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Contents

Protocols

Original Papers

Proposal

Protocol

Mobile.net: Mobile Telephone Text Messages to Encourage Adherence to Medication and to Follow up With People With Psychosis: Methods and Protocol for a Multicenter Randomized Controlled Two-Armed Trial

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Abstract

Background: Schizophrenia is a high-cost, chronic, serious mental illness. There is a clear need to improve treatments and expand access to care for persons with schizophrenia, but simple, tailored interventions are missing.

Objective: To evaluate the impact of tailored mobile telephone text messages to encourage adherence to medication and to follow up with people with psychosis at 12 months.

Methods: Mobile.Net is a pragmatic randomized trial with inpatient psychiatric wards allocated to two parallel arms. The trial will include 24 sites and 45 psychiatric hospital wards providing inpatient care in Finland. The participants will be adult patients aged 18–65 years, of either sex, with antipsychotic medication (Anatomical Therapeutic Chemical classification 2011) on discharge from a psychiatric hospital, who have a mobile phone, are able to use the Finnish language, and are able to give written informed consent to participate in the study. The intervention group will receive semiautomatic system (short message service [SMS]) messages after they have been discharged from the psychiatric hospital. Patients will choose the form, content, timing, and frequency of the SMS messages related to their medication, keeping appointments, and other daily care. SMS messages will continue to the end of the study period (12 months) or until participants no longer want to receive the messages. Patients will be encouraged to contact researchers if they feel that they need to adjust the message in any way. At all times, both groups will receive usual care at the discretion of their team (psychiatry and nursing). The primary outcomes are service use and healthy days by 12 months based on routine data (admission to a psychiatric hospital, time to next hospitalization, time in hospital during this year, and healthy days). The secondary outcomes are service use, coercive measures, medication, adverse events, satisfaction with care, the intervention, and the trial, social functioning, and economic factors. Data will be collected 12 months after baseline. The outcomes are based on the national health registers and patients' subjective evaluations. The primary analysis will be by intention-to-treat.

Trial Registration: International Standard Randomised Controlled Trial Number (ISRCTN): 27704027; http://www.controlled-trials.com/ISRCTN27704027 (Archived by WebCite at http://www.webcitation.org/69FkM4vcq)

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KEYWORDS

Adherence; text messages; psychosis

Introduction

Schizophrenia is a high-cost, chronic, serious mental illness [1]. The global prevalence of schizophrenia is about 1%-1.5% [2]. Among mental, neurological, and substance use disorders, schizophrenia is the third highest in the ranking of global burden in disability-adjusted life years [3]. Studies have shown that a prevalence among relapsed patients varies, for example from 52% [4] to 80% within 5 years [5]. Nonadherence to antipsychotic medication is highly prevalent, has a deleterious impact on the course of the illness [6], and is the single most important predictor of relapse and readmission [7], with all the subsequent costs being an additional burden [8-11]. People may be nonadherent to prescribed medications for many reasons. Forgetting to take the medication, feeling that it is unnecessary, and disliking adverse effects are all common [12]. In any event, it is probably an underestimate of real life that over half of people with schizophrenia stop medication within 1 year of discharge from hospital [13]. Individually tailored approaches to encourage adherence to medication have been called for [6].

Although simple and direct telephone calls [14-17] and well-timed prompting letters [18] may decrease nonattendance at psychiatric outpatient departments, short message service (SMS) with mobile phones may provide better access to a population group. Text messaging is common, inexpensive, and less intrusive than a phone call. It is also possible to send preprogrammed batches of messages. A trust-wide survey in the United Kingdom with 141 psychiatric inpatients (100 patients with psychotic illness and 41 who had a diagnosis of a nonpsychotic illness) showed that 55% had a mobile phone, 56% were able to use text messages, and 76% were willing to receive text messages from the National Health Service foundation trust [19]. We know of no similar data in Finland. In 2011, however, 98% of Finnish households had mobile phones, and about 20% had more than one mobile phone [20].

While there is a clear need to improve treatment and expand access to care for people with schizophrenia, mobile technologies could be developed to support this area [3]. As preparation for this trial, we are completing a Cochrane review [21]. We have identified relevant important pioneering work that has been reported in international conferences [22,23] (n = 865). There are already some applications in other areas of heath care. SMS has been used in asthma care [24], smoking cessation [25], promoting safer sex and sun safety in young people [26], and monitoring and coaching persons with chronic migraine [27]. People with schizophrenia or similar illnesses are, however, different from the standard health service population. SMS, if tailored and used sensitively, has the potential to be both potent and possible to implement in everyday care. To justify this, however, and not simply impose one more unevaluated intrusion into the lives of people with these disturbing illnesses, high-grade adequately powered data from randomized trials are required [6].

The Mobile.Net study will establish the impact of tailored mobile telephone text messages to encourage adherence to medication and to follow up with people with psychosis at 12 months. Mobile.Net is a short name for the trial to help health care professionals and participants be aware of the project.

Methods

Design

Mobile.Net is a multicenter, randomized controlled study with a two-armed trial conducted in Finland (24 sites and 45 hospital wards).

Hypothesis

We hypothesized that tailored mobile telephone text messages acceptable to the individual patient would reduce use of services by people with serious mental illness whose previous use of services has been high.

Inclusion and Exclusion Criteria

Inclusion criteria are patients aged 18-65 years, of either sex (Table 1), with antipsychotic medication [28] on discharge from a psychiatric hospital, who have a mobile phone, are able to use the Finnish language, and are able to give written informed consent to participate. We will include no formal test of capacity but will rely on the judgment of experienced health care professionals in their routine assessment, when nearing the point of discharge, of the patients' understanding, retention, assimilation, and communication of all information, including that relevant to the study. Further formalized assessment is not part of routine care.

Patients who have planned a nonacute treatment period or are being treated in forensic psychiatric services will be excluded.

Table 1. Dummy table for background characteristics in intervention (short message service) and control groups at baseline.

Characteristic	Intervention		Control	
	n	%	n	%
Age (years)	DUMMY TABLE - CELLS INTENTIONALLY EMPTY			
Sex				
Male				
Female				
Other				
Marital status				
Single				
Married				
Divorced				
Widowed				
Vocational education				
None				
Vocational training courses				
Primary vocational skill certificate				
Secondary vocational skill certificate				
University degree				
Employment status				
Employed				
Retired				
Self-employed				
Student				
Job seeker				
Number of previous psychiatric treatment periods				
1				
2 or more				
Age at first contact with psychiatric services (years)				

Interventions

Intervention Group

The intervention group will receive semiautomatic SMS messages after their discharge from psychiatric inpatient care. The intervention is patient led rather than researcher led to increase acceptability of the prompt. Therefore, during the discharge process from psychiatric hospital care, patients will choose text message content areas related to their medication and follow-up appointments. Additionally, they will be able to choose messages related to other daily issues (eg, hygiene, physical exercise, nutrition, daily routines, clothing, safety, communication, taking care of pets, following rules, hobbies, work or other activities, household tasks, symptom management, or other supporting messages). Timing, frequency, and conditions under which interventions will be withheld will be decided by the patient. The content of these messages had been designed by patients in a consumer association, and by health care professionals in hospital wards and outpatient clinics. The SMS messages will continue for the duration of the study period (12 months) or until participants no longer want to receive the messages. We do not envisaged that the intervention will interfere in any way with routine outpatient care. Patients will be encouraged to contact the researchers or health care staff if they feel that they need any adjustment of the message.

Control Group

Patients in the control group will receive standard treatment care in an outpatient unit based on the existing system in Finland.

All patients will receive usual care at the discretion of their team (psychiatry and nursing).

Randomization and Masking

The randomization codes (permuted block design with 4 patients per block) were computer generated by an independent statistician. Others, completely independent of the trial team, inserted these numbers into sealed envelopes. While this is a

multicenter study to be run in 24 sites—that is, health service organizations (and 45 study wards) with psychiatric beds in Finland—patients within each ward will be randomly allocated separately. The is an open-label study.

Written allocation of assignment will be sealed in individual envelopes marked with study identification numbers, which will be distributed to all study wards. Research nurses on study wards will sequentially assign sealed envelopes in a predetermined order to patients who fulfill the inclusion criteria and give their written informed consent during their discharge process. Investigators will be masked to data until the statistician releases the database, although a data management committee will undertake ongoing safety surveillance. Study participants and staff will not be masked; this would not reflect real-world care. However, randomization and analyses will be undertaken by investigators masked to treatment allocation.

The sealed envelopes with study identification numbers will be opened by a research nurse or a patient in an ascending manner. Patients will be allocated to the intervention or control group.

Allocation Concealment

Participants and the investigators enrolling the participants will not foresee assignment. We will use numbered sealed envelopes in different data collection organizations. Whereas patients and health care staff will be aware of the allocated arm, outcome assessors and data analysts will be kept blinded to the allocation.

Primary and Secondary End Points

The primary outcomes are service use and healthy days by 12 months based on routine data (admission to psychiatric hospital, time to next hospitalization, time in hospital during this year, and healthy days). The secondary outcomes are service use, coercive incidents, medication, adverse event, satisfaction with care, intervention, and the trial, social functioning, and economic factors. M1 referral is a referral for observation by any physician if he or she considers it likely that criteria for involuntary admission are fulfilled. This sets in motion the process by which the patient is later examined by a second doctor in a psychiatric hospital. This doctor must be a psychiatrist. At this stage, the patient can be admitted voluntarily or involuntarily, or discharged [29]. Data will be collected 12 months after baseline (see Table 2 [30,31]).

Table 2. Dummy table for primary and secondary outcomes and end points.

Outcome	Intervention			Control		
	n (%) or mean (SD)	RR[a] (95% CI[b])	*P* value	n (%) or mean (SD)	RR (95% CI)	*P* value
Primary outcome	DUMMY TABLE - CELLS INTENTIONALLY EMPTY					
Service use/healthy days						
Admission to psychiatric hospital						
Time to next hospitalization (days)						
Time in hospital during this year (days)						
Healthy time (days)						
Secondary outcomes						
Service use						
Type of admission						
M1 referral[c]						
Mental examination						
Determination of treatment						
Other						
Involuntary treatment						
General hospital treatment						
Use of private care						
Length of involuntary psychiatric treatment (days)						
Length of general hospital stay (days)						
Coercion						
Coercive incidence						
Type of coercive incidence						
Seclusion						
Physical restraint						
Intramuscular medication						
De-escalation						
Medication						
Type of medication						
Antipsychotic						
Antipsychotic + antidepressant						
Medication						
Adverse event						
Any (yes)						
Death (yes)						
Satisfaction with care/intervention/trial						
Satisfied with care						
Requested to stop SMS[d]						
Left the study early						
Social functioning						
Quality of life						

Outcome	Intervention			Control		
	n (%) or mean (SD)	RR[a] (95% CI[b])	*P* value	n (%) or mean (SD)	RR (95% CI)	*P* value
Disability support						
Economic factors						
Direct cost (€)						
Indirect cost (€)						

[a] Relative risk.

[b] Confidence interval.

[c] Referral for observation.

[d] Short message service.

The outcomes will be based on register data [30,31] and patients' subjective evaluations.

Adverse Event Reporting

Safety assessments will include all adverse or serious adverse events, and subjective symptoms reported by clinical staff or study personnel, participants, or relatives. Adverse event monitoring data will be collected by the following methods: (1) reports from clinical staff or study personnel, and (2) text message, mailing, phone call, or survey after 12 months during the 1-year intervention with the question "Have you experienced any new and serious health problems since you enrolled in the Mobile.Net Study? If yes, please describe them."

We will provide categories of possible adverse events. Adverse events will be categorized as severe if they are life-threatening or fatal, require or prolong a hospitalization, or result in a major disability. In addition, adverse event may be categorized as unexpected or expected (Table 3).

Table 3. Dummy table for number of adverse events.

	Intervention	Control
Expected severe adverse events	DUMMY TABLE - CELLS INTENTIONALLY EMPTY	
Life-threatening or fatal		
Requiring or prolonging a hospitalization		
Resulting in a major disability		
Unexpected severe adverse events		
Life-threatening or fatal		
Requiring or prolonging a hospitalization		
Resulting in a major disability		
Expected adverse events		
Medical		
Psychiatric		
Substance use		
Unexpected adverse events		
Medical		
Psychiatric		
Substance use		

The potential safety concerns about possible psychiatric effects of exposure to a mobile phone have been discussed for more than two decades [32], but published results are still inconsistent and inconclusive [33-35]. As the study intervention is a communication system and provides a method of supporting patients' adherence in regular mental health services, we do not expect serious adverse events as a result of the intervention. We will analyze treatment-emergent adverse events, defined as all adverse and serious adverse events occurring between randomization and when the patient completes the study.

Statistical Analysis Plans

Sample Size and Power Calculations

The study has been powered for the primary outcome measure. We have systematically searched for but not found any directly relevant published work. In London, for example, 65% of

potentially eligible people had been admitted to the hospital in the past 12 months [36]. Our aim in Finland will be to reduce use of acute care by at least five percentage points (a relative risk of 0.92). To do this with 80% power at a 5% 2-sided significance level, we would require 1511 participants in each of the two arms (Stata v10; StataCorp LP, College Station, TX, USA).

Type of Analysis and Missing Data

All analyses will be based on the intention-to-treat principle. For incomplete (missing) data, we will use multiple imputation by chained equations, which makes appropriate assumptions based on the predictors of outcome and predictors of loss to follow-up. Missing outcome data will be evaluated where they are balanced in numbers across intervention groups and with similar reasons across control groups. The same procedures will be used for secondary outcomes.

Statistical Tests

The primary outcome will be relative risk of admission to psychiatric inpatient services (Table 2). Secondary outcomes will involve calculation of relative risk or mean differences and their corresponding 95% confidence intervals. To evaluate the clinical outcomes of the study, we will use both descriptive and inferential statistics. Descriptive statistics will be used to evaluate outcomes at the end point and differences between individuals and groups by exploratory analyses (chi-square tests, *t* test or Mann-Whitney *U* test, and nonparametric bootstrap methods for skewed cost data). The principal analysis will compare the primary and secondary outcome measures at 12 months comparing for baseline (preintervention) measures using analysis of covariance.

Subgroup Analysis Planned

We will analyze subgroups for the primary outcome of people with schizophrenia-like illness compared with others who need antipsychotics. The direct and indirect costs of implementing this service will be examined through the prospective collection of staff time and resource requirements. Total costs of implementing the service will be estimated through local salary and overhead costs and by reference to nationally agreed-upon and unit costs. The cost effectiveness of the approach will be calculated through incremental cost-effectiveness ratios of costs per nonattendance avoided.

Ethics Issues

The Ethics Committee of the Hospital District of Southwest Finland approved the study on December 16, 2010 (ETMK 109/180/2010). Any regulations addressing the conduct of trials involving vulnerable populations and clinical trials investigating products will be taken into account [37].

We did will not use any formal tests of capacity to evaluate patient competence. We will rely on the judgment of experienced health care professionals in their routine assessment of patients' status and well-being. Study participants and staff will not be masked (blinded), so as to reflect real-world care. This may, however, cause ethical and practical outcomes. Participants may respond better if they know they have received a promising new treatment or worse if they received only standard care. Nurses may motivate patients more toward a specific group depending on which group (intervention or control) nurses prefer [38].

Informed Consent Form and Information Sheet

All participants will give their consent to participate on the basis of appropriate information and with adequate time to consider this information and to ask questions [39]. We will obtain written consent to participate in the study through an informed consent form evaluated by the Ethics Committee of The Hospital District of Southwest Finland. Patients will be invited to sign the consent form after they have received oral and written information about the study. Patients will receive two type of written information material: (1) a short, 1-page information leaflet about the study to help patients orient themselves to the study, and (2) later, near the discharge process, more detailed written information describing the study and its phases. Participants will be made aware, before consenting, that they are free to withdraw without obligation at any time and that such an action will not adversely affect any aspect of their care.

Independent Data Safety and Monitoring Committee

The members of the independent data safety and monitoring committee will consist of two experts in mental health care, a representative of a patient association, and a statistician.

Interim Analysis and Stopping Rules

An independent data safety and monitoring committee will be established. The trial statistician will carry out analyses, blinded to allocation, and report the results to the data safety and monitoring committee. Together with an independent statistician, the data safety and monitoring committee will review efficacy and safety data.

Due to the nature of the data collated on the national register, it is not possible to conduct an interim analysis after the recruitment has started. The information in the register data will be available to the researchers after 1 calendar year (ie, data have a 1-year lag time). However, adverse events, early dropout, nurses' opinions, and patients' experiences will be monitored and analyzed throughout the study.

Indemnities

The Finnish national patient insurance system covers patients' possible loss and compensates them for that loss based on the Patient Injuries Act [39] (585/1986; amendments up to 1100/2005 included). This insurance is held by professions in health care or medical care to compensate for harm caused to patients through accident or neglect. This insurance covers harm caused by treatment, infection, accident, equipment, facilities, or installations.

Publication Plan

We plan one major results paper authored by M Välimäki, H Hätönen, CE Adams, and a collective (Finland's Mobile.Net Collaborative Group) comprising all active collaborators, and published in parallel with a relevant Cochrane review. We propose making data available for prospective meta-analysis.

Funders

Grant support for the intervention was received from the Academy of Finland (132581), Satakunta Hospital District, State Subsidy System (EVO) (12/2010, 81096), and the Hospital District of Southwest Finland, EVO (13893).

Role of the Funding Source

The funders do not have any role in study design, data collection, analysis, decision to publish, interpretation, or preparation of the manuscript. The corresponding author will have full access to all the data in the study and will have final responsibility for the decision to submit for publication.

Recruitment Schedule

Recruitment started in November 2011 and will finish December 2012. Results will be reported in 2015.

Conflicts of Interest

None declared.

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Abbreviations

SMS: short message service

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Protocol

Design and Methods for a Comparative Effectiveness Pilot Study: Virtual World vs. Face-to-Face Diabetes Self-Management

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Abstract

Background: Type 2 diabetes (diabetes) is a serious threat to public health in the United States and disproportionally affects many racial/ethnic minority groups, including African Americans. Limited access to treatment and high attrition rates further contribute to health disparities in diabetes-related morbidity and mortality among minorities. Greater opportunities for increasing access and decreasing barriers to treatment are needed. Technology-based interventions have potential for accomplishing this goal but evidence of feasibility and potential effectiveness is lacking, especially for populations that traditionally have limited educational attainment and low computer literacy.

Objective: This paper describes the design and methods of a pilot randomized clinical trial that will compare the feasibility and potential efficacy of delivering a diabetes self-management intervention via a virtual world vs. a face-to-face format.

Methods: Study participants (n=100) will be African American women with uncontrolled type 2 diabetes recruited from primary care practices and affiliated health centers at a large safety net hospital in Massachusetts. Participants will be randomized into a virtual world-based (VW) intervention condition or a face-to-face control condition. Both conditions provide the same theory-based curriculum and equivalent exposure to the self-management program (eight group sessions), and both will be delivered by a single intervention team (a dietitian and a diabetes educator). Assessments will be conducted at baseline and 4 months. Feasibility will be determined by evaluating the degree to which participants engage in the VW-based intervention compared to face to face (number of sessions completed). Potential efficacy will be determined by comparing change in physiological (glycemic control) and behavioral (self-reported dietary intake, physical activity, blood glucose self-monitoring, and medication adherence) outcomes between the experimental and control groups.

