only paired responses were examined.

Because of the lack of variation in responses, 3 questions from Group 2, related to medical errors, and 1 question from Group 1, which asked respondents if they posted on social networking sites while working, were excluded from the survey.



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**Table 6.** Cronbach alpha for grouped survey questions.

| Question group | Week 1 | | Week 2 | |
|---|---|---|---|---|
| | All responses | Paired responses | All responses | Paired responses |
| Group 1: Utilization | .83 | .76 | .92 | .84 |
| Group 2: Performance | .08 | −.35 | .63 | .45 |
| Group 3: Impact | .89 | .96 | .97 | .96 |
| Group 4: Opinion | .82 | .89 | .89 | .85 |

### Floor and Ceiling Effect

The floor and ceiling effect is detected using the measures of central tendency of the data, including mean and median, as well as the range, SD, and skewness [24]; a score would be considered acceptable if the values are distributed in a normal or bell-shaped curve, with the mean near the midpoint of the scale. Some criteria for floor and ceiling effects recommend a skewness statistic between −1 and +l as acceptable for eliminating the possibility of these effects.

Responses to the Likert scales revealed that 16/32 (50%) questions on the pilot online survey had a ceiling effect (ie, higher than the recommended maximum of 15%). However, given the small sample size of the pilot online survey, floor/ceiling effect criteria could not be applied to the survey results.

### Open-Ended Questions

A total of 33/50 respondents (66%) from the pilot study added comments (some example comments are included in Table 7).

**Table 7.** Comments provided in response to open-ended questions in online pilot surveys.

| Question | Comment |
|---|---|
| If you have witnessed the use of personal communication devices negatively affecting either your or another nurse's performance, please describe here. | I have witnessed nurses' cell phones ringing while at the patient's bedside. The nurse answers it and walks away from the patient. I have also witnessed nurses staying at the nurses' station on their devices. |
| If you have witnessed the use of personal communication devices positively affecting either your or another nurse's performance, please describe here. | I receive one text message per day when my husband leaves his night shift work at the jail. I know he is safe and I can concentrate on my work. |
| Are you aware of your employer disciplining or terminating a nurse employee for excessive use of his/her personal communication device for nonwork-related activities while working? If yes, please describe here. | Staff in Labor and Delivery were on Facebook. Management declared that these employees were using employer's assets during work time. |
| Please describe how you think an employer should handle the use of personal communication devices at work. | Ringer must be put into vibrate mode only. Personal communications can be made only during breaks. Use for patient-related care should be encouraged. |

### Responsiveness

Responses to the online pilot survey were segmented by demographic variables (eg, gender, ethnicity, age, and job title). We performed regression analyses to determine if any divergent attitudes and/or behaviors based on demographics were statistically significant. None were statistically significant because of the small sample size.

### Missing Data

In the online pilot survey, the first dataset had an average percentage of missing data of 1.2% and the second dataset of 0.04%.

In the paired composite data, there were 35 missing answers, resulting in 0.03% missing data. However, only one respondent was responsible for 17/35 missing answers (48%) in the paired composite data. Eliminating this respondent reduced the sample size to 14 pairs and the percent of missing data to 0.01%. In analyzing the data, a listwise deletion was used because the percentage of missing data was small (<5%) and the listwise deletion has been shown to provide unbiased estimators [32].

## Discussion

### Principal Findings

The present study describes a validation process to examine the psychometrics of a newly developed questionnaire concerning the views of registered nurses on the impact of the use of personal communication devices on nursing units. It concludes that initial findings suggest that the questionnaire is a reasonable way to assess registered nurses' perceptions of use of personal communications devices. However, more work is needed to test it on a larger sample.

The test-retest results were found to be only fair to moderate [33]. This can be attributed to the following two reasons: (1) a small test-retest sample increases the statistical error and results in a low Cohen's kappa value, and (2) many questions relate to experiences and attitudes regarding personal communication device issues, which may change during a 1-week period. The changes within the 1 SD range from test to retest on the Likert scale indicate that even with the small sample, the stability is acceptable.



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No specific questions had more than 7% missing data, and the percentage of missing data did not increase toward the end of the surveys, indicating that respondents did not consider the questionnaire to be too lengthy.

Unknown factors could confound the differences identified in this study. Despite the small sample size, significant differences were found in specific areas where a focus on utilization issues and guidelines for use on nursing units would be expected to have an impact. Although none of the units where the respondents were working had formal policies on personal communication device use that were enforced, it is considered likely that the guidelines and general focus on utilization issues could be major contributors to the differences among registered nurses based on the surveys. As such, it is plausible that our questionnaire will detect differences among a larger sample of surveyed nurses.

With respect to construct validity, most of the questions were direct (ie, they were asked directly about the construct they wished to measure). This increases the chance of the instrument actually measuring the desired construct. The comments added by the respondents indicated that the questions had been understood and responded to as expected. According to Terwee et al [25], conducting surveys among health care professionals involves a fairly homogenous group to whom personal communication devices are well known. This also increases the chances of the instrument measuring the desired concepts.

### Validation Concerns

Tests for internal consistency and criterion validity may also be conducted during the validation of questionnaire instruments [22,25]. However, this was not applicable for the present instrument because there is no objective standard against which to test the correlation.

Another weakness of the validation study was the small sample size of the study. Because measuring the relation between nonresponse and the accuracy of a survey statistic is complex and expensive, few rigorously designed studies provided empirical evidence to document the consequences of lower response rates, until recently. Keeter et al[34] compared the results of a 5-day survey employing the Pew Research Center's usual methodology (with a 25% response rate) with those from a more rigorous survey conducted over a much longer field period, achieving a higher response rate of 50%. In 77 of 84 (91%) comparisons, the two surveys yielded results that were statistically indistinguishable. Among the items that manifested significant differences across the two surveys, the differences in proportions of people giving a particular answer ranged from 4 percentage points to 8 percentage points. Holbrook et al [35] assessed whether lower response rates are associated with less unweighted demographic representativeness of a sample. By examining the results of 81 national surveys with response rates varying from 5% to 54%, they found that surveys with much lower response rates were only minimally less accurate. Nevertheless, the small initial sample size did both increase the statistical error in the test-retest analysis and prevent extensive subanalyses in the comparison between the two tests. Further testing with a much larger sample would be necessary to overcome this limitation.

The low Cronbach alpha values for Group 2 questions may indicate that the assumptions underlying the Cronbach alpha calculation have been violated for this group of questions. In other words, the questions may not all be measuring the same underlying dimension, or the coding for some questions may need to be reversed. However, examining this set of questions in a variety of alternative ways (eg, not inverting the scale for negative questions) did not consistently increase the alpha values. Some of these modifications increased the estimate of reliability for Week 1 for at least some subsets of questions, but generally at the expense of the reliability for Week 2 or other question subsets. These results indicate that it may not be logical to consider the questions in this group as representative of a single underlying dimension.

Alternatively, the low Cronbach alpha score associated with these questions may reflect a tendency among respondents to underrecognize their own distraction, or a discomfort in reporting self-use. Nurses' reported observations of other registered nurses' use of personal communication devices were higher than the self-reported results. This discrepancy may be because nurses did not believe that they were distracted. In a study of drivers, Lesch and Hancock [36] found that drivers did not recognize that their driving ability worsened when they were using a cell phone. Strayer et al [37] also noted that drivers using cell phones described other drivers with cell phones as driving inconsistently, but believed that their own performance was unaffected, even when results showed otherwise. This led the researchers to believe that cell phone use may make drivers unaware of their own attention deficits. In the pilot survey, the participants' ambivalence about answering these difficult questions may therefore have been responsible for the low Cronbach alpha scores, but the importance of the answers argues for keeping the questions on the survey. The self-reported rate versus reporting of other nurses' behavior will provide a useful comparison in future studies.

The Cronbach alpha for the utilization scale (Group 1) was higher than that for the performance scale (Group 2). This may be because it is easier to identify specific behaviors associated with the use of personal communication devices than attitudes and values associated with job performance. Although the items in the performance scale appear related to one another and to the concept of behavior associated with job performance, they had low inter-item correlations. This indicates that there was some acceptable commonality among some of the items. Despite these acceptable correlations, the alpha for the factor was lower than desirable, implying that the items may not in fact belong together. These results may reflect the complex role of performance in nursing and the fact that although job performance is an important concept, it may not be possible to encapsulate it easily in a question.

### Limitations

Several limitations of the present study should be acknowledged. Self-selection bias affects any survey that allows respondents to decide whether to participate. To mitigate this potential problem, we compared the characteristics of the respondents in our study with those of California-based registered nurses and found that the respondents in our study were not systematically



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different from those of the state's average registered nurse in terms of gender, age, race/ethnicity, job title, and experience with personal communication devices. However, this is a potential problem should the survey be used elsewhere and more widely, and similar tests will need to be carried out to ensure there is no self-selection bias. Discussions during the validation process suggested that some responses might be skewed by the fact that respondents may prefer not to admit that they made a medical error or that their performance had suffered as a result of their use of personal communications devices. For this reason, questions were rewritten for the survey questionnaire to ask if respondents had seen other registered nurses making a medical mistake because of distraction caused by their personal communication device or if they knew of a major medical error that had been caused by a registered nurse who was similarly distracted. By reducing self-reporting in this manner, it was hoped that underreporting of "bad" behavior resulting from said distraction would be lessened.

In addition, the validation process was conducted in the United States. As the use of personal communication device varies in different cultures and across professions, the questionnaire may not be easily translated to other countries or professions. However, we believe that it will be useful as a model to develop different national questionnaires.

### Next Steps

The work set out in this paper is very much a preliminary stage in a much larger piece of work. We have reported on the initial development and pilot testing of an online survey to assess registered nurses' views on the use of personal communication devices. The next step is to make some specific changes, and then use the survey in a proposed study of California registered nurse licensees. The following three specific changes have been proposed for the survey. First, the definition of "personal communication device" needs to be clarified. There may have been some confusion about whether a hospital-owned device such as an electronic device should be considered as a personal communication device. When using the survey with a larger group, we plan to include a definition of "personal communication device" at the beginning, to make clear that it is the one that is owned by the nurse, and used for personal business or family matters, as compared with professional or work-related activities.

Second, the type of unit that the registered nurse respondent is working on may have some sort of bearing on the use of personal communication devices, for example, in terms of the levels of concentration required of nurses.

Finally, the length of time during use as well as the frequency of device use should also be kept in consideration.