Results: The primary outcomes of interest are feasibility of the VW intervention and its potential efficacy on glucose control and diabetes self-management behaviors, compared to the face-to-face condition. Analysis will use a two-sample Kolmogorov-Smirnov test for changes in variable distribution. *P* values will be calculated using binomial tests for proportions and *t* tests for continuous variables.

Conclusions: If the intervention is found to be feasible and promising, it will be tested in a larger RCT.

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KEYWORDS

Technology; Virtual systems; Education-distance; Patient education; Minority health; Health disparities; African Americans; Type 2 diabetes; Health behavior; Clinical trials

Introduction

Type 2 diabetes (diabetes) is a serious threat to public health in the United States and the world and is a costly disease at the individual and societal levels. In the United States, its prevalence has risen among all ethnic groups, especially among certain racial/ethnic minority groups such as African-Americans who have had a near doubling of prevalence (now 13%) since 1988 [1,2]. Diabetes has numerous and serious health risks associated with poor control [2]. Expert guidelines promote counseling for patient health behavior change targeting increased physical activity, reduction in caloric intake and weight, and promotion of adherence to medication [3]. Among individuals with diabetes, women and African Americans report the lowest levels of physical activity and more than half (66%) of African Americans with diabetes report high-fat diets [4,5]. Although self-management programs have proven efficacy, attrition rates are high [6]. Factors reported as contributing to attrition include competing family responsibilities, conflict with program hours, and distance to services [7]. Web-based methods to improve diabetes outcomes could improve access to behavior counseling and have shown promise in improving health behaviors and glycemic control [8]. However, the feasibility of intervening through web-based methods has been questioned due to a real or perceived digital divide or socioeconomic inequalities among individuals in access to information technologies. For example, only 49% of African Americans compared to 68% of Caucasians have a broadband Internet connection at home [9]. In addition to this divide in access to connectivity and hardware, researchers have identified a skill and knowledge divide on the basis of technological competency and digital literacy [10].

Virtual world (VW) environments are potentially suitable environments for supporting patient education delivery, including diabetes self-management programming. VWs are 3D, immersive, online places where people enter and participate as an avatar. Once in the VW, participant avatars can walk, run, fly, talk, travel, and interact with the other people or structures present in the virtual space. The rich visual landscape, in combination with the mediated presence via avatar, gives the participant a strong sense of "being there". VWs offer vast opportunities for interaction, intense engagement, and opportunities for scripted immersive experiences, simulations, role-playing, and constructivist learning. Sense of presence, easy access, and anonymity afforded by the avatar may lead to greater interaction and group cohesiveness, as well as engagement and attention, compared to other web-based approaches [11,12]. Currently there are over 300 such online VWs, such as Jibe, OpenSim, Spoton3D, Open Wonderland, and Second Life (SL). Created and maintained by companies, universities, or individuals, some of these online environments are free of charge or some assess monthly or per-use fees. Although the use of VWs has been shown to influence behavior in the "real" world [13], studies are limited and have not targeted the spectrum of diabetes self-management behaviors.

The objective of this paper is to describe the design and methods of a pilot study that will compare the feasibility and potential efficacy of delivering a diabetes self-management intervention via a VW (delivered in Second Life, or SL) versus a face-to-face format.

Methods

Design

Women in Control is a pilot randomized clinical trial funded by the National Library of Medicine/National Institutes of Health that will evaluate the feasibility and potential efficacy of a diabetes self-management intervention delivered through interactive sessions within a Virtual World (VW), compared to a face-to-face format, to improve glucose control and enhance adherence to diabetes self-management behaviors in a population of African American women.

Hypothesis

We hypothesize that the VW-based experimental intervention condition will produce outcomes related to feasibility and potential efficacy that are comparable or greater than those observed in the face-to-face control condition.

Interventions

The intervention content will be adapted from the CDC/NIH program "Power to Prevent" (P2P) [14], a culturally appropriate, evidence-based behavior-change curriculum designed for face-to-face delivery to African American patients with diabetes or pre-diabetes. The intervention approach is theory-based [15] and thus seeks to enhance diabetes knowledge, optimize attitudes toward diabetes self-management (ie, self-efficacy, outcome expectations), and develop behavioral self-management skills (eg, goal setting, tracking self-management behaviors and glucose levels, problem-solving) to facilitate changes in dietary intake, physical activity, blood glucose self-monitoring, and medication adherence. Curriculum objectives and topics are summarized in Table 1.

Table 1. Women in Control diabetes self-management program outline.

Session number	Session topics
1. (Individual)	Intake session—Program overview; Review of informational handouts; Take history of dietary and physical activity habits, medication intake, blood glucose self-monitoring; Discuss action plan and tracking; Set initial goal
2. (Group)	Getting Started—Welcome and introductions; What is diabetes; Diabetes self-management goals; Achieving control through small steps; Ways to increase physical activity
3. (Group)	Decreasing Your Hunger—Food and blood glucose; Healthy food choices from three food groups; Healthy fats; Fiber
4. (Group)	Using Food Labels to Track Carbs and Fat—Finding carbohydrates and fat grams in a food label; Healthy amounts of fiber per serving; Decreasing fat grams in food choices; Substituting healthful foods for less healthful foods
5. (Group)	What Have We Learned So Far?—Review of the effects of physical activity and food on blood sugar
6. (Group)	Diabetes Medications—Benefit of medications in diabetes management; How medications work; Importance of adhering to the medication regimen; Strategies to enhance medication adherence
7. (Group)	Physical Activity for You and Your Family—Review of overall benefits of physical activity for patient and family; Eliciting support for physical activity from others; Relapse prevention
8. (Group)	Managing Food Intake and Blood Sugar Outside of the Home—Understanding the difference between portion size and serving size; Strategies to improve food choices when eating out; Preventing overeating when eating out
9. (Group)	Empowering Yourself—Asking questions of health care providers; Remembering goal levels for A1c, blood pressure, and cholesterol; Graduation

We will deliver this curriculum through a series of weekly sessions that begin with an individual intake session, followed by 8 weekly sessions. Sessions will be delivered in either a VW or face-to-face environment in groups of approximately 12-15 participants by a single intervention team (a dietitian and a diabetes educator) for the same duration (90-minute sessions) using the same protocol and materials for both conditions. Participants in both conditions will receive 2 sessions of computer training and will be provided with an Internet-enabled laptop computer upon training completion. Multimedia Appendix 1 summarizes the specific activities conducted during each computer training.

The face-to-face group sessions will take place in a large conference room at Boston Medical Center. All face-to-face participants will receive transportation vouchers to facilitate attendance. VW-based sessions will take place in an open-air VW forum built especially for the intervention with adequate structures and required visuals/displays (see Figures 1 to 4). Although the VW sessions will last 90 minutes, these participants will be asked to log in 30 minutes prior to each session in order to test their sound and troubleshoot any connection problems. To facilitate session flow, a triage system will assign participants to “producers” (technical support staff) as technology needs arise. As in the face-to-face condition, both interventionists will attend every group session (alternating facilitation). In the VW condition, the non-leading interventionist will take notes in the local chat and provide general back-up, while in the face-to-face condition, the non-leading interventionist will provide logistical assistance. Multimedia Appendix 1 compares similarities and differences of intervention implementation among these conditions in greater detail.

Two members of the research team will oversee fidelity of intervention content and style for both conditions via direct observation and review of recorded sessions. Interventionists will be provided with feedback on errors of omission and commission, and additional support will be given on an ongoing basis as needed.

Figure 1. Virtual world forum.

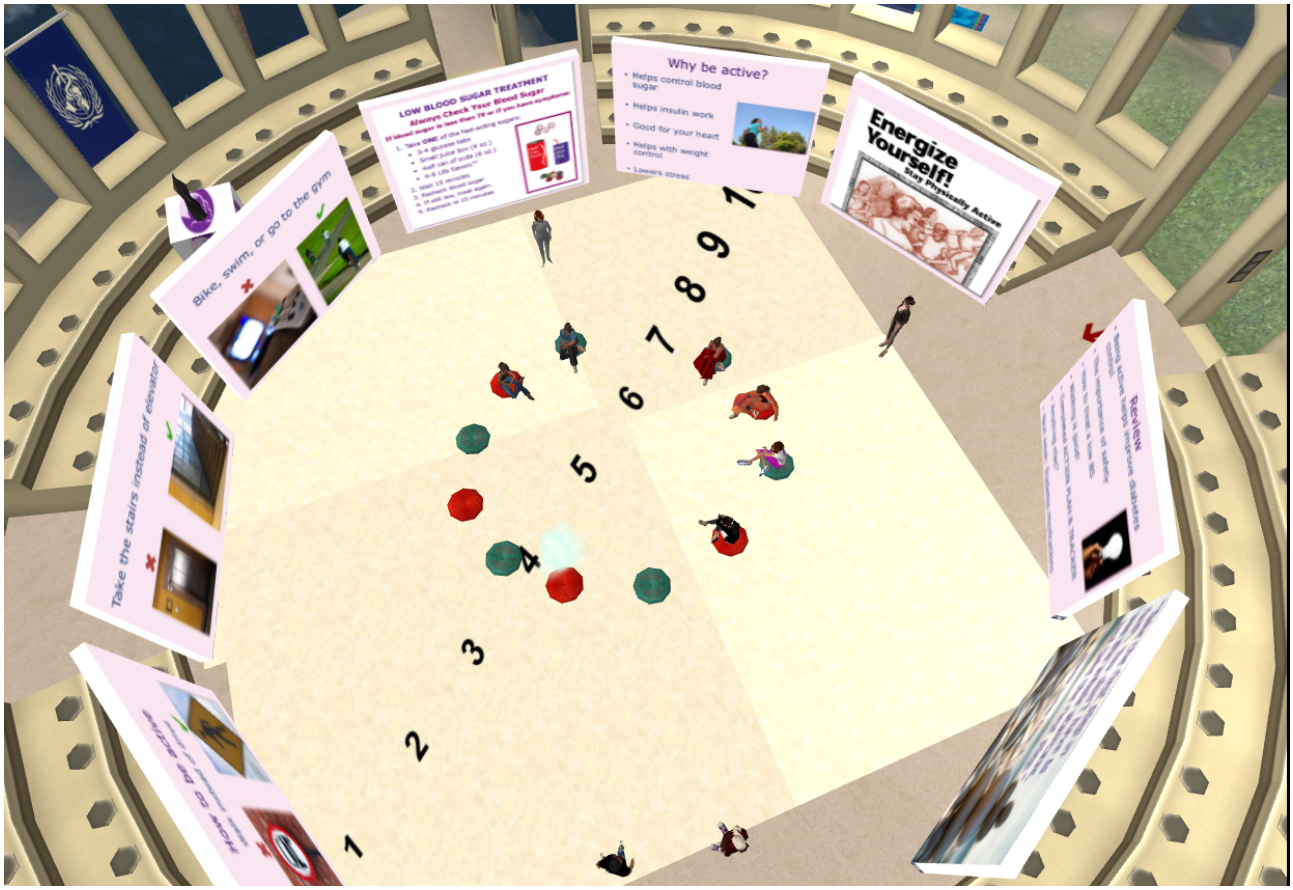

Figure 2. Floor pattern: self-efficacy ruler.

Figure 3. Club one island.

Figure 4. Dancing stage.

Study Setting and Population

The study will recruit 100 African-American (Afro-Caribbean) women recruited from primary care practices and affiliated health centers at a large safety net hospital in Massachusetts. Eligible subjects will be age >18 years, English-speaking, with a diagnosis of type 2 diabetes, and an HbA1c > 8 at their last outpatient visit, which has to occur within the year preceding recruitment. Subjects with the following conditions will be excluded: ulcerative colitis, renal failure, complications following abortion and ectopic and molar pregnancies, angina pectoris, and other forms of unstable ischemic heart disease and conditions precluding brisk walking.

The research protocol was approved by the Institutional Review Boards at Boston Medical Center and the University of Massachusetts Medical School. Potential participants will be identified from the medical record data warehouse at Boston Medical Center and affiliated community health centers based on the above criteria. Identified patients will receive a letter informing them about the study. The letter will provide a description of the study, announce a phone call from a study staff to determine final eligibility, and give patients the option to call in or opt out. During the telephone call, the staff will assess final eligibility (ie, self-reported ability to view a computer screen without difficulty, ability to read, no use of glucocorticoid therapy, no current participation in a weight loss program, and availability for weekly meetings), answer any questions they may have about the study, and invite fully eligible women to participate. A maximum of five calls will be made to each participant on different days and varying times. Interested women will be scheduled for an enrollment visit at the Boston Medical Center General Clinical Research Unit in which participants provide written informed consent. A reminder call will be made the evening prior to the appointment.

Randomization

Upon completion of all study assessments, we will randomize participants to either the VW-based experimental intervention condition or the face-to-face control condition. A block randomization scheme with a block size of 4, developed by StudyTRAX software (v3.0.0103), will be used. Randomization will be stratified on age and hemoglobin A1c measured at baseline. Participants will be informed about their randomization assignment via phone.

Outcomes and Study Measures

The primary outcomes of interest are feasibility of the VW intervention and its potential efficacy compared to the face-to-face condition. Feasibility will be determined by evaluating the degree to which participants engage in the VW-based intervention compared to face-to-face (number of sessions completed). Potential efficacy will be determined by comparing change in glucose control and self-management behaviors between the experimental and control groups, from baseline to the 4-month follow-up.

Assessments will be performed at baseline and at 4-month follow-up. HbA1c tests will be used to assess average blood glucose level over the previous 2-3 months. Non-fasting venous blood samples from an antecubital vein will be collected after the subject remains seated for 10 minutes, in accordance with standard research protocols [16]. Boston Medical Center laboratories will analyze the specimens. At each time point, dietary intake will be assessed by two unannounced 24-hr dietary recalls (24HRs) [17] administered on randomly selected days (60% probability of a weekday and 40% probability of a weekend day). 24HRs are well suited for the characteristics of the target population (ie, language, illiteracy/low educational level, ethnic foods) that limit use of other/additional assessment methods. Also at each time point, 24-hour physical activity recalls will be administered immediately after the 24-hr dietary recalls [18], followed by recalls of blood glucose self-monitoring and medication adherence. Other measures will include blood pressure [19], cholesterol, body mass index, waist and hip circumference, depressive symptoms [20,21], self-efficacy for diabetes management [22], health literacy [23], social support [24,25], perceived stress [26], and quality of life [27]. Demographic factors, smoking history, alcohol intake, current use of prescription and non-prescription medications, as well as use of home remedies, and experience with computers and the Internet will be assessed via survey. We will assess patient satisfaction at the 4-month follow-up. Intervention implementation costs (costs that would be incurred if the intervention were to be implemented outside the context of the research project) will be tracked.

Data Management

StudyTrax (v3.0.0103), a web-based electronic data capture software, will be developed to house case report forms for data collected throughout the study. Case report forms will be developed to include field-specific validation code, procedures to check data ranges, and reminders to enter required data to ensure data integrity. Research staff utilizing the database will be provided role-specific privileges to the database. Two members of the study staff will perform double data entry on all clinical measures. Dietary data will be collected using the Nutrition Data System for Research (NDSR) database. Physical activity data will be collected on case report forms designed in Microsoft Access.

Quantitative Evaluation: Analytic Plan

Sample Size and Power Calculations

As a comparative effectiveness study, patients in both arms will receive interventions potentially resulting in improvements in the primary outcomes. Hence, a very large sample size would be required to demonstrate either statistically significant comparative effectiveness or superiority of one group over the other. As a result, and in recognition of the project's status as a feasibility study, the study was powered to be able to demonstrate within group improvements in one of the key outcomes: physical activity. A sample size of 47 was determined to be sufficient to show a within group improvement, from pre- to post-, of 20% of the sample from inactive to moderate intensity physical activity, with a power of 80% at 0.05% level of significance.

Analysis and Statistical Tests

Our null hypothesis is that there will be no significant differences in outcome measures between the VW and

face-to-face conditions. We will test this null hypothesis against the alternative that the VW condition is not as effective as face-to-face intervention using a two-sample Kolmogorov-Smirnov test for changes distributions of A1c. In other words, the VW intervention will be as good as or better than face-to-face intervention in decreasing A1c. The *P* values will be calculated using binomial tests for proportions and *t* tests for continuous variables. We will use RStudio (version 0.96.330) [28] for statistical analysis.

Qualitative Evaluation

Following completion of the intervention delivery phase, focus groups will be conducted to qualitatively compare the experiences of participants assigned to the VW vs. the face-to-face condition. A total of 40 randomly selected participants will be invited to participate in four focus groups (expecting that 8-10 participants per group will attend): two groups will include VW participants, and the other two will include face-to-face participants. Participants will be consented for participation in, and recording of, the group discussions. We will offer a monetary incentive of US $40 and travel expenses to encourage participation. Two analysts will independently review transcripts of discussions, identifying key words and themes (in vivo coding) related to their experiences of living with diabetes, decision-making about treatments and lifestyle changes, and involvement in the VW or face-to-face intervention. A grounded theory approach will be used [29]. Constant comparative analysis will be used to relate the transcribed focus group interview data through ideas to core concerns. The first approach will involve open coding using a meaningful phrase by meaningful phrase strategy. During the open coding process, data will be coded for any and all categories. Focused codes will be created for sorting and synthesizing the initial codes to organize the data, using the most significant and/or frequent earlier codes to sift through the data. From focused codes, memos will be generated theorizing about how codes relate to ideas and characterizing the emerging theory. Memos will be sorted into concepts demonstrating relationships between concepts that derive from memos. The formulation of themes and codes drawn directly from different sections of the data, and then used to code the transcripts themselves, is a pivotal step toward building an in-depth analysis.

Discussion

Glycemic control is critical to preventing health disparities in diabetes morbidity and mortality among racial/ethnic minorities such as African Americans. Strategies to maximize access to treatment and self-management support are needed for this and other vulnerable populations. Technology-based interventions may be able to increase access but further evidence is needed to support the feasibility of such interventions with populations that have limited educational and computer literacy. By comparing a VW-based intervention format to a traditional face-to-face format for delivery of a diabetes self-management intervention to a sample of low-income African American women, this study will provide evidence of feasibility for a population with considerable health disparities in diabetes prevalence and outcomes and who also have limited experience with computers.

The strengths of the study are many. They include: (1) assessment of feasibility of utilizing a VW platform for patient health education, (2) randomization of study participants to a face-to-face condition (ie, traditional approach) vs. a VW environment condition, holding constant the intervention content, (3) recruitment of inner city minority participants thus addressing so called digital-divide issues, (4) standardization of hardware used to access the VW, (5) use of a control group that has similar hardware and training, (6) robust measurement of behavioral outcomes, and (7) inclusion of a qualitative post-intervention evaluation.

Limitations of this study include: (1) the pilot nature of the study. Adequately powering a comparative effectiveness study, given the characteristics of our primary outcomes, will require a larger sample size, beyond the scope of this project, and (2) the study focus is on a subset of the population, namely low-income African American women with uncontrolled diabetes. Thus, the generalizability of our findings to men and to non-underserved populations might be limited.