The results of the proposed study will provide data concerning the use of personal communication devices on nursing units and the opinion of nurses on the potential impact, both positive and negative, of personal communication devices on patient safety. These data may inform hospital policies and practices concerning the use of personal communication devices on hospital units. An acceptable hospital policy needs to be based on evidence and should aim to create a reasonable balance between work-related and personal use.

### Suggestions for Future Research

In future, it may be helpful to expand the survey to include additional questions to identify times and places where important information is transferred or interaction occurs, such as during attending rounds, morning huddle, or at the bedside. Mitigation techniques could also be surveyed to better understand how respondents handle distraction caused by their or others' personal communication devices.

### Conclusions

Knowledge about personal communication practices in hospital units is important to improve clinical practice and patient care, and a valid questionnaire assists in detecting the issues that need to be improved. Our results describe the development of one possible online questionnaire to establish registered nurses' views concerning the impact of personal communication devices on hospital units. Statistical tests showed both good and moderate areas of validity of the questionnaire. The psychometrics performed on the survey questionnaire indicated that the survey has the potential to be a useful tool to assess hospital nurses' perceptions of personal communication device use in the workplace, and we plan to use it to carry out a wider survey of nurses in California in the future.

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## Conflicts of Interest

None declared.

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Original Paper

# Purposive Facebook Recruitment Endows Cost-Effective Nutrition Education Program Evaluation

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## Abstract

**Background:** Recent legislation established a requirement for nutrition education in federal assistance programs to be evidence-based. Recruitment of low-income persons to participate and evaluate nutrition education activities can be challenging and costly. Facebook has been shown to be a cost-effective strategy to recruit this target audience to a nutrition program.

**Objective:** The purpose of our study was to examine Facebook as a strategy to recruit participants, especially Supplemental Nutrition Assistance Program Education (SNAP-Ed) eligible persons, to view and evaluate an online nutrition education program intended to be offered as having some evidence base for SNAP-Ed programming.

**Methods:** English-speaking, low-income Pennsylvania residents, 18-55 years with key profile words (eg, Supplemental Nutrition Assistance Program, Food bank), responded to a Facebook ad inviting participation in either Eating Together as a Family is Worth It (WI) or Everyone Needs Folic Acid (FA). Participants completed an online survey on food-related behaviors, viewed a nutrition education program, and completed a program evaluation. Facebook set-up functions considered were costing action, daily spending cap, and population reach.

**Results:** Respondents for both WI and FA evaluations were similar; the majority were white, <40 years, overweight or obese body mass index, and not eating competent. A total of 807 Facebook users clicked on the WI ad with 73 unique site visitors and 47 of them completing the program evaluation (ie, 47/807, 5.8% of clickers and 47/73, 64% of site visitors completed the evaluation). Cost per completed evaluation was US $25.48; cost per low-income completer was US $39.92. Results were similar for the FA evaluation; 795 Facebook users clicked on the ad with 110 unique site visitors, and 73 completing the evaluation (ie, 73/795, 9.2% of ad clickers and 73/110, 66% of site visitors completed the evaluation). Cost per valid completed survey with program evaluation was US $18.88; cost per low-income completer was US $27.53.

**Conclusions:** With Facebook we successfully recruited low-income Pennsylvanians to online nutrition program evaluations. Benefits using Facebook as a recruitment strategy included real-time recruitment management with lower costs and more efficiency compared to previous data from traditional research recruitment strategies reported in the literature. Limitations prompted by repeated survey attempts need to be addressed to optimize this recruitment strategy.

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**KEYWORDS**

nutrition education; folic acid; family meals; low-income; food security; Facebook; SNAP-Ed

## Introduction

A diet rich in nutrients and metabolites, as well as a physically active lifestyle with a balance between energy intake and expenditure are established components of health and vigor. Public health campaigns focus on nutrition education as a preventive medicine approach. Nutrition education has been defined as "…any combination of educational strategies accompanied by environmental supports, designed to facilitate voluntary adoption of food choices and other food- and nutrition-related behaviors conducive to health and well-being



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and delivered through multiple venues, involving activities at the individual, institutional, community, and policy levels" [1]. This definition has been adopted by the Supplemental Nutrition Assistance Program Education (SNAP-Ed), which is the educational arm of the Supplemental Nutrition Assistance Program (SNAP), formerly known as the food stamp program. SNAP-Ed, which is administered by the Food and Nutrition Services (FNS) of the United States Department of Agriculture, has budgeted US $401 million in Federal Fiscal Year 2014 to provide sound nutrition education to persons eligible to participate in SNAP and other income-based federal assistance programs [2].

Requirements for these nutrition education programs, as outlined in the SNAP-Ed Guidance [3], follow from the Healthy, Hunger-Free Kids Act of 2010 (Public Law 111-296), Section 241 that amends the Food and Nutrition Act of 2008. It includes, among other mandates, that SNAP-Ed activities are *evidence-based* [3]. Not as stringent as the Institute of Medicine or the National Institute of Health's Roadmap, but aligned with the transdisciplinary model to accommodate behavioral and social sciences [4], an evidence-based approach in SNAP-Ed activities is defined as "…the integration of the best research evidence with the best available practice-based evidence. The best research evidence refers to relevant rigorous nutrition and public health nutrition research including systematically reviewed scientific evidence. Practice-based evidence refers to case studies, pilot studies, and evidence from the field on nutrition education interventions that demonstrate obesity prevention potential" [3]. FNS expects SNAP-Ed practitioners to offer interventions with an evidence base derived from either a review of research or a SNAP-Ed operator-led evaluation documenting that the intervention is meaningful to the intended audience and has a desired impact on behavior [3]. Across disciplines, a critical component of establishing the evidence base for an intervention or treatment is the client perspective [4]. Program evaluation documents the clients' needs, values, and perspectives and thus, is an integral step in the process toward developing evidence-based practice.

Challenges in designing and implementing cost-effective and useful public health program evaluations have been well documented [5-9]. A related Cochrane Collection review recommended the need for more good-quality studies with interventions that effectively promote adherence to dietary advice [10]. Nutrition education programs that are not evaluated by the target audience do not fulfill any criteria of being evidence-based. Therefore, to implement the SNAP-Ed Guidance, attention to recruiting SNAP-eligible persons to nutrition education evaluation activities is vital.

Facebook was shown to be a cost-effective, useful tool to recruit young adults to a tobacco use survey [11] and the advertising mechanism of Facebook allowed effective and low cost recruitment of low-income women to a nutrition education program. However, retention to view and evaluate the nutrition program was not tested [12]. Review of literature on social media use supported studies of mechanisms to monitor and enhance health communication quality [13]. Thus, the purpose of our study was to examine Facebook advertising as a strategy to recruit participants, especially SNAP-eligible persons, to view and evaluate an online nutrition education program intended to be offered with some evidence base for SNAP-Ed programming.

## Methods

### Study Design and Recruitment

Facebook advertising was the recruitment strategy for two digitally delivered nutrition programs: *Eating Together as a Family Is Worth It* (*WI*) and *Everyone Needs Folic Acid* (*FA*). Facebook advertising offers two billing mechanisms: cost per click on the ad (CPC) or cost per appearance (or impression) of the ad to the target audience (CPM). Actual charges for each mechanism are based on competition for the target audience. A range of competitive bids is suggested at the time of ad development, which can be revised at any time to enhance ad competitiveness [14]. For each program evaluation, 3 routine Facebook advertising set-up functions were determined: costing action, daily spending cap, and population reach. Both the *WI* and *FA* evaluations utilized the CPC costing option; CPC bids were revised twice during the course of each evaluation to increase Facebook page impressions. Expenditures for each program were limited to US $100/day.

Audience reach (ie, the number of people who will see the ad) was calculated by Facebook, which was influenced by a number of demographic limitations (eg, age range, geolocation, and gender). Reach projections were revealed while delimiters and key words were entered. Ad development was considered complete when the projected target audience reached 124,460 and 201,380 for *WI* and *FA*, respectively. Ads targeted English-speaking, low-income Pennsylvania residents, 18-55 years with key profile words (eg, SNAP, food bank, and need money). *WI* and *FA* Facebook impressions each consisted of a short title, image with caption, and brief text, which included the ability to earn a US $15 gift card (Table 1). Finalized ads were submitted to Facebook for approval. The Institutional Review Board of the Office of Research Protections at Pennsylvania State University approved the studies and participants consented online. After clicking on the Facebook ad, respondents were directed to the welcome page on our secure website and left the Facebook platform. Confidentiality of the participants was maintained by unique codes for identification, securely encrypted data, and storage in password protected computers and servers.



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**Table 1.** Facebook ads.

| Facebook ad | | Cost per campaign | Survey started | Program evaluation | Low-income[a] survey started | Low-income[a] program evaluation |
|---|---|---|---|---|---|---|
| **Eating Together as a Family is Worth It** | | | | | | |
|  | Let Penn State study know of your family meals and if our info helps. Earn US $15 Wal-mart Card | US $1197.45 | US $16.40 | US $25.48 | US $32.36 | US $39.92 |
| **Folic Acid is for Everyone** | | | | | | |
|  | Earn US $15 gift card in-stantly for your thoughts on a Penn State research lesson: Folic Acid | US $1321.52 | US $12.01 | US $18.88 | US $24.03 | US $27.53 |

[a]Low-income defined as sometimes, often, or always worry about money for food and/or use of an income-based assistance program.

## Data Collection Process and Instruments

Data collection was staggered: *WI* data collection was completed prior to the start of the *FA* evaluation. Recruitment was realized with a click on the impression, which linked to the informed consent and agreement to participate (Figure 1). Participation required access to the survey link; the open survey format did not require password entry. As shown in Figure 1, respondents who clicked on the ad were linked directly to a Qualtrics platform (version 1527s, Qualtrics Labs Inc., Provo, UT; 2013), website that included a welcome page and a study consent form. On agreement to participate, subjects were invited to (1) complete a profile-oriented pre-evaluation survey, (2) view the program, and (3) respond to program evaluation survey items. In all, respondents completed a 53-item survey delivered across 13 screens.

The pre-program evaluation survey set identified demographics (9 items, included self-report height and weight), meal and food preparation habits (5 items), Internet and Facebook use (5 items), and nutrition assistance program use (eg, SNAP, food banks; 10 items). The survey set included the Satter Eating Competence Inventory for Low-Income (ecSI/LI), a 16-item, validated measure to assess eating competence (EC) [15]. EC refers to an intra-individual approach to eating and food-related behavior [16] that has been associated with several positive health outcomes, including less disordered eating [17], fewer cardiovascular risk factors [18,19], higher dietary quality [19,20], and greater physical activity [21]. ecSI/LI response options ranged from never or rarely (0 points) to always (3 points) so that the total score possible ranges from 0 to 48. Four subscales correlate with the 4 constructs of EC: Eating attitudes; eating context skills (eg, planning healthful meals); food acceptance; and internal regulation of intake. Possible subscale scores range from 0 to 15 for eating attitudes and contextual skills and from 0 to 9 for the remaining subscales.