Evidence of feasibility and potential efficacy is needed so that new interventions can be designed for VW implementation and high reach to diverse populations. Our previous work has demonstrated the ability of VW-based training to change the professional behavior of clinicians [30,31]. We anticipate that the current study will produce valuable data and insights to help guide application of these findings to VW-based interventions targeting not only diabetes self-management but also other chronic conditions and health behaviors, including such critical topics as medication adherence, substance abuse cessation and treatment, individual and group-based mental health treatments, many possible rehabilitative services, and other health services.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Comparison of virtual world (VW) versus face-to-face implementation of the Women in Control curriculum.

[PDF File (Adobe PDF File), 173KB - resprot_v1i2e24_app1.pdf]

Multimedia Appendix 2

NIH Reviewers Statements.

[PDF File (Adobe PDF File), 47KB - resprot_v1i2e24_app2.pdf]

Multimedia Appendix 3

Response to Reviewers Critiques.

[PDF File (Adobe PDF File), 103KB - resprot_v1i2e24_app3.pdf]

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Original Paper

A Serious Video Game to Increase Fruit and Vegetable Consumption Among Elementary Aged Youth (Squire's Quest! II): Rationale, Design, and Methods

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Abstract

Background: Youths eat fewer fruits and vegetables than recommended. Effective methods are needed to increase and maintain their fruit and vegetable consumption. Goal setting has been an effective behavior change procedure among adults, but has had limited effectiveness among youths. Implementation intentions are specific plans to facilitate goal attainment. Redefining goal setting to include implementation intentions may be an effective way to increase effectiveness. Video games offer a controlled venue for conducting behavioral research and testing hypotheses to identify mechanisms of effect.

Objective: This report describes the protocol that guided the design and evaluation of Squire's Quest! II, a video game aimed to increase child fruit and vegetable consumption.

Methods: Squire's Quest! II is a 10-episode videogame promoting fruit and vegetable consumption to 4th and 5th grade children (approximately 9-11 year old youths). A four group randomized design (n=400 parent/child dyads) was used to systematically test the effect of two types of implementation intentions (action, coping) on fruit and vegetable goal attainment and consumption of 4th and 5th graders. Data collection occurred at baseline, immediately post game-play, and 3 months later. Child was the unit of assignment. Three dietary recalls were collected at each data collection period by trained interviewers using the Nutrient Data System for Research (NDSR 2009). Psychosocial and process data were also collected.

Results: To our knowledge, this is the first research to explore the effect of implementation intentions on child fruit and vegetable goal attainment and consumption.

Conclusions: This intervention will contribute valuable information regarding whether implementation intentions are effective with elementary age children.

Trial Registration: ClinicalTrials.gov NCT01004094

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KEYWORDS

video game, nutrition, fruit, vegetable, children, intervention, action implementation intention, coping implementation intention, goal setting

Introduction

Consuming adequate amounts of fruit and vegetables (FV) is part of a healthy lifestyle [1] and has been associated with decreased risk of chronic diseases such as certain cancers, cardiovascular disease, stroke, and diabetes [2]. National guidelines recommend that 9-13 year old youths consume 7-11 servings of FV each day, based on calorie needs [3]. However, less than 4% of children meet the minimum guideline, and fewer than 20% consume at least five servings each day [4]. Since adolescent dietary behaviors track into young adulthood [5], increasing and maintaining youths' FV consumption prior to adolescence could have substantial and sustained public health significance.

Video games are popular among youths [6]. Many youths have ready-access to cell phones, game consoles, and computers on which video games can be played [6]. High-speed home Internet access has increased among households with youths [6]. Therefore, online video games may be a familiar and convenient method to reach youths with health-enhancing programs. They also offer a mechanism for ensuring consistent intervention delivery, thus controlling for potential lack of fidelity to standardized content and implementation procedures potentially introduced by live instructors [7].

Serious video games, ie, video games designed to entertain as well as achieve change of some type [8], is an emerging genre [9], with some reported success at changing health behaviors [8]. Squire's Quest! increased FV consumption among 4th grade children [10]; however post-study consumption was still well-below recommended levels, suggesting additional investigation was needed. Secondary analyses revealed that goal setting was weakly related to goal attainment and FV consumption [11], suggesting that enhancing the goal setting component of Squire's Quest! may offer a mechanism to further enhance participants' FV consumption.

Implementation intentions are specific plans that identify how to achieve a goal [12]. They can take two forms: (1) action intentions, a specific plan of how a goal will be attained (ie, what, when, who), and (2) coping intentions, an if/then plan that identifies what solution an individual will enact if a specific obstacle or problem is encountered [12]. When forming an implementation intention, an individual determines in advance how to meet a goal by examining possible situations and selecting the ones most likely to lead to goal attainment [12]. Environmental cues rather than conscious thought trigger a goal-directed response, thereby automating behavior and increasing the likelihood the goal will be attained [13]. Implementation intentions have enhanced goal attainment across a variety of adult health behaviors [14-18]. There is some evidence they may be effective with youths - ie, adolescents who formed implementation intentions prior to initiating an academic goal were more likely to achieve the goal than adolescents who did not form an implementation intention [19].

Long-term behavior change is the ultimate goal for behavioral interventions [20]. However, little research has specifically addressed the issue of maintaining dietary behavior change [21]. While some dietary change interventions have occurred over a two-year period [22], no conceptual distinction was made between initiation and maintenance of change. Desired changes in targeted dietary behavior in the intervention group relative to the control group have shown mixed effects [23]. Among adults, outcome expectancy was conceptualized to be related to behavior initiation, while perceived satisfaction with behavioral change was conceptualized to be associated with maintenance [20]. Satisfaction is a continual assessment of whether the "benefits" of change were worth the effort to make and/or continue the change. Since high expectations may be more likely to lead to dissatisfaction, high outcome expectancies were hypothesized to be associated with greater behavioral initiation, but lower maintenance, while more modest expectations, were hypothesized to be associated with lower behavioral initiation, but greater maintenance [20].

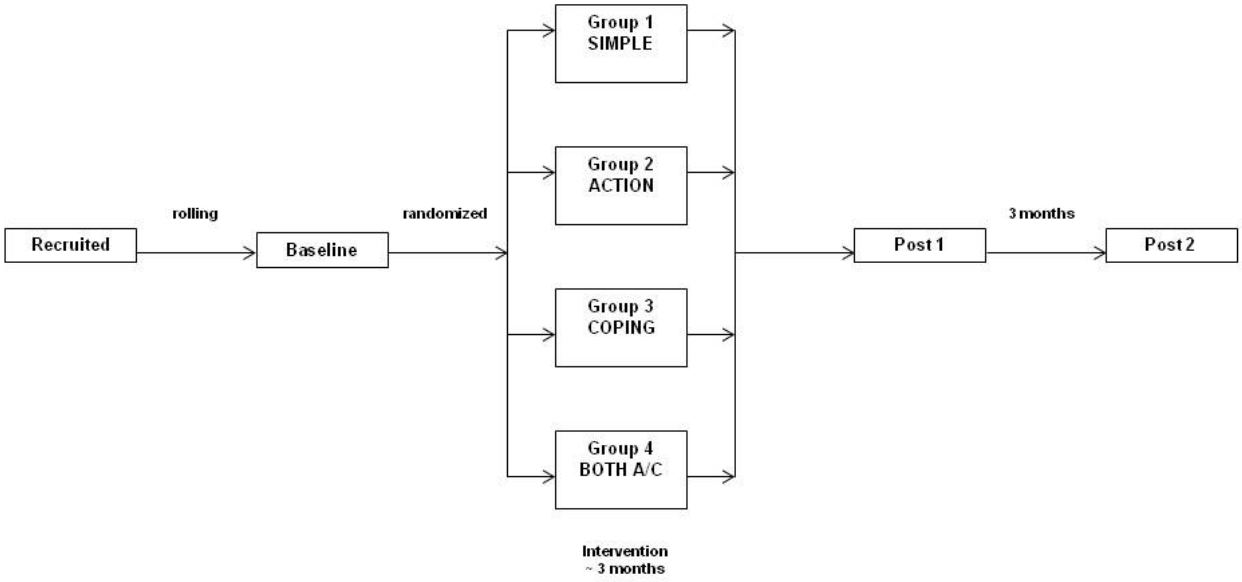
Squire's Quest! II: Saving the Kingdom of Fivealot (SQ!2) is a 10-episode online video game designed to increase FV consumption among 4th and 5th grade children (roughly 9-11 year old youths). It is an updated and enhanced version of an earlier video game, Squire's Quest!, evaluated in 1999 and 2000 [10]. SQ!2 was supported by a parent component which included electronic newsletters and access to a parent-only website. The primary aim of SQ!2 was to test the effect of implementation intentions on FV goal attainment and consumption in pre-adolescents. An exploratory aim was to examine factors associated with maintenance of consumption. The protocol was approved by the institutional review board of the Baylor College of Medicine (H-18488) and registered with ClinicalTrials.gov (NCT01004094). This report describes the study protocol that guided the design and evaluation of the SQ!2 randomized controlled trial.

Methods

Study Design

This evaluation used a four-group, randomized design, with three data collection periods (baseline, post 1, post 2). Following baseline assessment, children were randomized to one of four groups: goal setting only (simple), goal setting + action intentions (action), goal setting + coping intentions (coping), or goal setting + action and coping intentions (both). Youths had up to three months to play all 10 episodes of the video game, where the appropriate goal-setting/implementation intentions were embedded in four versions of the game. Post 1 data collection occurred immediately upon completion of the 10 episodes or approximately 3 months after beginning game-play, whichever occurred first. Post 2 data collection occurred approximately 3 months after post 1 (Figure 1). The study was conducted from November 2009 through March 2011.

Figure 1. Research design.



Participants

Eligibility criteria for participants included: (1) a child in the 4th or 5th grade at time of enrollment, (2) fluent in English, (3) had access to a computer with high speed Internet, and (4) had a parent (or legal guardian) fluent in English or Spanish who was willing to participate in the study. Recruitment methods included standard procedures (ie, flyers and attendance at community events) and the volunteer database at the Children's Nutrition Research Center. Prior to participation, eligible parents and children provided written informed consent and child assent. The child was the unit of randomization.

Sample Size and Power

Sample size requirements were based on a power analysis (the number of participants needed to find an actual group difference) with FV as the primary outcome variable. A repeated measures analyses of variance with a 4-group design and 3-measurment periods was assumed. Allowing for a 30% attrition rate, a sample of 400 parent/child dyads (100 per group) provided adequate power (>80%) to detect a small effect size (ES=0.17) using a standard deviation of 1.5 from the original Squire's Quest! and a two-sided alternative with type I error rate of 0.05. This effect size (ES=0.17) translates to a detectable 0.51 or greater serving (ie, a half of a serving per day) group difference.

Sample Characteristics

Four hundred multi-ethnic parent/child dyads were enrolled in the study. Fifty three percent of children were girls, while 47% were boys; racial/ethnic distribution was 37% White, 27% Hispanic, 26% Black, and 10% Other. Most parents were female (96%), and parent racial/ethnic distribution was similar to that of the children (41% White; 26% Hispanic; 26% Black; 7% Other).

Setting

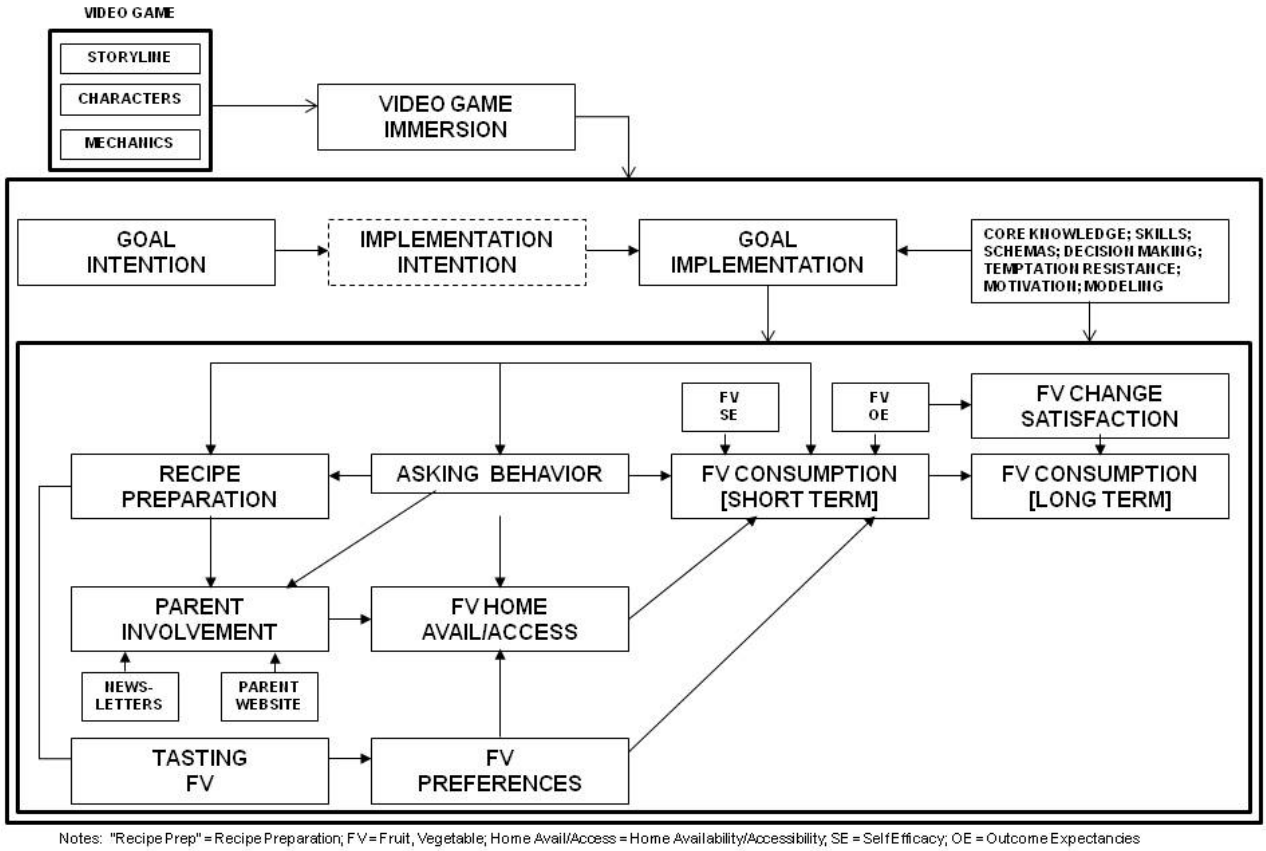
Parents and children participated in separate intervention and data collection activities electronically (Internet or telephone) from locations of their choice (home or community). There were no face-to-face sessions.

Intervention

The intervention had both child and parent components. The child played a 10-episode online video game, while the parent received electronic newsletters and access to a parent website which was updated with new information10 times, corresponding to the 10-episode video game. The intervention was guided by a theoretical framework that incorporated social cognitive (behavioral and environmental factors) [24], self determination (motivation) [25], the elaboration likelihood model (information processing) [26], behavioral inoculation (resistance to temptation) [27], and maintenance theories (long-term behavior change) [20]. The conceptual model that

guided the intervention is presented in Figure 2. It provides an overview of how the intervention promotes short and long term FV consumption. The story, characters, and game mechanics (eg, interactivity) promote immersion, which increases exposure to the behavior change components (ie, program dose). Setting a goal and/or creating an implementation intention, developing core knowledge and skills, and engaging in key behavioral procedures (eg, schemas, decision making, resisting temptation, motivation, and character modeling) contribute to FV self efficacy and outcome expectations. FV self efficacy and outcome expectations influence short and long term FV consumption (maintenance). Outcome expectations also influence satisfaction, which influences long term consumption. In addition, the parent component (newsletters, website), coupled with child asking behaviors and recipe preparation, influence parent involvement; parent involvement, FV tasting, and FV preferences influence FV home availability and accessibility and short and long-term FV consumption.

Figure 2. Conceptual model.



Child Component: Video Game

Development

Multi-ethnic 4th and 5th grade children provided information for the development and initial testing of the video game. Children (n=15) provided feedback on behavior change components, the storyline, and the characters. Children (n=10) also participated in alpha and beta testing sessions. An experienced 4th grade teacher reviewed materials to assess developmental appropriateness and comprehension of key components. Children and their parents (n=20 dyads) also participated in a pilot study, which served as a final test for the intervention components, procedures, and data collection activities of the video game.

Storyline

The story, written by a professional writer, was designed to appeal to 4th and 5th grade youths (ie, humor appropriate for children). It integrated the behavior change components into the action, which, in turn, advanced the storyline. The "backstory" (ie, the history) provided context for the storyline.

Backstory

The medieval kingdom of Fivealot is a happy one; its prosperity is based on ancient knowledge of healthy nutrition and an abundance of good food, under the gentle guidance of King Brocwell and Queen Nutritia. Recently, Fivealot entered a truce with their underground-dwelling enemy, the Mog – or so they thought.

A nation of subterranean serpents and myopic moles, the Mog were jealous of Fivealot's good fortune. Although Brocwell and Nutritia had offered to share their country's bounty, the

Mog who were raised on a diet of sweets and fried foods, stubbornly refused to change their ways. The Mog King Snake, Sssynster, instead insisted that Fivealot change *their* habits – and the struggle was on.

Discovering that their army of fattened moles and slovenly snakes were no match for the energetic knights of Fivealot, Sssynster withdrew, realizing he could never best Brocwell and Nutritia in open conflict. His best hope was treachery.

The King and Queen of Fivealot's Head Chef, Supremo, was preparing to go to market one day. With the truce in effect, he suspected nothing – certainly not the tunnel dug into his kitchen by the Mog. Unbeknownst to Brocwell and Nutritia, Supremo simply disappeared, spirited away to the land of Mog.

Then came the second part of Sssynster's plan: a double agent, Moledred, had been placed on the kitchen staff, waiting for the opportunity to advance to the Head of the Kitchen. With the majority of knights away spreading the bounty of Fivealot, Moldred's mission was to prepare his specialty - fattening, unhealthy meals - for the King and Queen, and thus bring the kingdom to ruin. But what Sssynster and Moledred had not counted on was a Squire answering the King and Queen's call for brave young men and women to train in the ways of Fivealot and become knights themselves. A Squire…like you.

Quest

To become a knight, the Squire had to acquire the coveted knowledge and skills of the Fivealot Knights. This is where the game began. In the quest for knighthood, the Squire had to overcome challenges. The challenges involved attaining "real world" FV consumption and recipe goals. As the Squire (ie, the participant) met their challenges, they earned badges and progressed in their journey towards knighthood. Because children typically consume well below the recommended level of daily FV [4], promoting a more modest goal appeared prudent; therefore, the goal promoted in the game was to ultimately consume at least 5 daily servings of FV.