Traditionally, *FA* and *WI* were designed for delivery on a digital photo frame, video or computer monitor, or a power point show as education to view while waiting for services (eg, in a clinic, grocery store, or government agency). For purposes of this evaluation, each program was converted to a short video loop (approximately 2 minutes long), then inserted into the Web-based survey for viewing after completion of the pre-evaluation survey. A video loop eliminated the need for slide advancement, enhancing program viewing. Respondents were required to view the video at least once in its entirety before advancing to the program evaluation survey; however, the video loop could be viewed as many times as preferred prior to program evaluation.

The evaluation survey completed after viewing the program featured a variety of question types and response options. A list of program descriptors (8 items) was included and respondents selected all statements that were true for them. (eg, I learned a lot. This program was helpful.) Additionally respondents rated the amount of information in the program (not enough, the right amount, or too much) and the speed of the program (needed more time, had enough time, or moved too slowly). Individual slides were displayed and respondents rated each for likability, importance, or clarity with the Likert scale, heat map, and rating scale formats. Participants were encouraged to type in comments and suggestions.



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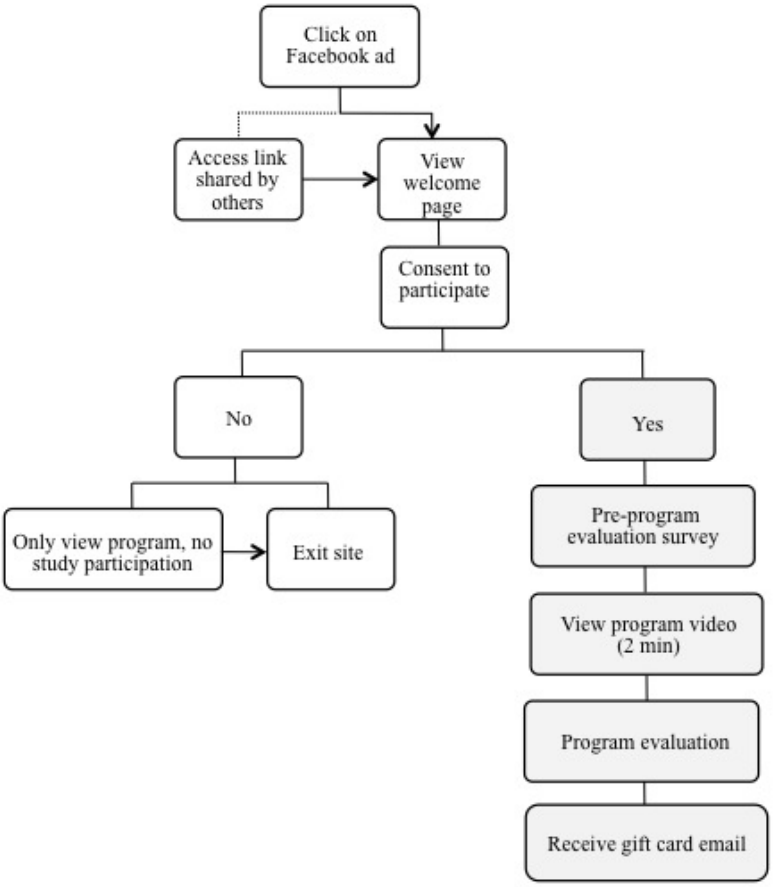
**Figure 1.** Program recruitment and evaluation path.




## Data Analysis

Data were captured with Qualtrics and analyzed using the Statistical Package for Social Scientists (v 20, IBM SPSS, Armonk, NY; 2010). Facebook log data were compiled from Facebook ad manager campaign reports that included daily information such as number of impressions, click-through rates, and expenditure.

A 2-step process eliminated data from repeated survey attempts. First, computer Internet Protocol (IP) addresses were screened for frequency. If an IP address was duplicated, only the initial survey response, as determined by the survey time stamp, was included in the data set. After eliminating duplicate IP responses, email addresses with redundancy were assessed in the log file analyses. If email addresses were very similar, and demographic information (including age, number of children, height, and weight) matched, and the IP address indicated the same geographic area, then only the first survey was included in the data set.

*FA* evaluation also utilized Qualtrics' *ballot-box stuffing* survey protection option as a measure to control repeated survey attempts by preventing a user from taking the survey from the same computer and browser. Participants completing the initial submission of IP-identical surveys with dissimilar entries for age, height, weight, number of children, ages of children, and email addresses were contacted by email to ascertain the probability that subsequent surveys from the same IP address were respondent duplicates. Email contact was made with the initial responder only. Responses to the email query that fit the data were retained. For example, we retained both surveys from the same IP address when our queries confirmed that one respondent was the mother and the other the daughter who used the same computer. Responses that did not fit or were questionable were not included.