Characters

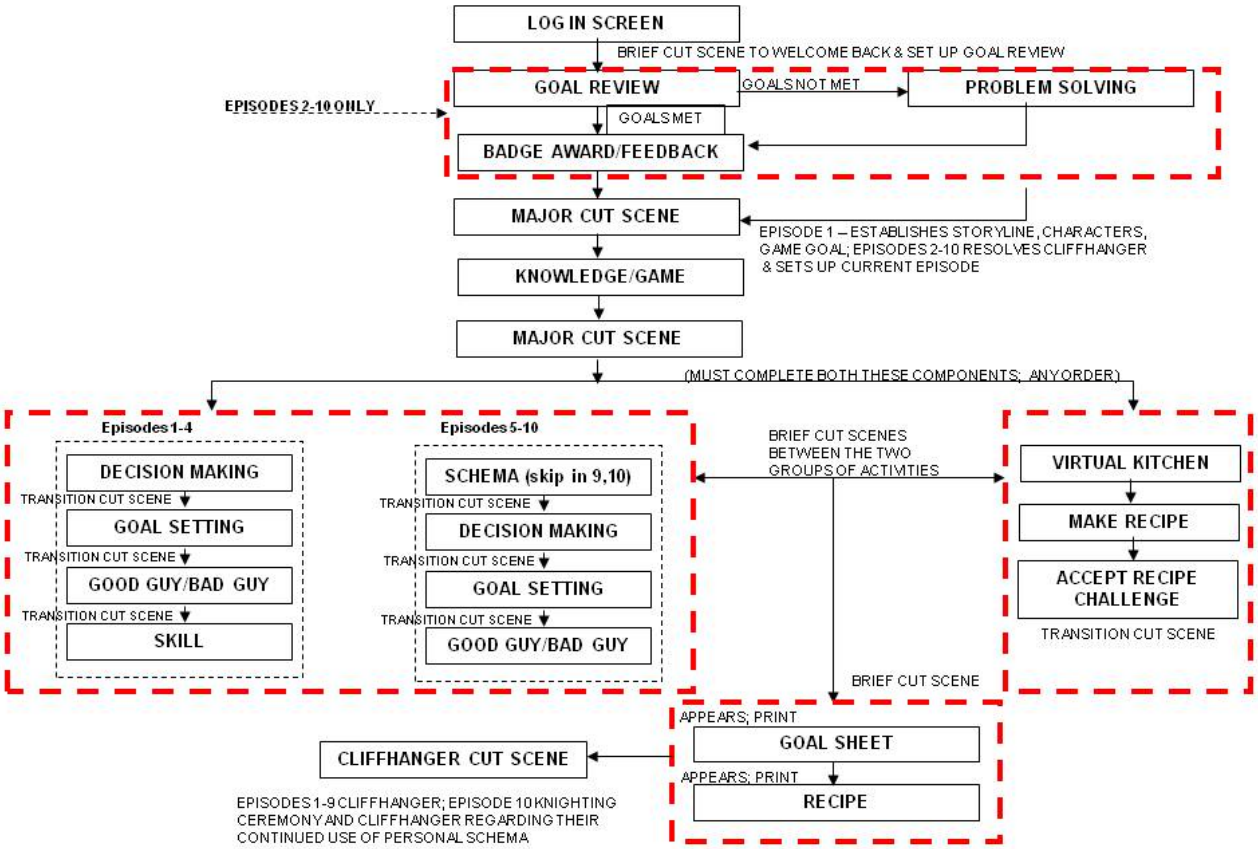
The protagonists included six characters that were "human" in appearance (King Brocwell; Queen Nutritia; Merlin the Wizard; Knights Alex and Julie; Chef Supremo) and a robot (M.I.C.H.A.E.L.), who assisted with kitchen tasks. The antagonists were snakes (King Sssynster, a cobra; the snake army) and moles (Moledred, the imposter chef) (Figure 3).

Figure 3. Characters.

Game Content and Structure

The genre was action adventure. The game contents and flow diagram (ie, the video game structure) are presented in Figure 4 and are briefly described below.

Figure 4. Game flow diagram.



Login Screen

Players were assigned a unique username and password with which to login to the game. After completing baseline data collection, players were randomly assigned to one of four versions of the game. Their username automatically routed them to their assigned version. The only differences between the groups were the implementation intentions described in the goal review and goal setting sections below.

Goal Review and Problem Solving

Goal review appeared in episodes 2-10. It occurred at the beginning of each episode and was led by the Wizard. Players reported whether they met the two types of goals set during the previous episode: a FV consumption goal and a FV recipe preparation goal. In the video game, goals were referred to as challenges to be consistent with the "quest" towards knighthood. Players in one of the three groups that created an implementation intention reported whether they followed it. Players, regardless of group assignment, also reported whether they used the skills learned in the video game (ie, self monitoring, problem solving, and asking/negotiation) to help them meet their goals. For each unmet goal, the player participated in a problem solving sequence to identify the problem that kept them from meeting their goal. Players received feedback statements (tailored to their level of success in meeting their goals and/or whether they used skills to help them meet their goals). Players were then asked whether the effort they put into eating FV was worth it (an assessment of satisfaction). To reinforce goal commitment, they were then encouraged to type in a positive self statement (eg, "Setting and meeting my challenges shows I've got what it takes to be a winner!") and read it out loud with conviction.

Badges

Badges were awarded in episodes 2 - 10 for meeting the goals set in the previous episode. Players could earn up to two badges each episode, one for meeting the FV goal and one for meeting the FV recipe goal. Total number of badges earned determined level of knighthood. There were five levels, ranging from the lowly Honorary Knight to the coveted Platinum Knight. Badges appeared on the player's coat of arms (or shield) displayed in the castle foyer (Figure 5).

Figure 5. Shield with badges.

Cut Scenes

The cut scenes were animated video clips that presented the story. The story was told from the second person perspective. The cut scenes provided an opportunity for the characters to serve as role models through dialogue and action. To make the player feel “part of the action”, the characters “spoke” to the player by referring to him/her as “Squire”.

Knowledge + Mini-Game

This component appeared in episodes 1 - 10. It presented basic knowledge [24] about fruit, 100% juices, and vegetables (Table 1) and then reviewed, refined, and reinforced it in a timed “mini-game” (Table 2). The knowledge provided information the player needed to successfully complete the episode. Mini-games (Figure 6) contained progressively more difficult levels to promote mastery learning [28]. Game characters led this component.

Table 1. Knowledge topics.

Episode	Topic
1	100% fruit juices vs imposters; juice portion size
2	Real fruit vs fruit imposters
3	Real vegetables vs vegetable imposters
4	Recipe substitutions
5	Reinforcing portion size; memory joggers (eg, baseball, tennis ball)
6	FV for breakfast; breakfast on the go
7	FV in fast food restaurants
8	FV vs non-FV
9	Identifying number of FV in recipes
10	Review

Table 2. Mini-game descriptions.

Episode	Game	Description
1	100% Fruit Juice	The player creates chains by linking together 100% juices, 100% juice blends, or Not Juices.
2	Find the Fruit	From the various foods floating in the bubbles, the player must pop the bubbles with the fruits. The player must also identify fruit imposters – ie, high fat items containing some or no fruit.
3	Find the Veggies	From the various foods floating in the bubbles, the player must pop the bubbles with the veggies. The player must also identify veggie imposters – ie, high fat items containing some or no veggies.
4	Lunch-a-Bunch	The player must add fruit and vegetable items to the passing lunch trays to create lunches with 2 servings of fruit and/or vegetables.
5	The Mole Pole 1	A trivia game which tests the player's knowledge of the information presented this episode; each correct answer allows them to progress through a tunnel. The goal is to exit the tunnel and get past the moles that guard it.
6	Breakfast Blunder	The player must add possible breakfast fruit and vegetable items to the food trays to create a breakfast with 2 servings of fruit and vegetables.
7	Fast Food Frenzy	The player must find possible fruit and vegetable choices on the menus of 3 different types of restaurants.
8	The Good Stuff	From the various foods floating in the bubbles, the player must pop the bubbles with fruit and vegetables.
9	The Mole Pole 2	A trivia game which tests the player's knowledge of the information presented this episode; each correct answer allows them to progress through a tunnel. The goal is to exit the tunnel and get past the moles that guard it.
10	The Mole Pole Review	This trivia game is structured similarly to the others; the difference is it tests knowledge presented from all previous episodes.

Figure 6. Mini-game screen shot.

Decision Making

Decision making, led by the Wizard, occurred in episodes 1 - 10. In episode 1, players selected their top three personal values; for each value, they then selected "reason statements" that linked meeting their FV goals with each personal value they selected [29]. For example, if a player chose "being successful" as one of their personal values, they were presented with the following

reason statements: “Meeting my FV challenge” (ie, FV goal); “shows I can meet my challenges”; “shows I can make hard decisions and stick to them”; and “shows I work hard for what I want”. Each episode, the Wizard identified their goal (ie, challenge) (eg, “to eat fruit for snack”), then asked: “Which of these is a good reason to [insert challenge]?” The three values and corresponding reason statements the player selected in episode 1 were then presented for selection. This component was guided by Self Determination Theory, particularly the basic psychological need of “relatedness” - ie, one’s sense of connection [25].

Goal Setting

Goal setting, led by the Wizard, appeared in each episode. This component was tailored and interactive. In episode 1, players selected their favorite FV. In each episode, they were then presented with their favorite FV and decided which ones to use to meet their goal; they also selected the day(s) they would meet their goal. The FV goals became more difficult as the game progressed (Table 3). The groups varied only on whether they created an implementation intention during goal setting (eg, group 1 created no implementation intentions; group 2 created action intentions; group 3 created coping intentions; group 4 created both action and coping intentions).

Table 3. FV goals per episode.

Episode	Food	When	# of Days
1	F	Breakfast	1
2	F	Snack	1
3	V	Lunch	1
4	F or V	Dinner	1
5	V	Snack	2
6	F	Breakfast & Snack	2
7	V	Lunch & Dinner	2
8	FV schema	All day	3
9	FV schema	All day	3
10	FV schema	All day	daily

Behavioral Inoculation

Led by King Brocwell (the Good Guy) and King Sssynster (the Bad Guy), this component strengthened the player’s resistance to potential temptations [27]. King Brocwell supported the player’s decision to meet their goal and identified a potential temptation (ie, friends). King Sssynster then tried to tempt the player to not achieve their goal. King Brocwell refuted the temptation by reminding the player why meeting the goal was important to them (ie, the value-reason statement they selected in decision making).

Skills

This component appeared in episodes 1 – 4 to teach self-regulatory skills (ie, self monitoring, problem solving, asking/negotiation). This component was led by the game characters. Skills were taught through character modeling and dialogue.

Schemas

Schemas are guides for complex behavior [30-31]. In the video game, schemas were presented in episodes 5 - 8 to demonstrate various ways in which to consume 5 servings of FV a day. In these episodes, characters (Knights Julie and Alex, King, Queen, Wizard) each presented their schema (Table 4) then created a sample menu to demonstrate how they used it to plan their meals/snacks each day. The character then asked the player to locate the FV in the sample menu.

Table 4. Schemas.

Character	Schema
Knight Julie	1B, 1L, 1D, 2S
Knight Alex	2B, 1L, 1D, 1S
King	1B, 0L, 2D, 2S
Queen	1B, 2L, 1D, 1S
Wizard	1B, 1L, 2D, 1S

Virtual Kitchen

The virtual kitchen appeared in all ten episodes. It taught food preparation skills, planning, sequencing, and kitchen safety and promoted parent involvement. This component was interactive and included pre-steps involved in recipe preparation (ie, asking for permission, washing hands, etc) as well as a “virtual preparation” of the recipe (ie, a video clip that demonstrated

how to prepare the recipe). With the exception of episode 1, players had a choice of recipes to prepare (Table 5). Recipes were selected from the Knight-in-Training cookbook. The robot, M.I.CH.A.E.L., guided the player through the Virtual Kitchen. At the end of this component, the player selected one of the recipes presented in each episode and set a goal to make the recipe at home.

Table 5. Recipes by episode.

Episode	Recipe Type	Recipe 1	Recipe 2	Recipe 3
1	Juice	Razzle Dazzle Juicy Delight	n/a	n/a
2	Fruit	On-the-Run Trail Mix	Fantastic Fruit & Chocolate	n/a
3	Vegetable	Fiery's Black Bean Burrito	M.I.C.H.A.E.L.'S Veggie Wrap	n/a
4	Fruit & Vegetable	Fivealot's Famous Fruit Salad	Knight Brocwell's Stuffed Potatoes	n/a
5	Vegetable	Knight Julie's Veggie Snack	Fiery's Bean Dip	n/a
6	Fruit	Royal Smoothie	Squire's Strawberry Split	n/a
7	Fruit & Vegetable	Power Pudding Dip	Wizard's Magic Pocket	n/a
8	Fruit & Vegetable	Celebration Sundae	Chef Supremo's Cinnamon Carrots	n/a
9	Fruit & Vegetable	Queen Nutritia's Dip	Platinum Sweet Potatoes	n/a
10	Fruit & Vegetable	Knight Alex's Banana Pops	Golden Knight Burrito	Moledred's Ice Pops

Parent Component

The parent component consisted of newsletters and access to a parent website. Each is briefly described below.

Newsletters

Parent newsletters were designed to promote parent involvement (Figure 7). There were ten newsletters – one matched to each episode of the video game. Newsletters were emailed to parents prior to each episode of the video game. Each newsletter identified the child's general FV and recipe goals for the upcoming episode and provided tips for what the parent could do to help their child meet their goals. Each newsletter also identified vocabulary words (ie, words used in video game with which the child may not be familiar, such as "ingredients") and provided healthy FV recipes and suggestions for overcoming common FV problems families face when attempting to eat FV (Table 6).

Table 6. Parent newsletter.

Episode	Focus	Recipe
1	100% Fruit Juice	Peach Cobbler
2	Added Sugar in Fruits	Strawberry Shortcake
3	Vegetables	Black Bean Soup
4	Fruit and Vegetable Substitutions	Vegetable Lasagna
5	Serving Size Review	Tomato and Bean Dip
6	Vegetables for Breakfast	Breakfast Potatoes
7	Eating Out	Hearty Rice
8	Empty Calories	Round Table Pizza
9	Serving Size Comparisons	Vegetable Soup
10	Final Tips	Blueberry Dessert Cups

Figure 7. Parent newsletter.

Website

The parent website provided information to create a healthy home nutrition and activity environment. It included family-friendly recipes and addressed topics such as grocery shopping, eating on the go, and getting the family involved in physical activity. Information was routinely updated (ie, ten updates corresponding to the ten-episode video game) (Table 7).

Table 7. Parent website.

Episode	Focus	Recipes
1	Shopping Lists & A Well-Stocked Kitchen	Baked apples, cinnamon roasted sweet potatoes, spinach and strawberry salad
2	Getting Kids Involved in the Kitchen	Vegetable pasta, baked bananas, veggie grilled cheese
3	Family Meals	Spanish paella, gazpacho, and strawberry flurry
4	Family Activity Time	Bran muffins, vegetable omelet, fruit parfait
5	Buying & Storing Food	Chicken salad sandwich
6	Food & Kitchen Safety	Veggie couscous, turkey, light fish, pineapple orange frozen yogurt
7	Nutrition Facts Labels	Slow cooker chicken, three bean chili, tossed salad, potato bake
8	Portion Control	Layered salad, brown rice casserole, fruit salad, and chocolate berry cake
9	Eating on the Go	Fruit and nut mix, hummus with veggies, chicken salad sandwich
10	Substitutions	Broccoli mac-and-cheese, baked chicken nuggets, black bean brownies, pineapple angel food cake

Procedures

Intervention

When children were eligible to play the next episode of the video game, an email with a link to the login page was automatically generated and sent to them. Simultaneously, parents received emails with links to the online newsletters and the parent website. An access database tracked participants (parents, children) through the program. Alerts notified the research team when parents and children were eligible to receive the next intervention component (ie, next game episode; next newsletter) and when they were eligible for data collection. The video game was programmed to notify the intervention staff when the child completed an episode, and emails were automatically generated when a parent opened the newsletter email or when the parent website was accessed. If the child did not log on to play the next episode of the game within approximately five days, they were contacted by the intervention staff. The intervention research team was available by email or phone to provide technical assistance. As part of process evaluation, all participant contacts were recorded in the access database.

Data Collection

To assess usual dietary intake, three unannounced 24-hour dietary recalls were obtained at each data collection period using the Nutrient Data System for Research (NDSR-2009), University of Minnesota [32]. The 24-hour dietary recalls were conducted directly with the child; two weekday and one weekend day recalls were obtained using a laptop computer, NDSR-2009 software [33], and 2-dimensional food and measurement models. A paper copy of the models was given to the family for use in the telephone interviews. The child was asked where each meal/snack was eaten, who else was present, whether a TV was on, and whether they watched TV during the meal. The dietary recalls were analyzed for servings of FV [34].

Child psychosocial characteristics (FV preferences [35], asking behaviors [36], self efficacy [37], and outcome expectancies [38]) were collected using existing measures, some of which were adapted for this study. Using the work of Rothman [20] and Green and Brock [39] respectively, child satisfaction and game immersion were assessed using scales developed for this study. Social desirability [40-41] was also collected to control for potential bias in self report data. Brief, semi-structured interviews were conducted with children to further assess their reactions to the game. Parents provided self report data (parent FV consumption [42], home FV availability [43], home FV accessibility [36, 44], family barriers to eating FV [45], parent self efficacy to get their family to eat FV [45], child FV asking behaviors [36], and child executive function [46]). In addition, they provided demographic information at baseline. Self-report data were collected online over a secure, password protected website. Parents and children were each provided unique passwords with which to log on to the data collection website.

Following the framework of Baranowski and Jago [47], process data were collected through staff logs, as children navigated the game, and as parents accessed the parent components. Examples of process data included: recruitment of participants, maintenance of participation, implementation (fidelity and extent), implementation barriers, program exposure, initial use of program, continued use of the program, and contamination. Implementation and exposure assessments were documented using electronic logon records. Game-play data (Figure 4) were collected as children played each episode (eg, logons, goals set, goals attained, values and reasons, number of badges, recipes selected, action intentions, coping intentions). Email open rate (parent newsletters) and visits to the parent website were also collected. Self-report appeal and use of intervention components were collected from children and parents at post 1 data collection (Table 8).

Table 8. Measures

Who	How	What	Baseline	During	Post 1[a]	Post 2[b]
Child	Phone	FV intake (3, 24hr DR [c])	x		x	x
	Online	FV Preferences	x		x	x
		FV Asking Behaviors	x		x	x
		FV Self Efficacy	x		x	x
		FV Outcome Expectations	x		x	x
		Satisfaction With Change		x	x	x
		Immersion			x	
		Social Desirability	x			
		Game Likability			x	
	Gameplay	Logons		x		
		Responses/Choices (ie, goals set/attained, values/reasons, etc)		x		
	Interview	Game Reactions			x	x
Parent	Online	FV Intake (self)	x		x	x
		Home FV Availability	x		x	x
		Home FV Accessibility	x		x	x
		Family Barriers	x		x	x
		Self Efficacy	x		x	x
		Child Asking Behaviors	x		x	x
		Child Executive Function	x		x	x
		Demographic Information	x			
		Overall Reactions/Use			x	
		Email Open Rate		x		
		Website Visits		x		
Staff	Logs	Process Evaluation	x	x	x	x

[a]3 months after baseline assessment

[b]6 months after baseline assessment

[c]dietary recall

Data Analyses

Repeated measures analyses of variance/covariance, controlling for key demographic factors, baseline FV consumption, and energy intake, accommodated a two-level within factor (post 1, post 2) and a four-level between-groups factor design. The group's main effect allowed investigation of group differences, regardless of whether it was post 1 or post 2. The group-by-time interaction term allowed investigation of group differences over time, thus identifying if the treatment was maintained. Univariate outcomes (the number of goals achieved, number of newsletters read, etc) were analyzed using a univariate one between-group factor design. Secondary analyses included investigation of trends in goal attainment, FV consumption, and psychosocial factors across study weeks through the use of Chi-square analyses for ordinal repeated measures. A dose-response analysis was also planned.