Assistance program participation was identified by affirmation. Low-income was defined as using at least one of the means-based assistance programs *or* sometimes, often, or always worrying about money for food. ecSI/LI item responses were summed to provide total and subscale scores. EC was defined as a total score ≥32 [19]. Response rates were calculated as directed in the Checklist for reporting Results of Internet E-Surveys (CHERRIES) [22] using a unique IP address as a proxy for a unique site visitor. The informed consent page was denoted as the first page of the survey. The *view rate* was calculated as the ratio of unique visitors to the first survey page divided by the unique visitors to the study site (ie, the welcome page that appeared after clicking the Facebook ad). The *participation rate* was the number of study consenters divided by unique visitors to the informed consent page. Finally, dividing the number of respondents who completed the last survey page by the number who had agreed to participate was the *completion rate* [22].



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## Results

### Participant Description

Characteristics of *WI* and *FA* program evaluators were similar (Table 2). In general, they were white, under 40 years, overweight or obese and dissatisfied with their weight (mean self-report body mass index, BMI: *WI*, mean 30.0, SD 7.4; *FA*, mean 29.7, SD 8.9), and not eating competent. The *WI* mean ecSI/LI score was: mean 29.76, SD 6.47 (range 12-41). Subscale means were: mean 9.96, SD 2.43 (eating attitude); mean 4.61, SD 2.30 (food acceptance); mean 6.02, SD 1.79 (internal regulation); and mean 8.94, SD 3.01 (eating context). The *FA* mean ecSI/LI score was: mean 28.71, SD 8.22 (range 12-48). Subscale means were: mean 10.19, SD 3.09 (eating attitudes); mean 4.66, SD 2.21 (food acceptance); mean 5.81, SD 2.16 (internal regulation); and mean 8.05, SD 3.26 (eating context).

For both studies, more than half were identified as low-income (*WI*: 37/59, 63%; *FA*: 55/77, 71%). An income-based assistance program was used by 39% (23/59) *WI* and 42% (32/77) *FA*. Always, often, or sometimes worrying about money for food was reported by 51% (30/59) *WI* and 60% (46/77) *FA*.

*WI* and *FA* respondents liked to cook or thought cooking was okay (48/57, 84%; 63/74, 85%, respectively). Most prepared meals at home at least 4 times a week (*WI*: 51/59, 87%; *FA*: 59/77, 77%) and spent 15-45 minutes preparing the meal (*WI*: 48/57, 84%; *FA*: 50/72, 69%). From a list of 5 meal preparation options, in which any or all could be selected, most chose home-style, made from scratch meals (*WI*: 50/72, 69%; *FA*: 51/77, 66%) with speed-scratch from mixes or meal kits ranking as the second most common (*WI*: 36/73, 49%; *FA*: 47/77, 61%). Meals described as healthy, low fat, low-sodium were selected less frequently (*WI*: 28/73, 38%; *FA*: 31/77, 40%).

Facebook access frequency was reported at least daily by 88% (53/60) *WI* respondents, and by 95% (73/77) *FA* respondents. Facebook recruitment revealed two paths: (1) clicking on the Facebook page impression; and (2) Web-link sharing (eg, in an email) by a Facebook friend (30/59, 51% for the *WI* study, and 22/77, 29% for the *FA* study).

### Recruitment and Response Rates

Facebook posted 4,278,732 and 4,192,197 impressions of the *WI* and *FA* ad, respectively, during the study timeline; the higher the daily/competing bid the more often the ad was displayed. *WI* responses were collected over 14 calendar days from April 24 to May 12, but paused on April 25, May 8-9, and part of May 10, for a total of 343 hours. The Facebook campaign was closed on May 15 at noon; however, the survey remained open to responses in Qualtrics for an additional 24 hours. Three surveys were submitted after the Facebook closing date and reached the study site by the second access pathway described above.

A total of 807 Facebook users clicked on the *WI* ad (which represented 807/124,460, 0.6% of potential reach) with 73 unique site visitors and 47 of them completing the program evaluation (ie, 47/807, 5.8% of clickers and 47/73, 64% of site visitors completed the evaluation). Completion pattern analyses revealed afternoon and evening as the most common times with 30% initiating the survey between noon and 6 pm and 47% after 6 pm. Average time spent on the survey site was 14 minutes.

*FA* data were collected over 17 calendar days from September 12 to 29, pausing on September 28 for a total of 384.3 hours reaching 0.4% (795/201,380) of potential accounts.

A total of 795 Facebook users clicked on the ad with 110 unique site visitors, and 73 completing the evaluation (ie, 73/795, 9.2% of ad clickers and 73/110, 66% of site visitors completed the evaluation). Average time spent on the survey site was 20 minutes. Similar to the *WI* program, 49% initiated the survey between noon and 6 pm and 38% after 6 pm.

IP address and log analyses identified 38 *WI* and 9 *FA* duplicate attempts at survey completion; these attempts were from 20 *WI* and 6 *FA* respondents. Psychosocial and demographic (eg, ecSI/LI score, age, self-report BMI, number of children, assistance program use, and low-income status) characteristics were similar between respondents making repeated attempts to complete the survey and those accessing the survey only once. Facebook campaign reach figures are displayed in Table 3.

For the *WI* program, CHERRIES view, participation, and completions rates were 88%, 97% and 76%, respectively. For *FA*, CHERRIES view, participation, and completions rates were 71%, 100%, and 95%, respectively.