Discussion

This report provides a description of the protocol, procedures, and assessment tools for a video game designed to increase FV consumption among children. This research has several strengths. First, it is based on an earlier video game that successfully increased FV consumption in 4th grade children [10]; it was designed within a multi-theoretical framework; and it systematically varies only one component, implementation intentions. Strengths also include a large sample size, a focus on both parents and children, and examination of maintenance effects. Finally, it uses a strong measure of dietary data collection (3, 24 hour dietary recalls at each data collection period). However, this study is conducted in one specific geographic region, thus limiting its generalizability.

To our knowledge, this is the first study to test the effect of implementation intentions on FV goal attainment and consumption and to examine the relationship between

satisfaction and maintenance of behavior change in pre-adolescents. The intervention includes a parent and child component designed within an integrated theoretical framework to maximize the likelihood of behavior change. The successful implementation of this intervention will generate valuable information regarding the effectiveness of this approach for young children.

Acknowledgments

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Authors' Contributions

DT was principal investigator of the study, conceived the project; guided the design of the intervention components; oversaw data acquisition, analysis, and interpretation; and drafted the paper. RB was with the Department of Pediatrics, Baylor College of Medicine when this study was conducted and assisted with design, managed the project, including intervention delivery and data acquisition; she also assisted with revising the manuscript. She is now with the Department of Family and Community Medicine, Baylor College of Medicine. ML was the Director of Marketing with Archimage, Inc (Houston, TX) when the Squire's Quest! II game was designed and the executive producer for the Squire's Quest! II game with responsibilities including project management, client communications, documentation, and copywriting; she assisted with design and participated in revising the manuscript. KC was a co-investigator and assisted with conception; dietary data collection, analyses, and interpretation; and revising the current manuscript. JB helped design and manage the original Squire's Quest! study; she also participated in the design of the Squire's Quest! II study and participated in revising the present paper. TB was the principal investigator for the original Squire's Quest! study; he participated in the conception and design of the Squire's Quest! II study and participated in analysis and interpretation; he also participated in revising the present paper. All authors read and approved the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

B: Breakfast
FV: Fruit(s), vegetable(s)
L: Lunch
D: Dinner
N/A: Not applicable
S: Snack
SQ!2: Squire’s Quest! II: Saving the Kingdom of Fivealot

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Protocol

A Personalized Automated Messaging System to Improve Adherence to Prostate Cancer Screening: Research Protocol

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Abstract

Background: Public adherence to cancer screening guidelines is poor. Patient confusion over multiple recommendations and modalities for cancer screening has been found to be a major barrier to screening adherence. Such problems will only increase as screening guidelines and timetables become individualized.

Objective: We propose to increase compliance with cancer screening through two-way rich media mobile messaging based on personalized risk assessment.

Methods: We propose to develop and test a product that will store algorithms required to personalize cancer screening in a central database managed by a rule-based workflow engine, and implemented via messaging to the patient's mobile phone. We will conduct a randomized controlled trial focusing on prostate cancer screening to study the hypothesis that mobile reminders improve adherence to screening guidelines. We will also explore a secondary hypothesis that patients who reply to the messaging reminders are more engaged and at lower risk of non-adherence. We will conduct a randomized controlled trial in a sample of males between 40 and 75 years (eligible for prostate cancer screening) who are willing to receive text messages, email, or automated voice messages. Participants will be recruited from a primary care clinic and asked to schedule prostate cancer screening at the clinic within the next 3 weeks. The intervention group will receive reminders and confirmation communications for making an appointment, keeping the appointment, and reporting the test results back to the investigators. Three outcomes will be evaluated: (1) the proportion of participants who make an appointment with a physician following a mobile message reminder, (2) the proportion of participants who keep the appointment, and (3) the proportion of participants who report the results of the screening (via text or Web).

Results: This is an ongoing project, supported by by a small business commercialization grant from the National Center for Advancing Translational Sciences of the National Institutes of Health.

Conclusions: We believe that the use of centralized databases and text messaging could improve adherence with screening guidelines. Furthermore, we anticipate this method of increasing patient engagement could be applied to a broad range of health issues, both inside and outside of the context of cancer. This project will be an important first step in determining the feasibility of personalized text messaging to improve long-term adherence to screening recommendations.

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KEYWORDS

Early Detection of Cancer; Text Messaging; Prostatic Neoplasms

Introduction

Cancer is the second most common cause of death in the United States. In 2012, it is estimated that 1.6 million new cancer cases will be diagnosed and 577,190 Americans will die from cancer [1]. At least half of all new cancer cases can be prevented or detected by screening. Cancer screening not only prevents unnecessary cancer deaths, but it also can reduce the morbidity of cancer before it progresses to more advanced aggressive stages [2]. Despite the benefits of cancer screening, public adherence to guidelines for cancer screening is often poor. *Healthy People 2020*, the 10-year health agenda released by the US Department of Health and Human Services, reported only modest screening rates for breast cancer, cervical cancer, and colorectal cancer. For example, only 59% of adults reported being up-to-date with colorectal cancer screening [3].

Although screening can be beneficial, it is important that patients consult their doctor to determine which types of screening are appropriate for them. Screening guidelines vary widely depending on the type of cancer, patient age, gender, ethnicity, and family history [2]. Patient confusion over multiple recommendations and modalities for cancer screening has been found to be a major barrier to screening adherence [4]. Complicating this matter is the fact that cancer screening schedules often need to be dynamically adjusted for each individual based on previous screening results and comorbidities. For example, the recommended interval between prostate-specific antigen (PSA) tests depends on the most recent PSA level, with longer intervals (ie, less frequent testing) for men with lower PSA levels [5]. Similar dynamic screening and intervention algorithms have been suggested for other types of cancers, such as breast cancer [6,7].

Patient engagement and reminders improve adherence to cancer screening guidelines [8]. The Community Preventive Services Task Force, an independent group of public health experts appointed by the Director of the Centers for Disease Control and Prevention, recommends using client reminders to increase cancer screening based on strong evidence of effectiveness; reminders have been shown to increase mammography screening by a median of 10% and increase colon cancer screening by a median of 15% [9]. Although short message service (SMS) text-based reminders sent to mobile phones have not been studied specifically for cancer screening, SMS-based reminders have been demonstrated to reduce patient appointment no-shows by up to 40% [10], and reduce nonadherence with chronic disease follow-ups by up to 35% [11]. SMS reminders have been used successfully in driving positive behavior changes in areas such as medication compliance [12], weight loss [13], smoking cessation [14], and physical activity promotion [15]. A recent review of the use of SMS technology for health behavior change interventions found that SMS interventions yielded positive behavior changes in 93% of studies reviewed. The authors found that SMS was an effective delivery method for tailored advice and reminder messages for behaviors such as smoking cessation, diabetes self-management, and medication compliance [16].

In the United States, mobile messaging solutions have the potential to reach vast numbers of patients. It is estimated that 82% of American adults have cell phones, with the penetration rate skewed higher among African American and Latino populations [17]. A survey conducted in 2010 concluded that 79% of Medicaid patients with mobile phones are active SMS users [18]. Although this project focuses on prostate cancer screening, the product we propose to develop and test has wide-ranging implications for adherence to screening for many other types of cancers and for chronic disease management.

In this project, we propose to develop technology-based interventions, specifically, automated reminders sent to consumer mobile phones to help patients stay motivated and adherent with their personalized cancer screening schedules. The interventions are based on the theory of planned behavior [19], in particular the unified theory of acceptance and use of technology (UTAUT) [20] and the Patient Activation Measure (PAM) [21]. The UTAUT is a theoretical model and instrument used to assess the likelihood of user acceptance for new technology that posits that performance expectancy, effort expectancy, social influence, and facilitating conditions are direct determinants of use [20]. The UTAUT instrument is widely used to evaluate the factors affecting adoption of new technology solutions [22]. Patient activation refers to a person's ability and willingness to manage their health and health care [23]. The PAM is a 22-item assessment used to evaluate an individual's knowledge, beliefs, and confidence in managing their health [21]. High patient activation has been shown to be positively associated with utilization of preventive services, self-management behaviors, medication adherence, self-reported quality of care, and perceived doctor-patient communication [24-26].

We will conduct a randomized controlled trial to study the hypothesis that mobile reminders improve adherence to screening guidelines. Mobile messaging is an intervention that can be applied to a large population at low cost because it can be easily automated. We will also explore a secondary hypothesis that patients who reply to the messaging reminders are more engaged and at lower risk of nonadherence. The impact is that low-cost mobile messaging could be used as a signaling mechanism to predict patients with high risk of nonadherence, and resources could be optimized to target those patients for more intensive follow-ups.

In this project, we focus on prostate cancer to examine proof of principle for our general approach. We will use screening algorithms adapted from evidence-based prostate screening guidelines and multimedia content tailored for mobile phone use. We plan to subsequently develop and test algorithms for

other types of common cancers, such as breast cancer and colorectal cancer.

Methods

Study Objectives

Our primary hypothesis is that use of the mobile messaging reminders will increase patient adherence to screening. To evaluate this hypothesis, we will conduct a randomized controlled trial in a sample of males between 40 and 75 years (eligible for prostate cancer screening) who are willing to receive text messages, email, or automated voice messages. The sample will be recruited from male clinic patients who may or may not be in the clinic for prostate-related problems at the time of recruitment.

Eligibility Criteria

The project will solicit participation from men aged 40-75 years of all ethnicities who visit 3 designated primary care clinics or 2 area community health fairs in Texarkana and New Boston, Texas, and Hope, Arkansas. No one will be excluded from the study on the basis of race/ethnicity or disability. Participants must have Internet access at home or at work and be willing to receive message-based communications on their choice of communication channels, including mobile messaging, email, and automated voice messages. Participants must be willing to pay for any communication costs charged by their wireless carrier, Internet provider, or phone company. Participants will be excluded if they have been diagnosed with prostate cancer, have had a PSA test in the previous 12 months, or have a current appointment for prostate cancer screening.

Recruitment

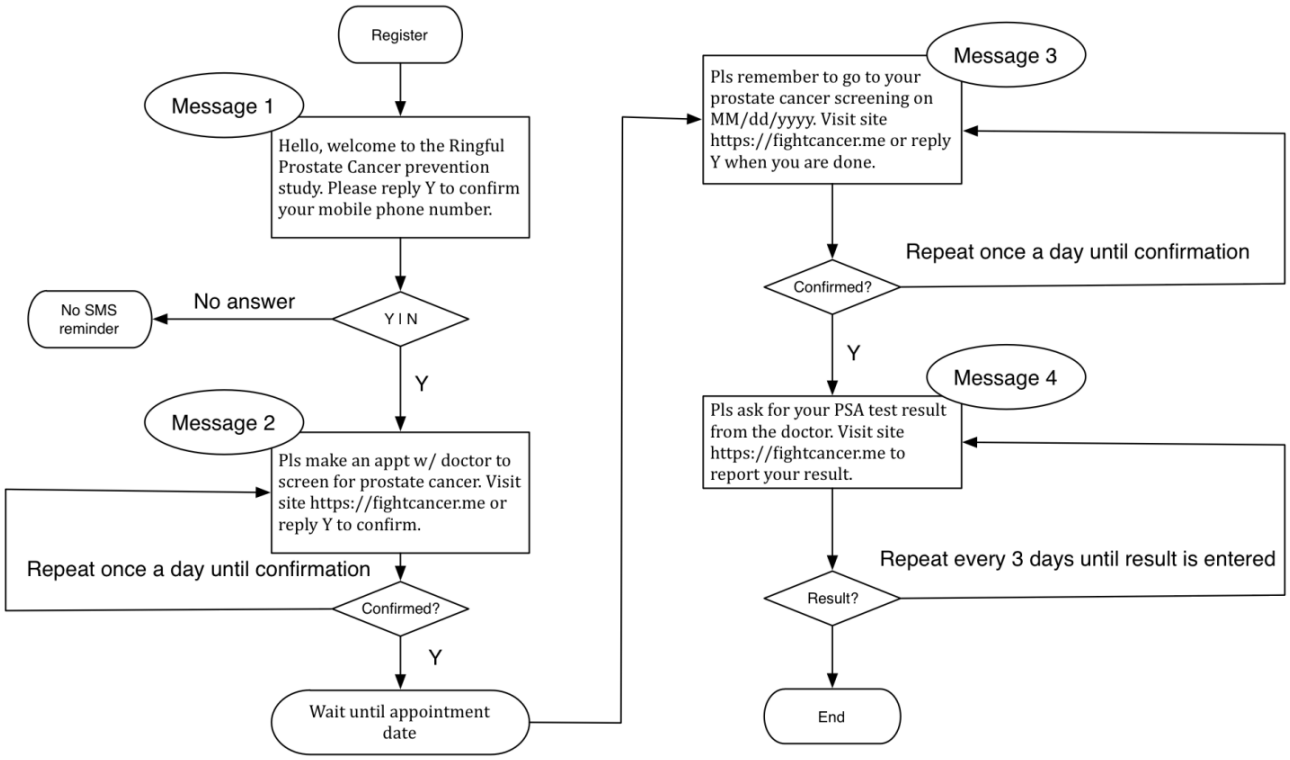
All eligible participants will be given a study information sheet upon check-in at the clinic. The information sheet will include a brief description of the study, including the study purpose, procedure, and relevant risks and benefits. The information sheet will instruct interested participants how to enroll in the study through a secure Web portal where they will give their informed consent and mobile phone number to the research team. When available, a trained research nurse will explain the details of the study to eligible participants, answer any questions, and give the participants the opportunity to enroll during check-in at the clinic. Depending on their communication preference stated at the time of sign-up, participants will receive a text message or email on their phone or a voice message asking them to confirm that they would like to participate in the study. Patients must respond yes to this message to enroll in the study.

Study Procedures

After initial recruitment, participants will be asked to complete a brief questionnaire about their basic sociodemographic details and relevant health history, as well as a Technology Acceptance Model questionnaire [22] and the PAM [21] to measure patient engagement in health care. Participants will be randomly assigned to the intervention or the control group using a random number generator. Randomization will be implemented automatically by a secure password-protected algorithm at the time the user signs up. This guarantees that assignment cannot be predicted before or changed after the participant is registered in the study. All participants will be asked to schedule prostate cancer screening at the clinic within the next 3 weeks, but only the intervention group will receive reminders and confirmation communications for (1) making an appointment, (2) keeping the appointment, and (3) reporting test results back to the investigators.

A flowchart of the reminders/confirmations and the expected responses from participants is illustrated in Figure 1.

Figure 1. Study flowchart.



Screening Reminders

A screening schedule reminder will be sent to remind the participant to make an appointment for the screening test. One week after the participant confirms his appointment, the system will ask the participant whether he has seen the doctor yet. This message will repeat every 2 weeks until the participant confirms that he has kept the appointment and seen the physician. Then the system will ask the participant whether he has received his test results. This message will repeat every 3 days until the participant confirms that he has received the test results. The participant will then be asked to report back his test results to the research team using the secure Web portal.

In addition to the messages, we will also provide patient education and health promotion materials to the participants as part of the communication process. Upon initial registration on the secure website, a short video will explain the importance of prostate cancer screening and what to expect from the screening tests to both the control and intervention group participants. Once the intervention group participants confirm and report back their test results, another short video will explain ranges and meanings of test results, and the preventive actions the participant can take to reduce prostate cancer risk.

At the end of the study period, all patients will be contacted again through their preferred communication channels as indicated at sign-up (eg, text message, email, or voice message). All participants will be asked to report whether they have made appointments for prostate screening, kept their appointments, and reported back the test results. All participants will also be asked to complete a second questionnaire on the secure website that is a repeat of all initial questionnaire items except the sociodemographic items. The study period will last 8 weeks. Participants will receive a US $10 gift card as compensation for their participation in this study.

Evaluation

Three outcomes will be evaluated: (1) the proportion of participants who make an appointment with a physician following a mobile message reminder, (2) the proportion of participants who keep the appointment, and (3) the proportion of participants who report the results of the screening (via text or Web). To facilitate comparison with existing literature, each outcome will be examined independently as a separate outcome. Adherence rates in the intervention and control group will be compared using the Fisher exact test.

Our second goal is to examine user adoption, identify factors that foster or hinder adoption, and identify patients who are at high risk of nonadherence. Examination of these questions will utilize data from the intervention group only. We hypothesize that those who respond to texts will show higher levels of adherence and patient activation than those who do not respond. For these analyses, we will focus on both user responses to reminders and adherence, which will be treated as a continuous variable by counting the total number of adherence behaviors (eg, made the appointment, kept the appointment, and followed up after results). Factors that foster or hinder adoption will be examined both preintervention and postintervention utilizing all available measures, particularly those related to technology acceptance factors defined in the UTAUT model. Examination of user adoption and factors fostering or hindering adoption will be accomplished through ordinary least-squares regressions. The UTAUT survey questionnaires are designed to measure 4 latent factors that drive technology adoption: performance expectancy, effort expectancy, social influence, and facilitating conditions. The first 3 factors are linked to behavior intention,

another latent factor. We will conduct confirmatory analysis using structural equation modeling technique against the data. This will result in a path diagram that weights each latent factor's contribution to user adoption of this technology. The analysis will help to identify the key drivers of user adoption and give the team directions for further product improvements.

The PAM survey contains 13 questions that measure 4 different aspects of patient activation. We will calculate a mean score and standard deviation for each question in the following groups: intervention, control, intervention who reported outcomes, and intervention who did not report outcomes. We will then detect any significant differences in PAM scores among those groups. A significant difference between intervention and control could indicate that the reminders themselves help activate the patient; a significant difference between the ones who reported outcomes and the ones who do not could provide a signaling mechanism to identify high-risk patients through automated means.

Based upon the patterns of adherence among patients receiving the intervention, it may be possible to identify those patients at highest risk for nonadherence and to identify which variables differentiate those at risk of nonadherence from those who are most likely to adhere.

Discussion

The increasing complexity of cancer screening algorithms is such that the burden of ensuring compliance needs to shift from individual patients and health care providers toward centralized and automated systems. What may seem overwhelming for a patient or physician, such as graduated screening intensities contingent on the previous PSA level, can be implemented in a relatively straightforward fashion by computer. We believe that use of centralized databases and SMS text messaging could improve adherence with screening guidelines. Furthermore, we anticipate this method of increasing patient engagement could be applied to a broad range of health issues, both inside and outside of the context of cancer. This project will be an important first step in determining the feasibility of personalized text messaging to improve long-term adherence to screening recommendations.

Acknowledgments

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Conflicts of Interest

This research is supported by a small business commercialization grant from the National Institutes of Health (NIH). The outcome of this study could result in financial benefit for the PI institution, Ringful Health. Dr Michael Yuan is a significant shareholder and officer of Ringful Health. Ron Johnson and Emily Hébert are employees of Ringful Health. Dr Elizabeth Vandewater, Dr Andrew Vickers, and Dr Ju Long are consultants for Ringful Health through this grant project.