Facebook recruitment campaign costs are summarized in Table 1. Evaluation costs related to respondent incentives and personnel are not included.



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**Table 2.** Demographic characteristics of evaluators recruited using Facebook.[a]

| | Full sample, n | | PA residents, n | | Low income,[b] n | |
|---|---|---|---|---|---|---|
| | WI (n=59) | FA (n=77) | WI (n=27) | FA (n=73) | WI (n=37) | FA (n=55) |
| **Body mass index (BMI)** [c] | | | | | | |
| Below 18.5 (underweight) | 2 | 1 | 0 | 1 | 3 | 0 |
| 18.5-24.9 (normal) | 20 | 34 | 22 | 34 | 24 | 33 |
| 25-29.9 (overweight) | 39 | 20 | 33 | 21 | 24 | 22 |
| 30 and above (obese) | 34 | 42 | 41 | 40 | 41 | 42 |
| **Eating competence** [d] | | | | | | |
| Not eating competent | 60 | 73 | 61 | 66 | 83 | 69 |
| **Assistance program use** [e] | | | | | | |
| Supplemental Nutrition Assistance Program | 22 | 29 | 19 | 26 | 35 | 40 |
| Women, Infants, and Children (WIC) | 24 | 21 | 22 | 19 | 38 | 29 |
| Cash assistance benefits | 2 | 9 | 4 | 7 | 3 | 13 |
| Temporary assistance for needy families | 2 | 7 | 4 | 4 | 3 | 9 |
| Medical assistance benefits | 24 | 23 | 33 | 22 | 38 | 33 |
| Medicaid | 14 | 12 | 19 | 8 | 22 | 16 |
| Medicare part D-prescription drug coverage | 7 | 8 | 11 | 8 | 11 | 11 |
| Low income home energy assistance program | 7 | 17 | 15 | 15 | 11 | 24 |
| Expanded food and nutrition education program | 2 | 3 | 4 | 1 | 3 | 4 |
| Food bank or food pantry | 15 | 12 | 26 | 10 | 24 | 16 |
| **Education** | | | | | | |
| Less than high school | 2 | 0 | 4 | 0 | 3 | 0 |
| High school graduate or equivalent | 18 | 21 | 19 | 22 | 23 | 26 |
| Some college or 2-year degree | 28 | 51 | 37 | 49 | 31 | 49 |
| 4-year college degree | 30 | 22 | 19 | 22 | 23 | 22 |
| Postgraduate college | 23 | 7 | 22 | 7 | 20 | 4 |
| **Number of children per household** | | | | | | |
| 1 child | 36 | 41 | 40 | 43 | 32 | 46 |
| 2 children | 44 | 32 | 33 | 33 | 41 | 35 |
| 3 or more children | 18 | 25 | 27 | 20 | 27 | 14 |

[a]Table entry is %, numbers may not add to100 because of rounding.

[b]Low income defined as sometimes, often, or always worry about money for food and/or government assistance program use.

[c]Self-reported height and weight were missing so BMI was not calculated for 5% of WI and 4% of FA participants.

[c]EC is defined as ecSI/LI score ≥32.

[e]More than one choice could be selected.



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**Table 3.** Facebook campaign response (N=).

| Campaign metric | Eating As a Family is Worth It | Everyone Needs Folic Acid |
|---|---|---|
| Clicks on Facebook ad | 807 | 795 |
| Clicks on study welcome page | 111 | 119 |
| Duplicate attempts removed from data set | 38 | 9 |
| Unique site visitors clicked on study welcome page from a unique IP address | 73 | 110 |
| Unique survey visitors visited informed consent page | 64 | 77 |
| Agreed to participate | 62 | 77 |
| Program evaluation started (ie, answered at least 1 item) | 60 | 73 |
| Program evaluation completed | 47 | 73 |

## Discussion

### Principal Findings

This study demonstrated that Facebook was an efficacious and cost-effective strategy to recruit low-income persons to evaluate online nutrition education programs. Findings contributed to the growing body of evidence that Facebook is a useful, lower-cost tool for health communication [13,23], public health surveillance [24], recruitment to health-related surveys [25-27], and online interventions including those targeting weight [28] and physical activity [29].

### Cost Effectiveness and Campaign Management

The findings confirmed that Facebook-driven nutrition education recruitment efforts are a cost-effective means to reach low-income persons. Our costs of US $24.03 (*FA*) and US $32.26 (WI) to recruit each low-income person to a nutrition behavior survey were higher than the US $15.30 reported in an earlier study of Facebook as a strategy to recruit low-income persons [12]. That study, which attracted more participants, had a lower respondent burden because it focused only on recruitment and did not include a program evaluation component. Costs to recruit each low-income participant were much lower than the US $51.59 expended when traditional methods of flyers, postcards, and telephone calls were used [30]. Likewise, costs for each program evaluation completion were more than 55% (*WI*) to 70% (*FA*) lower than the US $94.36 incurred by these traditional recruitment methods [30]. The findings were not delimited by program message because one was nutrient-based and the other focused on family mealtime issues.

Disappointing Facebook recruitment efforts for pre- and perimenopausal women [31] and for targets audiences with conditions or characteristics not easily captured by key words (eg, depression) [32] have been reported. Therefore, like Chu and Snider [25] we adjusted CPC bids and campaign hours to capitalize on our target audience's Facebook routines to promote reach.

### Reaching Low-Income Persons

Nearly two-thirds of respondents were low-income. Each Facebook campaign recruited a low-income sample similar in age, BMI, EC (overall and component constructs), level of worry about money for food [12,15,21,33,34], and food preparation habits [12] to those recruited for other nutrition education studies. Program evaluation was not superficial: 44% (21/48) of *WI* and 15% (11/73) of *FA* evaluators viewed the program more than once, completion rates were high (*WI*: 47/62, 76%; *FA*: 73/77, 95%), and useful program improvement comments were provided. One study limitation was the need to rely on a proxy definition of low-income (ie, worry about money for food or self-reported assistance program use) rather than confirmed records of income, which are difficult to secure and interpret. However, in addition to prior support for use of this index [12], its merit was supported because frequency levels of overweight and obesity (*WI*, $P<.001$; *FA*, $P=.05$) and frequency of a high school or less education (*WI*, $P=.049$; *FA*, $P=.11$) were greater for index-denoted low-income persons; similar to earlier reports [17], a smaller proportion of low-income persons were categorized as eating competent (*WI*, $P<.001$; *FA*, $P=.05$).

### Cautions: Chain Sampling and Repeat Survey Attempts

Facebook is a utility to encourage communication and sharing among friends and this extends to letting friends know how to access a survey with a gift card incentive. This "word of click" access (also known as "chain sampling" [27]) was especially noted in the *WI* evaluation. Although a means to enrich a dataset without paying for Facebook clicks, circumvention of eligibility criteria has the potential to contaminate study outcomes. Our goal to recruit Pennsylvania residents was a funder-imposed goal, thus we included non-Pennsylvania residents in our program evaluation findings and relied on Qualtrics' skip logic to enforce nongeographic eligibility criteria. *WI* respondents living in other states were not dissimilar from the Pennsylvania residents in proportion of low-income, EC, education level, Internet use, amount of worry about money for food, BMI, liking to cook, or participation in SNAP or the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). The only difference noted was that 56% (15/27) of Pennsylvania residents reported cooking each day compared to 25% (8/32) of non-Pennsylvanians ($P=.03$). Only 4 *FA* respondents were not Pennsylvania residents; however, those 4 were similar to Pennsylvanians on all parameters measured with one exception—all out-of-state responders were EC. Consideration of "word of click" recruitment implications will depend on study goals and restrictions. For this study, the



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recruitment of a broader audience to evaluate the nutrition education programs, thereby improving the generalizability of our findings, was a plus. Fenner et al [27] also reported that the participants recruited from Facebook friends' sharing the survey link (ie, chain sampling/word of click) did not influence study outcomes.

Providing gift cards, money, or prizes meant to incentivize study participation or reimbursing respondents for cost incurred to participate (eg, parking, childcare) and access to the survey site resulted in repeated attempts to access and complete the survey. The "ballot box stuffing prevention" feature of the Qualtrics platform prevents duplicate IP addresses from accessing the survey. However, using applications to ensure anonymity may nullify this protection. Our protocol of checking IP and email addresses with follow-up data review and telephone confirmation prevented duplicate payment and ensured database fidelity with minimal personnel effort.

### Future Research

Our focus was the evaluation of an online nutrition education program; however, numerous nutrition education programs (eg, WIC, Expanded Food and Nutrition Education Program) are based on face-to-face classes and meetings. Limited research is available to discern efficacy of Facebook to recruit persons to these on-site programs. Facebook campaigns successfully recruited young women to complete a health-related survey at a conveniently located study site and provided an option for completion online by those declining a site visit. An equal number agreed to come to the study site or accepted an invitation to complete the survey online [27]. The findings encourage use of Facebook to recruit to face-to-face nutrition education programs, especially if they are conveniently located. However, those opting for the online survey format were overweight and in the lowest socioeconomic status, thereby challenging recruitment to programs that serve low-income women, such as WIC.

Facebook ads specifically targeting low-income, Spanish-speaking Latinos could be tested for ability to recruitment to nutrition education programs. An online smoking cessation campaign was shown to be an effective way to recruit Spanish-speaking Latino smokers. However, this campaign utilized 4 websites that did not include Facebook and costs were US $209.34 per participant [35].

### Conclusion

This study confirmed that Facebook is a cost-effective strategy to recruit low-income persons to a nutrition program. Two separate evaluations of a nutrition education program supported the use of Facebook as a cost-effective strategy to additionally recruit low-income persons to view a nutrition education program and provide substantial evaluation. Potential application to recruitment for on-site nutrition education programs (eg, WIC) should be explored. Researchers are cautioned to monitor for duplicate survey attempts and to identify mandatory eligibility criteria to facilitate data management and analyses congruent with study aims.

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### Conflicts of Interest

None declared.

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## Abbreviations

**BMI:** body mass index
**CHERRIES:** Checklist for Reporting Results of Internet E-Surveys
**EC:** eating competence
**ecSI/LI:** Satter Eating Competence Inventory for Low-Income
**FA:** Everyone Needs Folic Acid
**FNS:** Food and Nutrition Services
**IP:** Internet Protocol
**SNAP:** Supplemental Nutrition Assistance Program
**SNAP-Ed:** Supplemental Nutrition Assistance Program Education
**WI:** Eating Together as a Family is Worth It
**WIC:** Special Supplemental Program for Women, Infants, and Children

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