Multimedia Appendix 1

Reviewer comments and summary statement from NIH peer reviewers.

[PDF File (Adobe PDF File), 67KB - resprot_v1i2e20_app1.pdf]

Multimedia Appendix 2

NIH Approval and Funding.

[PDF File (Adobe PDF File), 117KB - resprot_v1i2e20_app2.pdf]

Multimedia Appendix 3

IRB Review and Approval.

[PDF File (Adobe PDF File), 288KB - resprot_v1i2e20_app3.pdf]

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Abbreviations

PAM: Patient Activation Measure
PSA: prostate-specific antigen
SMS: short message service
UTAUT: unified theory of acceptance and use of technology

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Proposal

A Collaborative Quality Improvement Model and Electronic Community of Practice to Support Sepsis Management in Emergency Departments: Investigating Care Harmonization for Provincial Knowledge Translation

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Abstract

Emergency medicine departments within several organizations are now advocating the adoption of early intervention guidelines for patients with the signs and symptoms of sepsis. This proposed research will lead to a comprehensive understanding of how diverse emergency department (ED) sites across British Columbia (BC), Canada, engage in a quality improvement collaborative to lead to improvements in time-based process measures and clinical outcomes for septic patients in EDs. To address the challenge of sepsis management, in 2007, the BC Ministry of Health began working with emergency health professionals, including health administrators, to establish a provincial ED collaborative: Evidence to Excellence (E2E). The E2E initiative employs the Institute for Healthcare Improvement (IHI) model and is supported by a Web-based community of practice (CoP) in emergency medicine. It aims to (1) support clinicians in accessing and applying evidence to clinical practice in emergency medicine, (2) support system change and clinical process improvement, and (3) develop resources and strategies to facilitate knowledge translation and process improvement. Improving sepsis management is one of the central foci of the E2E initiative. The primary purpose of our research is to investigate whether the application of sepsis management protocols leads to improved time-based process measures and clinical outcomes for patients presenting to EDs with sepsis. Also, we seek to investigate the implementation of sepsis protocols among different EDs. For example: (1) How can sepsis protocols be harmonized among different EDs? (2) What are health professionals' perspectives on interprofessional collaboration with various EDs? and (3) What are the factors affecting the level of success among EDs? Lastly, working in collaboration with the BC Ministry of Health as our policy-maker partner, the research will investigate how the demonstrated efficacy of this research can be applied on a provincial and national level to establish a template for policy makers from other jurisdictions to translate knowledge into action for EDs. This research study will employ the IHI model for improvement, incorporate the principles of participatory action research, and use the E2E online CoP to engage ED practitioners (eg, physicians, nurses, and administrators, exchanging ideas, engaging in discussions, sharing resources, and

amalgamating knowledge) from across BC to (1) share the evidence of early intervention in sepsis, (2) adapt the evidence to their patterns of practice, (3) develop a common set of orders for implementing the sepsis pathway, and (4) agree on common indicators to measure clinical outcomes. Our hypothesis is that combining the social networking ability of an electronic CoP and its inherent knowledge translation capacity with the structured project management of the IHI model will result in widespread and sustained improvement in the emergency and overall care of patients with severe sepsis presenting to EDs throughout BC.

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KEYWORDS

Knowledge translation; continuous quality improvement; emergency medicine; sepsis

Introduction

Project Overview

Recent medical research literature on emergency sepsis management demonstrates that early goal-directed therapy (EGDT), composed of the rapid implementation of a sequence of diagnostic and management steps by a cohesive, interprofessional team in the emergency department, can positively influence morbidity and mortality rates. One urban emergency department in British Columbia (BC), Canada, has successfully integrated the EGDT protocol into the emergency care map of septic patients and demonstrated significant improvement of septic patients' outcomes. A care map can be viewed as a workflow diagram using basic flowchart symbols, such as process block, decision, and document, to map out and describe the details of the care process. Disseminating and diffusing this team-based practice throughout the rural and urban emergency departments in BC is integral to significantly reducing morbidity and mortality provincially.

The practice improvement model advocated by the Institute for Healthcare Improvement (IHI) is recognized as an effective strategy to assist teams and organizations to implement system improvement processes. In addition, a community of practice (CoP) is touted as a useful social networking model to aid health care teams toward mutual learning and knowledge exchange. Meanwhile, modern information technologies connected through the Internet are revolutionizing how individuals and groups from disparate geographic locations can effectively communicate and collaborate together. The opportunity is ripe in health care to examine and rigorously evaluate how information technologies can facilitate the construction and nurturing of an electronic community of practice (eCoP) to support the implementation of a quality improvement model (informed by the IHI practice improvement model) to harmonize team-based health practices.

Study Objectives

What are the impacts of engagement in the sepsis quality improvement collaborative on uptake of and adherence to evidence-based sepsis guidelines and the management of sepsis in the context of emergency medicine? A collaborative, as defined by the IHI, is a time-limited effort (usually 9–18 months) of multiple organizations that come together to learn about and to create improved processes in a specific topic area. The expectation is that the teams share expertise and data with each other; thus, "Everyone learns, everyone teaches."

Specific research questions include (1) How is the quality improvement collaborative implemented, and how do members within and across emergency department sites engage in the collaborative? What are participants' perceptions, experiences, and satisfaction levels related to engaging in the collaborative processes? (2) What are the practice patterns of sepsis management within and across emergency department sites? Have the patterns of sepsis care at emergency department sites changed over time? To what degree have patterns been harmonized across the emergency department sites? and (3) What change has occurred in clinical sepsis data collected over time within and across emergency department sites? What are the contextual factors that influence clinical impact?

Study Design and Evaluation

The University of British Columbia Faculty of Medicine, in collaboration with the BC Ministry of Health, the six BC Health Authorities, and emergency departments throughout BC conducted a needs assessment of emergency departments across BC in 2007 and formed a trial collaborative in 2008 under the Evidence to Excellence Initiative, referred to as the E2E pilot. This current research will build on the work of the E2E pilot to engage 18 emergency department teams from across BC to form a quality improvement sepsis management collaborative supported by an eCoP, to implement the sepsis EGDT guidelines during a 3-year period. Mixed method evaluation will include (1) tracking five clinical outcome indicators in each participating emergency department, (2) understanding health professionals' and administrators' perspectives, and (3) evaluating the development, implementation, and change of each emergency department's clinical care mapping. This is a timely and novel area of research, as there are no published studies demonstrating and documenting the combination of a quality improvement collaborative with an eCoP to support a community-building approach toward systemwide practice coordination of sepsis management in emergency departments.

Background

This section highlights three key areas salient to our research proposal. First, we discuss the scope of the problem and evidence-based management of patients with sepsis in emergency departments. Second, we highlight the knowledge translation challenge of systematically implementing evidence-based strategies into emergency departments in BC. Third, to meet the provincial objective of enhancing sepsis management to optimize knowledge translation, we explore the literature on the IHI collaborative process in quality improvement implementation, and the literature on CoP and eCoP in enhancing team communication and knowledge

exchange. Fourth, with some existing examples to illustrate the application of an eCoP in practice, we propose combining a quality improvement model with an eCoP as the theoretical basis of our study proposal.

Sepsis Management in the Emergency Department

Sepsis is a complex syndrome comprising a range of clinical conditions caused by the body's response to an infection, which can develop into severe sepsis resulting in organ failure and death. Severe sepsis is a major and underappreciated cause of morbidity and mortality worldwide. There are 750,000 cases of severe sepsis annually in North America, and approximately 1400 people worldwide die daily of sepsis [1,2]. Due to its aggressive and multifactorial nature, of those who die of sepsis, about 30% die within a month of diagnosis and about 50% within 6 months [3,4]. In addition to being a leading cause of intensive care unit admissions, sepsis consumes tremendous emergency department resources. Data indicate that suspected sepsis accounts for 500,000 emergency department visits annually in the United States, and that these patients spend an average of almost 5 hours in the emergency department [5].

Recent years have seen a revolution in the diagnosis and treatment of sepsis, starting with the development of operational definitions for severe sepsis and septic shock [6]. Increasing evidence demonstrates that timely delivery of appropriate therapy significantly improves outcomes in patients who have severe sepsis [7]. Such therapies include the rapid delivery of appropriate antibiotics and aggressive resuscitation [3]. Kumar et al demonstrated an average 7.6% decrease in survival for each hour's delay in giving antibiotics from the time of onset of hypotension (shock) [8].

In 2004, the Surviving Sepsis Campaign brought together critical care and infectious disease experts representing 11 organizations, including the Society of Critical Care Medicine and the European Society of Intensive Care Medicine. The work of this campaign resulted in the development of guidelines for the early and comprehensive management of severe sepsis, known as EGDT, with the aim of reducing mortality by 25% within 5 years [7]. Key components of this strategy include aggressive fluid administration, early antibiotic usage, use of various physiologic measurements to guide the resuscitation of the acutely septic patient, and prompt admission of patients to close monitoring and care such as in intensive care units. The EGDT guidelines were endorsed by the IHI, who translated them into resuscitation bundles, or grouped interventions. These guidelines were updated in 2008 [9].

One example of success achieved with these guidelines in BC has been the experience at St Paul's Hospital, a 500-bed tertiary care academic hospital in Vancouver, with a 15-bed intensive care unit and an emergency department that sees over 60,000 patients per year. The implementation of the EGDT guidelines included a set of early identification indicators, a computerized physician order entry system set for suspected sepsis, the introduction of invasive hemodynamic monitoring, and a sepsis kit in the emergency department. By converting the evidence from the guidelines into a clear algorithm, raising awareness of sepsis with an extensive education campaign, and integrating several key interventions into the emergency care map of septic patients, they achieved their targets of clinically significant improvements in process outcomes and in the survival of patients who presented to the emergency department because of severe sepsis. In the 6 months following introduction of the guidelines, improvements were observed in time to initiation of EGDT (3.2 vs 10.4 hours, $P = .001$) and to achievement of resuscitation goals (10.4 vs 30.1 hours, $P = .007$), as well as a trend toward more rapid antibiotics administration (1.4 vs 2.7 hours, $P = .06$). This was associated with a decrease in hospital mortality rate to 27.0% from 51.4% in the preprotocol patients (absolute risk reduction = 24%; 95% confidence interval 3%–37%). Improvements in process measures and clinical outcomes, including mortality, were sustained at 16 months after implementation.

Challenge of Systemwide Knowledge Translation of EGDT in BC

Implementation of evidence-based guidelines and protocols into a health system with multiple health teams is a recognized and significant challenge [10,11]. It is clear that simply disseminating the latest evidence to health professionals through conferences and other traditional educational settings lacks the ability to influence individual health professionals or health system change. Clearly, to effectively incorporate evidence-based guidelines for patient care management in the emergency department, much work needs to be done beyond making the team aware of such protocols.

For health care teams and their members in the health system who are actively seeking practice improvement together, knowledge translation requires intervention beginning with the individual and progressing through to health care teams in the system. Acquisition of necessary knowledge and skills by individual health professionals needs to be synchronized with the establishment of quality improvement strategies to implement change and measure outcome by the entire team. In addition, a mechanism of knowledge exchange between teams in the health system is necessary to spur mutual learning and mentoring. Therefore, three key aspects are needed to bring about an effective and lasting change: (1) an evidence-based approach to guide clinical practice, (2) an engaged interprofessional team of emergency health care providers, and (3) an effective implementation and quality improvement process to engineer the redesign of clinical pathways among different teams to work together in a health system.

In the case of sepsis management in BC, as earlier stated, the emergency department team at St Paul's Hospital has successfully provided pilot evidence of the benefits of EGDT. How can we now help spread this practice throughout emergency departments in BC to magnify these health outcome benefits provincially? How should the variations of the different emergency departments (eg, urban, regional, and rural practice environments) with variability in resources availability (eg, laboratory testing, access to intensive care units) be appropriately accounted for in EGDT implementation? How do we promote mutual learning and knowledge exchange among these different emergency department teams? How do we facilitate the establishment of provincewide quality improvement and evaluation mechanisms for measuring change? BC will

need a three-pronged strategy to (1) assist individual emergency department health professionals in knowledge acquisition and behavioral change based on this evidence-based approach of EGDT, (2) establish a provincial implementation and quality improvement process with buy-in from all participating emergency departments to share the joint vision to improve provincial sepsis outcomes, and (3) engage the rural, regional, and urban emergency department teams in BC to establish their own team approach for implementing EGDT based on best evidence, available resources, and their unique contexts to animate the provincial quality improvement process.

While there is no proven, unified model in the literature to achieve all three prongs of the strategy, the literature offers three separate approaches, each specifically fulfilling an important aspect of the overall knowledge translation strategy. They are (1) the collaborative quality improvement model advocated by the IHI for establishing a quality improvement initiative, (2) the CoP approach in building a community of health professionals, and (3) the use of information technologies to capture knowledge and promote communication that overcomes geographic barriers. Each of these three approaches is highlighted in detail below.

The Quality Improvement Collaborative Model

The proposed research incorporates the IHI's quality improvement collaborative model [12]. Recall that a collaborative is a time-limited, structured improvement project. Teams participate in a series of sessions where they learn how to plan, implement, and measure the impact of changes intended to create improvement. Between sessions, ideas are incrementally applied and tested locally. Improvement teams also share with other teams what has and has not worked for them.

Several health care organizations have seen breakthrough improvements in quality while reducing costs by adopting the IHI collaborative improvement model. Between 1995 and 2003, IHI sponsored over 50 collaborative projects. The results of these projects were dramatic and included reducing waiting times by 50%, reducing worker absenteeism by 25%, reduced intensive care unit costs by 25%, and reduced hospitalizations for patients with congestive heart failure by 50% [11].

Communities of Practice in Health Care and Emergency Medicine

Etienne Wenger, the acknowledged pioneer of the term community of practice [13], defined it as: "…groups of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis" [13]. Key aspects of CoPs are (1) defining the scope of the community, (2) engaging committed participants, (3) identifying common needs, (4) outlining the goals or terms of reference of the community, (5) maintaining members' interest and involvement, (6) growing the community, (7) developing a knowledge base, and (8) adding value [13]. This CoP concept was supported and applied in organizational behavior in business [14], and has also been shown to be an effective means for promoting evidence-based practice, patient-centered collaborative care, knowledge sharing and creation, and emotional or collegial support [15]. The resultant infrastructure allows sharing of clinical and operational practices, and allows that information to be contextualized and adapted to the local medical environment, thereby improving uptake. We see this to be an effective social networking environment to promote collaboration for health practitioners and administrators working in BC emergency departments. Health practice is more than an individual pursuit, and the learning process has to be seen, conceptualized, and realized as an iterative process.

The Use of Information Technologies to Enhance Knowledge Translation

Information technology enhances the capabilities of a CoP [16]. An online emergency medicine CoP can provide members with the opportunity for peer-to-peer learning and problem solving from anywhere at any time. This can help to overcome the challenges of geography and time that face emergency medicine health care providers. Several empirical studies have shown the benefits an eCoP can have within the health care sector generally [17-20], and in the context of emergency medicine specifically [21,22]. We intend to build on past sepsis management research by purposefully embedding information technologies into the CoP and measuring its utility in enhancing communication and knowledge sharing. In addition, we intend to demonstrate process improvement and subjective perception of learning of health professionals, as well as the progressive harmonization of practice patterns between emergency departments throughout the Sepsis Quality Improvement Collaborative.

Context: Evidence to Excellence Pilot

In 2007, the BC Ministry of Health provided funding to the E2E pilot and conducted a needs assessment with emergency health professionals to better understand their needs in optimizing the quality improvement of clinical areas and operational processes in emergency services delivery. This assessment revealed the necessity to share resources, have access to the latest evidence, network with their peers, have a means to implement the latest evidence, and have access to assistance to facilitate quality improvement implementation.

In 2008, the E2E pilot ran a trial collaborative on the clinical topic of sepsis and the operational topic of triage. The committees selected these topics during the needs assessment. The E2E pilot's trial collaborative has recruited 55 teams (18 sepsis collaborative teams and 27 triage collaborative teams) from 31 emergency department sites across BC. There were 170 participants across these 55 teams working to improve sepsis care and triage processes at their sites through the IHI collaborative process that is administered by the E2E pilot. This operational pilot provided an understanding of the mechanics of running a collaborative; however, no evaluation was completed for the trial collaborative.

Electronic Community of Practice

The E2E pilot also built a trial beta version of an eCoP environment for the trial collaborative. This included an overarching E2E eCoP, which allowed all practicing BC emergency medicine professionals to share resources, participate in discussion forums, and view relevant upcoming events. The

eCoP's purpose is to build a virtual CoP by providing an online (Web-based) space to exchange ideas and discussions, share resources, and amalgamate knowledge. In the context of E2E, the eCoP will build this virtual community for professional (clinicians and administrators) working in emergency departments across BC.

The key components of the eCoP are *resources*, *discussion forums*, *events*, *WikiDocuments*, and *members*. The resources component provides the ability to post, view, and download resources or files that would be beneficial to personnel working in emergency departments. The resources are organized in folders. The discussion forum component provides threaded discussion forums. The eCoP can accommodate as many forums as the community needs, which are organized by folder and then by the topic. The events component allows moderators and organizers to add events to a calendar function that are of interest to the community, which can be viewed by all members. The WikiDocuments component provides a working document where multiple people can collaboratively develop a body of work, which can be viewed by all members of the community. Finally, the members component allows members to search for their colleagues and have access to the contact information that each member has granted permission to be shared by the community.

The architecture for access to the eCoP for the E2E pilot is described below. The main portal to the eCoP would be from the E2E website. Once first-time users access the eCoP, they can sign up for immediate access by entering their profile information, and returning users will simply log in. The E2E eCoP will be open to all interested people, and there will be no approval process for access. This E2E eCoP will be an exchange for all areas relating to emergency medicine, including clinical topics, operational topics, and improvement methods or strategies. This overarching E2E eCoP will provide access to the current time-limited, project-based eCoPs that E2E is facilitating, such as the sepsis collaborative, which is relevant to this proposal. The sepsis eCoP (and other topic eCoPs) will be restricted to those people who are participating in the sepsis improvement project to provide a safe collaborative space to share ideas and overcome barriers to improvement. No log-in will be necessary; however, users will need approval prior to access. Each eCoP will have all the key components previously described.

Additionally, there was an eCoP for each active trial collaborative, which provided a discussion around improvements and best practices, and provided a forum to post data and change concepts. This beta eCoP, with active membership of approximately 160 and started on May 15, 2007, had 637 visits and over 12,000 pages viewed since inception. The unprecedented opportunity to carry out a rigorous evaluation of this eCoP in its contribution to interprofessional learning, knowledge exchange and capturing, and contribution to quality improvement in provincial sepsis management will be both highly relevant and timely.

Methods

The overarching purpose of the proposed research is to implement a *quality improvement collaborative* and evaluate how emergency departments across BC engage in this model to make improvements in *sepsis management*. We use the IHI definition of a collaborative: "a time-limited effort (usually 9–18 months) of multiple organizations that come together to learn about and create improvement processes in a specific topic area" [12] through sharing of knowledge, experiences, and data. We will evaluate the processes of collaboration and harmonization of sepsis management within and across emergency department sites engaging in the collaborative.

This research study will employ a multiple case studies approach and will use both qualitative and quantitative methods of analysis. It will incorporate the principles of participatory action research and use an eCoP to engage emergency department practitioners (eg, physicians, nurses, and administrators) from across BC. Specific outcomes of this study include (1) sharing the evidence of early intervention in sepsis (eg, exchanging ideas, engaging in discussions, sharing resources, and amalgamating knowledge), (2) adapting the evidence to their patterns of practice, and (3) developing a common set of guidelines or protocols for implementation of the sepsis pathway.

Research Questions

The principal research question for the proposed study is as follows: What are the impacts of the sepsis quality improvement collaborative on uptake of and adherence to evidence-based sepsis guidelines and the management of sepsis in the context of emergency medicine?

This will be addressed through the following specific research questions:

1. How is the quality improvement collaborative implemented, and how do members within and across emergency department sites engage in the collaborative? What are participants' perceptions, experiences, and satisfaction levels related to engaging in the collaborative processes?

2. What are the practice patterns or care maps of sepsis management within and across emergency department sites? Have the patterns of sepsis care at emergency department sites changed over time? And to what degree have patterns harmonized across the emergency department sites?

3. What change has occurred in clinical sepsis data collected over time within and across emergency department sites? What are the contextual factors that influence clinical impact?

4. In what ways has the eCoP contributed to the change in individual health professionals' attitude, knowledge, and skills, and in the practice patterns and septic patient care maps of the emergency departments involved?

Overview of Procedures

Evaluation will use a participatory action approach. Throughout the course of this project, we will evaluate the collaborative and collect case study data including care map data and clinical outcome data. Table 1 highlights some of the main activities during the 3-year project.

Table 1. Main activities of the 3-year sepsis quality improvement collaborative project.

Year	Objective	Associated activities
1	Synthesize E2E[a] pilot data	Synthesize the E2E pilot data and its trial collaborative to inform the current project and best prepare for the sepsis collaborative in year 2.
	Develop data collection system and infrastructure	Develop an online data collection system and a strategy for uniform collection of clinical sepsis data. This includes training and recruitment of personnel in central data collection.
	Complete prework for sepsis collaborative	Recruit emergency department sites and teams to engage in the sepsis collaborative and associated case study research.
2	Develop baseline care maps for each recruited site	Systematically and uniformly create baseline care maps for each participating site to outline current sepsis management care processes.
	Establish a common quality improvement framework	At the beginning of year 2, hold a common session to look at evidence of early goal-directed therapy, jointly examine the protocol, and agree through a consensus-building process on a set of five core indicators of measurement to be collected (see Clinical Sepsis Data in the Measures section) to facilitate cross-site comparisons.
	Run the sepsis collaborative; conduct three sepsis learning sessions for emergency department personnel	(1) Hold learning session 1 in May 2010, with first action period from May to September 2010, (2) hold learning session 2 in September 2010, with action period from September 2010 to January 2011, (3) hold learning session 3 in January 2011, with final action period from January 2011 to March 2011.
	Develop postcollaborative care map	Using the same methods for developing the baseline care map, create postcollaborative care map.
3	Evaluate sepsis collaborative	Analyze findings, conduct participant focus groups and survey, and evaluate sepsis indicators from data that were collected.
	Evaluate sustainability and dissemination of sepsis improvements	Evaluate the success and barriers to the sustainability and translation of the sepsis improvements that have been realized through the collaborative.
	Develop sustainability and dissemination strategy	Develop a strategy to sustain gains in sepsis management and a strategy to disseminate best-care practices to other sites across British Columbia.

[a] Evidence to Excellence.

Design

The proposed research uses a multiple case studies design, which relies on both qualitative and quantitative data and analysis. The 18 sites engaged in the pilot will be approached and recruited for the proposed research. Multiple data sources will be documented and examined to effectively "tell the stories" of the 18 cases in terms of practice, engagement in the collaborative, and quality improvement in sepsis care.

Community engagement will be an iterative process that spans the initiative (including planning), implementation, training, evaluation, and future direction settings (eg, sustainability). Ethical approval to conduct this proposed research will be sought whenever and wherever necessary. The project team will establish and work according to the guidance of an advisory committee comprising collaborative members and health professionals. Research is intended to engage individuals in the emergency department sites (including both health professionals and health administrators of the department, or the hospital or health authority) to be part of the evaluation team and develop research and evaluation skills. Finally, to engage the participating emergency department sites in all aspects of the study, the research framework will be flexible and responsive to member input.

Settings and Participants

We define a *case* as a participating emergency department site. The care map related to sepsis management will be a core aspect of the case study. For this proposed research, *care mapping* can be viewed as a workflow diagram using basic flowchart symbols, such as *process* block, *decision*, and *document*, to map out and describe the details of the care process. The collaborative or team members represent the individual participants. The current trial collaborative, facilitated by the E2E pilot, has provided an understanding that the participants agree to collect clinical data and are willing to volunteer their time to this work to improve sepsis management. Because each emergency department site is resourced differently, different clinical sepsis data are collected at each site. For the proposed research, core sepsis data available across sites will be examined.

Measures

The proposed research will identify and describe each case, collect baseline and comparison data, gather participant perception data, monitor practice changes, and track clinical sepsis measures.

As earlier stated, multiple case studies will be used to document practice and engagement in the collaborative at individual sites, as well as to understand the interaction within and across sites in the context of the sepsis collaborative. In systematically describing the cases, we will gather information related to the participants, workflow, and sepsis management at the emergency department and artifacts created through engagement in the sepsis collaborative. These include usage data from the eCoP platform, perceptions and experiences, and documents created by participants as they engage in quality improvement projects in the sepsis collaborative.

Understanding the relationships and interactions within, among, and between the case sites will provide the basis for documenting and evaluating how change occurs. Clinical sepsis data will be used to understand the improvements that potentially result from engaging in the collaborative. We will include three main areas of measurement, as follows.

Perception and Experience Data

We will use a variety of qualitative and quantitative measures to evaluate and understand the participants' perspectives on the following: implementation of protocols; participant engagement and collaboration through the use of the eCoP environment; collaboration within and across emergency department sites; and implementation and use of the IHI collaborative model within and across sites throughout the project. This will enable a foundational understanding of the processes that emerge. We aim to understand differences and similarities across sites, as well as how the eCoP is used and contributes to collaboration processes. Data collection will include focus groups of health care practitioners at the emergency department sites and individual surveys (3–20 participants/site). eCoP usage data will be collected to understand level of engagement and processes of collaboration, thus providing recommendations for future use in the collaborative. The usage data will include the following: (1) data on the number of visits to the eCoP website, which can be distilled to monthly, weekly, and daily, as well as the location of the visiting member, (2) data on the average time each user spent on the website, and (3) the number of pages viewed, which will indicate which resources, discussion forums, and calendar events were most popular.

We will interview a cross-section (multiple sites with various health professionals) of collaborative participants. Interviews will capture pre- and postinvolvement expectations, experiences engaging in the collaborative, and perceptions of impact of engagement in the collaborative on sepsis management. This will constitute a formative evaluation of participant engagement. Online focus groups will be carried out throughout the project, within the eCoP's discussion boards. Data captured from the eCoP (eg, discussions and downloaded resources) will be examined. Online surveys will be used to assess participant satisfaction and provide feedback at regular intervals.

At the end of year 3, we will conduct focus groups of emergency department site participants to gain postcollaborative (end point) perspectives. Participants will be asked to reflect on future sustainability of the collaborative and sepsis improvement processes. These same issues will be addressed in detail through interviews with a subsample of stakeholders and participants.

Practice Change Data

Another important component of the proposed research is to evaluate the extent to which the various participating emergency departments across the province become harmonized in their respective management of patients with sepsis. Central to the ability to evaluate the degree of harmonization is care mapping. Each emergency department site will create an initial (baseline) care map (ie, a care map of how sepsis patients are, on paper, to be managed) and will be asked to develop subsequent care maps at the end of each year during the 3-year proposed research to accurately reflect current practice in sepsis management. Early on, participating sites will be invited to participate in a learning session related to care mapping led by collaborative member(s) with expertise in care mapping processes.

We recognize there is a potential for the Hawthorne effect—a change in behavior or performance due to a change in environmental conditions—to take place; however, an asset of the 3-year duration of this research is that the potential impact of the Hawthorne effect is reduced with the reinforcement of improved practices over time. Further, engagement in the collaborative will provide opportunities for participants to systematically reflect on their practices in the course of the learning sessions, and ongoing discussion of best practices with colleagues and experts.

While the concept of care mapping is not new, the unique aspect of our proposed research is that funding from the Canadian Institutes of Health Research will enable us to develop a quantifiable index that highlights the harmonization of sepsis management across emergency department sites in BC to compare the degree of similarity of care maps across the province and the change in similarity (either more or less similar) over the 3-year time frame. Calculating this index would be similar to the bioinformatics' approach in calculating the similarity of genes between different people with similar illnesses, thereby locating the responsible segments of the genes that lead to the expression of the disease. Furthermore, the process of evaluating and analyzing the adherence to care maps and successes and challenges may eventually lead to a context-specific clustering of care maps for emergency departments in rural, regional, urban, and provincial contexts. This approach can set a benchmark for future endeavors in refining the application of protocols in different contexts.

Clinical Sepsis Data

The evidence-based literature shows that several clinical measures are important in the management of sepsis. Recognizing that emergency department sites across the province have varying resource capacities and to prevent the collection of clinical sepsis data becoming too cumbersome for the participating emergency department sites, five *core* measures will be collected for this proposed research: (1) time to administration of antibiotics, (2) time to doing blood cultures before antibiotics are administered, (3) emergency department length of stay, (4) length of time between the patient's arrival and when the provincial bed management transfer call is made (to facilitate the transfer of patients to a facility with intensive care capabilities or contacting a consultant for admission and definitive care) or admission to the hospital's own intensive care unit, and (5) mortality within 2 months, the cause of death, and its relationship with the sepsis episodes. These measures have been found to be practical and feasible to collect at each of the sites.

Members of the E2E pilot have demonstrated their willingness to collect clinical sepsis data in addition to their day-to-day workflow. Relying solely on nurses' and physicians' notes as the primary source of recorded data can be challenging; therefore, we will develop a formalized structure for recording the data, including a 1-page data form with all the core indicators

(clinical sepsis data) that can be filled out in real time and faxed to a central location for collection. This form will also be able to be filled out digitally and sent through the eCoP to a central location for collection. Therefore, the eCoP can also become a medium for emergency department practitioners to upload their data in a secure and user-friendly manner that enhances the degree to which clinical sepsis data are collected.

The proposed research would contribute to the realization of various benefits for participating emergency department sites. Engaging in the collaborative and the evaluation will enhance awareness of sepsis management and create a more streamlined implementation of treatment for septic patients. Further, the proposed research will enhance the capacity of each emergency department to collect measurement data, using local knowledge to improve local systems.

Analysis

The complexity of the natural environment necessitates a multiple case study model. Content analysis using the constant comparative method will be used to analyze the survey, focus group, and interview data. Thematic analysis will be used to understand participants' perceptions, satisfaction, practice patterns, and collaborative engagement patterns. Some quantitative data will also be collected for technical usage statistics. For example, the eCoP will be set up to track what information was accessed, for how long, and in what sequence. This will be an anonymous process and will be used simply to understand how users interact with the content (not a surveillance of individual usage patterns). The five commonly agreed-on process and clinical sepsis indicator data will be compared within sites across time from baseline, at midpoint, and postintervention. We will use these data to analyze the influence of eCoP on practice and outcome change by seeing which group(s) improved and when, and how these improvements correlate with the qualitative data from eCoP.

Care maps will be analyzed and compared within and across sites to document evolutions in their approximation to the clinical practice guidelines, similarities and differences between different care maps, and changes in these care maps over time. Clinical care maps will also be analyzed based on their geographic locations to see whether there might be more similarities between rural, regional, or urban locations.

We will compare clinical sepsis data within and across sites to capture benefits to sepsis management. By looking across sites, we may identify certain processes that connect with clinical outcomes and further disseminate that information along with associated contextual factors across sites.

Contingency Planning

At this phase in our research, we anticipate that all the aspects of this proposal can be reasonably achieved. However, we foresee potential issues and difficulties that may affect the scope of our research. We also propose strategies to alleviate the foreseeable challenges that we may encounter during this proposed research.

Data Collection Rules and Regulations

Various BC health authorities may have differing rules and regulations governing the release of patient data. Before beginning data collection, we will consult the respective risk management or information services department for each health authority to ensure that we can obtain the appropriate permission to collect the required sepsis indicator data.

If receiving permission to collect sepsis indicator data poses a barrier, we will consult with the existing E2E pilot to examine the data that have already been collected as part of its sepsis collaborative for use in our proposed research.

The challenge is that the data that have been and are being collected by the E2E pilot may not be as comprehensive as what we require within the scope of our research.

Data Collection Capacity of Emergency Departments

Members of each emergency department's team participating in this research will be required to record and collect specified indicator data. This will be in addition to their existing clinical workload. Team members may not be able to fully capture the required indicator data because of their current workloads. If this is the case, additional resources may be put in place to provide emergency department sites with dedicated staff to collect necessary indicator data. These dedicated staff may take the form of a research assistant designated to collect and report the indicator data at respective sites.

Quality of Data Collection

In addition to the resource capacity of various emergency department sites participating in this research, emergency departments will have varying levels of experience in implementing sepsis protocols. Some emergency department teams may have already been implementing a sepsis protocol for a few years, while it may be the first time for other sites. As such, the experienced emergency department teams may be able to provide very rich indicator data, while the teams implementing a sepsis protocol for the first time may be able to provide a high level of basic data only in the short term.

Committees Guiding This Initiative

We will establish an advisory committee to guide our project development, implementation, and evaluation over the 3-year project and ensure it aligns with the development of the provincial health system. Representatives on this committee will include a senior policy maker from BC Ministry of Health, a senior policy maker in one of the health authorities, the chair of E2E committee, the Department Head of Emergency Medicine from the Faculty of Medicine, University of British Columbia, an expert in the area of CoP and related research, and an information technology expert. This committee, with a maximum of 10 people including the principal investigators and co-investigators of this project, will act as a sounding board to explore interface issues between the health authorities and Ministry of Health, the health professionals, the provincial emergency institutions, and the patients. This committee will also provide feedback on progress, give advice regarding the iterative harmonization of this initiative with the provincial

emergency medicine landscape, and engage within their own organizations and others for future knowledge translation and sustainability of our initiative beyond the project period. The Australian representative, with strong experience in stimulating collaboration among emergency departments in Victoria, will provide great insights into our efforts to ensure ongoing success [21]. Further, since September 2007, the E2E pilot established a provincial working committee, composed of emergency physicians, nurses, and emergency department and health authority administrators, supported by funding from the Ministry of Health. This group will form a common vision of how to use an eCoP and the IHI collaborative model to improve emergency care. The working group, with relevant and solid clinical experiences in applying health evidence to emergency care practices, will provide the invaluable opportunity to support and rigorously evaluate the efficacy of and gain invaluable insights into this IHI-eCoP approach in the provincial implementation of clinical evidence into practice.

Dissemination of Findings and Translation of New Knowledge

We expect that this project will ascertain the role of an eCoP in the IHI change management process in harmonizing provincial evidence-based medicine in the emergency medicine community. The close working relationship with policy makers through their project involvement and the advisory committee will ensure that health professionals, policy makers, health administrators, and researchers work synergistically toward systems improvement, helping to achieve true knowledge translation and using evidence to guide the evolution of the health system. The relationship foundation established through this project will be important for not only the sepsis protocol, but also future clinical practices in emergency medicine.

In addition, we will share the findings of the proposed research with the professional community through the following. (1) We will submit our results for publication in peer-reviewed journals and present abstracts at professional conferences. We will emphasize effective eCoP approaches in implementing clinical practice guidelines by emergency health professionals through the IHI process of practice improvement. (2) We will collaborate with the BC Ministry of Health and health authorities to ensure that lessons learned from implementing sepsis guidelines using the eCoP-supported IHI process in this initiative will be translated into future clinical pathways for health professionals. (3) We will distribute reports of the findings to organizations whose primary focus is, and whose membership has interest in, knowledge translation and patient safety, such as the Canadian Patient Safety Institute and the Canadian Health Services Research Foundation, or provincial organizations such as the Michael Smith Foundation for Health Research. (4) We will collaborate with the BC Medical Association, Association of Registered Nurses of BC, and the University of British Columbia's Faculty of Medicine, Department of Emergency Medicine in devising ways to effectively promote eCoP to their respective membership. (5) We will disseminate the eCoP-supported IHI process to physicians, nurses, and other allied health professionals in BC and beyond through continuing medical education conferences and workshops to influence health professionals' behavioral change in evidence-based health practices through interprofessional learning and team-based practices. (6) We will raise awareness of eCoP to promote intercollegial communication so that it becomes an integral component of patient safety and evidence-based medicine in health care delivery and in quality improvement. (7) We will develop and implement an educational program to help health practitioners use eCoP and IHI processes effectively, tailoring this program to the needs of health professionals (eg, physicians and nurses) in practice and in training, as well as the needs of interdisciplinary teams of health care providers.

Significance

Overall, the findings of this project will contribute to the overall goal of the provincial initiative to increase care harmonization and incorporation of clinical evidence into routine practices in the emergency medicine environment through eCoP-supported IHI process. Further, this research proposal is significant for several key reasons. First, this is a novel area of research because there are no published studies combining CoP and information technologies to promote community building and the IHI improvement process supported by this community-building approach. Second, it will provide an understanding of how to best facilitate uptake of evidence-based health practices and education into the workflow of health professionals in the emergency department throughout the province to maximize utility and engagement. Third, it will help us understand how best to improve patient safety through the accurate recognition and management of acute sepsis. Fourth, it will benefit many groups in the following manner: (1) physicians, nurses, and other health professionals in emergency medicine will have useable and convenient online tools to assist them in providing better patient care and patient self-management, (2) health professionals will enhance their skills, (3) patients will benefit from the accurate identification of sepsis by emergency health personnel, and (4) communication among all three CoPs—health professionals, health administrators, and policy makers—will be facilitated and sustained. Our study will help health care professionals to maximize their skills, will ensure that technology is used appropriately, and will work together with health administrators and policy makers to ensure harmonization of best practices as we know them today, and an optimal provincial networking structure to support evidence-based health practices tomorrow. Finally, this study will help to develop the ability to measure harmonization of clinical practices using the clinical care map method and to elucidate how we might be able to look at the variation in care map evolution due to geographic differences, based on research evidence that often gets synthesized into only one set of clinical practice guidelines for urban practices. This will help professionals in the health care system to not only understand tangibly but also support the optimal care models.

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Conflicts of Interest

None declared.

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Abbreviations

BC: British Columbia
CoP: community of practice
E2E: Evidence to Excellence
eCoP: electronic community of practice
ED: emergency department
EGDT: early goal-directed therapy
IHI: Institute for Healthcare Improvement

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Original Paper

Development of Smartphone Applications for Nutrition and Physical Activity Behavior Change

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Abstract

Background: Young adults (aged 18 to 35) are a population group at high risk for weight gain, yet we know little about how to intervene in this group. Easy access to treatment and support with self-monitoring of their behaviors may be important. Smartphones are gaining in popularity with this population group and software applications ("apps") used on these mobile devices are a novel technology that can be used to deliver brief health behavior change interventions directly to individuals en masse, with potentially favorable cost-utility. However, existing apps for modifying nutrition or physical activity behaviors may not always reflect best practice guidelines for weight management.

Objective: This paper describes the process of developing four apps aimed at modifying key lifestyle behaviors associated with weight gain during young adulthood, including physical activity, and consumption of take-out foods (fast food), fruit and vegetables, and sugar-sweetened drinks.

Methods: The development process involved: (1) deciding on the behavior change strategies, relevant guidelines, graphic design, and potential data collection; (2) selecting the platform (Web-based versus native); (3) creating the design, which required decisions about the user interface, architecture of the relational database, and programming code; and (4) testing the prototype versions with the target audience (young adults aged 18 to 35).

Results: The four apps took 18 months to develop, involving the fields of marketing, nutrition and dietetics, physical activity, and information technology. Ten subjects provided qualitative feedback about using the apps. The slow running speed of the apps (due to a reliance on an active Internet connection) was the primary issue identified by this group, as well as the requirement to log in to the apps.

Conclusions: Smartphone apps may be an innovative medium for delivering individual health behavior change intervention en masse, but researchers must give consideration to the target population, available technologies, existing commercial apps, and the possibility that their use will be irregular and short-lived.

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KEYWORDS

cellular phone; young adult; primary prevention; lifestyle; health behavior

Introduction

Across developed countries, the average person owns 1.18 mobile phones with this number continuing to rise [1]. Much of this growth has been in smartphone ownership (mobile phones with computer and Internet capabilities); there were more than 490 million shipments of smartphones globally in 2011 compared to approximately 300 million in 2010 [2]. The growth in the smartphone market has been concentrated in young adults, especially in the United States, with 62% of mobile phone users aged 25-34 owning a smartphone in 2011, an increase from 41% in 2010 [3].

The development of smartphones has led to a proliferation of smartphone software applications ("apps"), which are programs able to run on these mobile devices. From a public health perspective, smartphone apps can potentially enhance the delivery of health behavior change interventions to individuals en masse and result in favorable cost-utility. Despite this, researchers to date have largely developed apps to intervene in the clinical care setting for patient self-management, whereby a patient monitors themselves and receives therapeutic feedback [4,5], or for real-time therapy where no self-reported data is required from the patient [6,7]. The commercial sector has developed numerous apps for weight loss that include information on nutrition and physical activity, although the majority are based on calorie counting approaches and may not always reflect best practice guidelines for weight management [8].

In most Western countries, young adults (ages 18 to 35) are a population group at high risk for becoming overweight or obese [9,10]. For example, in the US Coronary Artery Risk Development in Young Adults (CARDIA) cohort, it was reported that females gained an average 0.7 kg and males gained an average 0.8 kg, each year [11]. There are four key lifestyle behaviors that appear to play an important role in the etiology of weight gain in this population group. These behaviors include a decline in physical activity [12,13], excessive intake of high-fat take-out (fast food) meals [14], over-consumption of sugar-sweetened drinks [15,16], and an inadequate consumption of fruit and vegetables [17]. However, there is limited evidence to inform what method of intervention might be effective for preventing weight gain in this group [18], although easy access to treatment and providing support for planning and self-monitoring behavior may be important [19,20]. Hence, we embarked on building a series of smartphone apps to assist young adults in forming healthier lifestyle habits. This paper describes the process of developing four separate smartphone apps and discusses our insights from this process.

Methods

The development process consisted of four stages: (1) deciding on the specifications, (2) selecting the platform, (3) creating the design, and (4) testing the prototypes.

Stage 1: Deciding on the Specifications

The first stage of this process involved defining the purpose of each app. This required specifying the relevant public health guidelines to inform the goals for behavior change, the specific strategies for behavior change, the visuals or graphic design, and the potential data to be collected.

The fundamental purpose of the apps was to support change in the lifestyle behaviors identified. To assist young adults with improving their dietary habits, goals for these behaviors had to be defined to create rules about what is adequate [21,22]. Relevant public health guidelines were consulted for physical activity levels [23,24], intake of fruit and vegetables [25], and recommended limits for take-out meals and sugar-sweetened drinks [26,27]. For example, the physical activity app (ePASS) included a "good health" target of 30 minutes of moderate level physical activity daily based on the World Health Organization's physical activity guidelines of at least 150 minutes of aerobic activity per week for adults [24], and a "healthy weight" target of 60 minutes of moderate level physical activity daily based on expert consensus that up to 60 minutes of moderate activity daily is required to prevent unhealthy weight gain [23] (see Figure 1B). The fruit and vegetable app (eVIP) provided users with a graphical display of the number of fruit and vegetable servings they recorded out of the two servings of fruit and five servings of vegetables recommended by the Australian Government Department of Health and Aging (see Figure 1A) [25]. The sugar-sweetened drinks app (eSIYP) presented users with a color display of their total energy, sugar, and alcohol intake from all drinks consumed, in which green, orange, and red indicated the "ideal," "acceptable," and "too much" threshold levels of intake, respectively. These threshold levels were based on nutritional expert opinion of the recommended limits on consumption of added sugars, as per the Australian Dietary Guidelines [26]. The take-out food app (eTIYP) also presented users with a color display of the average energy and fat content of take-out meals, in which green indicated acceptable intake and red indicated excessive intake, equating to ≤30% and >30% of the dietary intake recommended by the Australian National Health and Medical Research Council and the New Zealand Ministry of Health, respectively, according to age and gender [27].

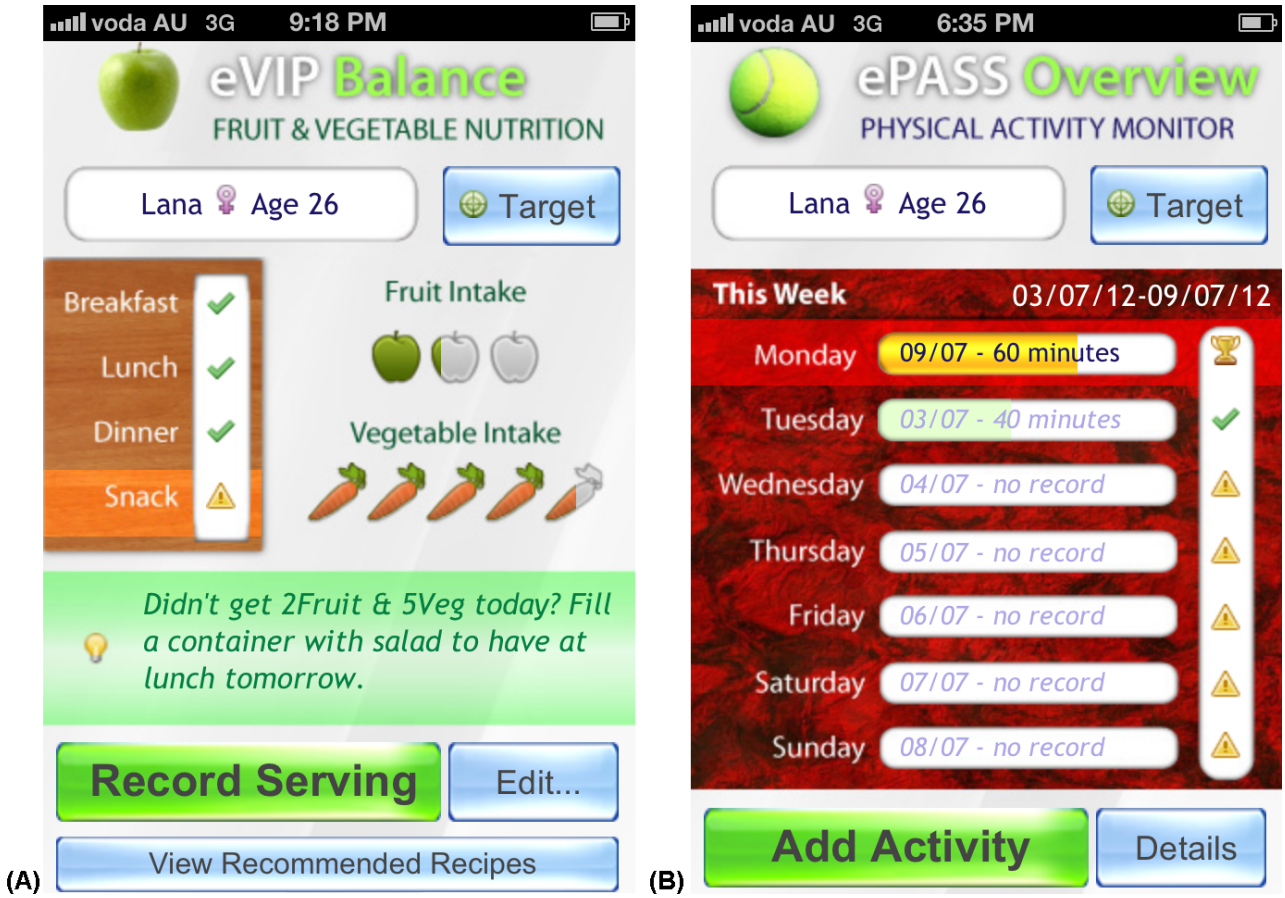
In terms of behavior change strategies, young adults often lack the self-regulatory skills, such as self-monitoring and planning, required to adopt and maintain healthy behaviors [20]. Self-regulation was fostered in each app by providing users with a platform to create daily entries of their behavior (eg, physical activities performed or vegetables consumed) from which they were provided daily or weekly summaries of their reported behavior, in reference to public health guidelines, to enable their monitoring of and planning around these behaviors. Providing feedback that is personally relevant may also be an important strategy for changing young adults' behaviors [18]. Encouragement from success of attaining a goal and social persuasion can enhance self-efficacy, and has been identified as important in achieving behavior change, particularly during busy or stressful situations [28,29]. All apps provided motivational tips as a source of positive encouragement that would assist the young adults in creating more positive beliefs around their ability to change their behavior (eg, "You can split up your exercise target into as little as 15-minute bursts"). These tips were also tailored to users' self-reported behavior. For

example, if a user's reported physical activity did not meet recommended guidelines, they were shown a relevant motivational tip (ie, "Plan exercise in advance and write it down if you can—try phone reminders").

Consideration was also given to the graphic design and how this might influence behavior. The behavior-image model suggests that through processes of social- and self-comparison, individuals will compare themselves to similar human images and create projections of themselves possessing the desired characteristics of the humans in those images [30]. This process is referred to as "self-reevaluation" in the Transtheoretical Model, which uses healthy role models and imagery to assist ones progression from contemplating behavior change to preparing for changing behavior [31]. Hence, in the apps we used images of young adults who were performing the target behaviors (eg, riding a bike or drinking water) and possessing desirable characteristics of a normal healthy appearance and lifestyle, to motivate users toward changing the target behaviors. Similarly, we displayed healthier foods and drinks, rather than "junk" foods, to model these foods as ideal for consumption. All images were purchased from a commercial graphics company to avoid potential breaches in copyright.

To facilitate future research, we enabled the following data items to be exported: user identification (ID), log-in ID, sex, age, and the date and time of log-ins into each app. Additional information that was able to be exported from each app included: physical activities performed and their duration; drinks consumed and their volume, total sugar, alcohol, and energy content; energy and fat content of take-out meals, the restaurant where the meal was consumed, and the contents of the meal; and the number of servings and types of fruit and vegetables consumed. This data could be exported into comma-separated value files from our relational database (described later), which could then be exported into statistical software for further analysis.

Figure 1. Screenshots taken on an iPhone device illustrating the user interface: home screen provides an overview of fruit and vegetables recorded in eVIP (A) or physical activity recorded in ePASS (B), in light of reference population health guidelines.



Stage 2: Selecting the Platform

Traditionally, apps are developed for one specific operating system (*native* app), such as iOS, Android, Windows, Symbian, and BlackBerry, or developed as *Web-based* apps. Native apps run locally on a smartphone's operating system in a way that is analogous to programs running on a desktop computer. Web-based apps run like a Web page, whereby the app operates on an external server and the user accesses the app through the Web browser on their mobile device. Due to these functional differences, Web-based apps may be used on all smartphones regardless of the operating system as long as the user has Internet access; however, there is less opportunity to utilize the existing hardware built into the phone (eg, the camera, geopositioning, or calendar). In our case, we developed Web-based apps because we did not require the use of existing hardware on the phone and we wanted to enable downloading of data recorded by users and allow the apps to be used on multiple operating systems and through the Internet for those who did not own a smartphone. However, Web-based apps are

increasingly becoming able to perform like native apps with an offline mode that can be accessed without Internet connectivity. Similarly, there is increasing potential for native apps to possess Internet connectivity, enabling the user to download updates and data from the user to be uploaded to a server. This emphasizes the dynamic nature of mobile technologies and why the type of platform selected should be discussed with an information technology specialist.

Stage 3: Creating the Design

To enable users to record their behavior, each app had to be linked with the relevant data for that behavior. The following data items were included for each app:

1. ePASS: type of activity (ie, gym, sports, recreational, or housework) and the intensity (ie, moderate vs vigorous) of 91 unique activities, where "moderate" was defined as a metabolic equivalent of task (MET) value of 3-6 and "vigorous" was defined as > 6, derived from the compendium of physical activities [32].

2. eVIP: serving size equivalents for 48 types of fruit and 61 vegetables, where 1 serving was equivalent to 150 g of fruit or 75 g of vegetables [26] (eg, 0.5 cups chopped or 4 spears of cooked asparagus are both equivalent to 1 serving of vegetables).

3. eTIYP: total energy and fat content of 504 take-out food and drink menu items.

4. eSIYP: drink category (eg, waters, vitamin waters, hot chocolate, tea/coffee, alcohol, soft drinks, sports drinks, cordials, fruit juices, fruit drinks, flavored milks, and milkshakes) and the total energy, sugar, and alcohol content of 114 unique drinks.

Nutrient composition data for eTIYP and eSIYP were sourced from the Australian government food and nutrient database, NUTTAB [33]. The foods listed in this database were chemically analyzed or, when unavailable, sourced from food manufacturer nutrient label data which may or may not be based on chemical analysis.

These data items were all contained within one relational database, which is essentially a database where the data items (or variables) are arranged into a series of tables with each table representing a different aspect or "relation" in the data. For each app, there were 1-2 tables containing the behavioral data. For example, the eVIP app required one table for the types of fruit and vegetables, such as "eggplant/aubergine (cooked)," and a second table listing the portion sizes, such as "0.5 cups diced," "3 thin slices," or "1 thick slice," with their respective serving equivalents of 1 serving, 1 serving and 0.5 servings. An additional table was included for each app containing the motivational tips and another table contained user details (ie, name, age, gender, log-in ID, and user ID). The relational database management system software, MySQL (Oracle Corporation, Redwood Shores, California, United States), was used to access and query data items contained within the relational database using structured query language (SQL). For example, if a user logged into the eVIP app at lunchtime, SQL was used to identify a motivational tip about including fruit or vegetables at the lunch meal to present to the user from the motivational tips table in the relational database for the eVIP app.

Programming for the apps was written with Python programming language software (Python Software Foundation, Wolfeboro Falls, New Hampshire, United States) to communicate with the relational database and generate the user interface (ie, what the user sees and interacts with), including the HyperText Markup Language (HTML) (ie, the building blocks of a Web page) and the cascading style sheets (CSS) (ie, the visual formatting of the HTML). The HTML and CSS information was then interpreted by the Web browser on the user's mobile device to create the user interface (see Figures 1-5). To illustrate an example of this programming, if a user recorded 0.5 servings of fruit, this data was stored in the relational database and the user was instantly presented with an image of half of one apple shaded green (representing 0.5 servings of fruit) on the home screen of the eVIP app (see Figure 1A). A separate app was created for each of the four behaviors, rather than creating a combined app, to permit the targeting of different behaviors in future intervention research, such as addressing only those behaviors that are particularly challenging for the individual. Further, there was a need to limit each app to < 6 screens, five of which were common to all of the apps (Figures 1-5), to simplify and increase the speed at which users could navigate their way through the apps.

Stage 4: Testing the Prototypes

Data presented and manipulated in the prototype version of each app were crosschecked against the relational database by two authors (LH and AC) for accuracy. This involved recording intake and activity behaviors at random in each of the four apps and checking whether the data presented to the users were correct (eg, the total energy of a take-out food item) and that the data were accurately manipulated in the apps (eg, converting fruit and vegetable portions recorded into the number of equivalent servings or summing the total energy content of all sugar-sweetened drinks recorded).

Twenty-one adults aged 18 to 35 years who were participating in a weight loss trial were provided access to the apps, and were asked for their feedback on the performance of the apps as part of an online survey. This survey included two questions assessing the usability of the apps, including: "Did you have any problems downloading the smartphone apps?" and "Did you have any problems using the smartphone apps?" with three response options: "yes," "no," or "did not access them." If they responded "yes," they were then prompted in an open-ended question: "Please tell us what problems you experienced." Two other open-ended questions asked, "How could the smartphone apps be improved?" and "Please tell us any other comments that you have." Re-occurring themes in the qualitative responses to these open-ended questions were identified and summarized. Procedures for collecting this information were approved by the University of Sydney Human Research Ethics Committee (approval #13698).

Results

The apps took 18 months to build including creation of the relational databases, exploring behavior change strategies, reviewing research with young adults on the key behaviors, creating the designs with information technology support, and testing the prototypes. Once the first app was developed, the others took less time with the physical activity app developed most rapidly. The development involved the fields of marketing, nutrition and dietetics, physical activity, and information technology. The cost of building all of the information into an app was approximately US $5000 per app—less than half the cost of mainstream commercial companies because we employed Information Technology students for the development.

The four apps were found to return the correct data to the user from the relational database and calculations performed by the apps were accurate (eg, calculating the energy, sugar, and alcohol content in 390 mL of a beverage recorded by the user). The same generic user interface (ie, what the user sees and interacts with) was used in all four apps. Figures 1-5 present two examples (A and B) for each of the five generic screens of the user interface. The first screen users see when they launch one of the apps is a log-in screen (Figure 2), that requires users to enter a unique 4-digit log-in ID code. This was to protect the privacy of users (in the case that these apps were used in future human research), as well as the intellectual copyright of the university. The second screen seen by the users after they log in shows the home screen (Figure 1), that displays a summary of the user's behavior compared with reference guidelines. Screens presented in Figures 3 and 4 allow users to record their behaviors and review or edit data they have entered, respectively. Details about reference guidelines are then displayed in a "targets" screen (Figure 5).

Of the 21 participants offered to use these apps, only 10 evaluated them. These participants reported no difficulty with downloading the apps. Overall, participants did not like having to log in to use the apps. Some participants complained the apps operated slowly on their mobile devices (eg, "The smart phone app was a good idea but as it was a Web app, it often froze and it was a bit slow in general and scrolling lists were not functional on some operating systems" [from a 19-year-old female] and "Some parts of the apps didn't work for me, such as the scroll, so I couldn't enter many fruits/veg" [from a 22-year-old female]). Only one respondent (33-year-old female) provided a suggested improvement: "Applications could be designed to reward/monitor good behaviors only..."

Figure 2. Screenshots taken on an iPhone device illustrating the user interface: log-in screens where users enter their unique ID for user privacy and protection of intellectual property.

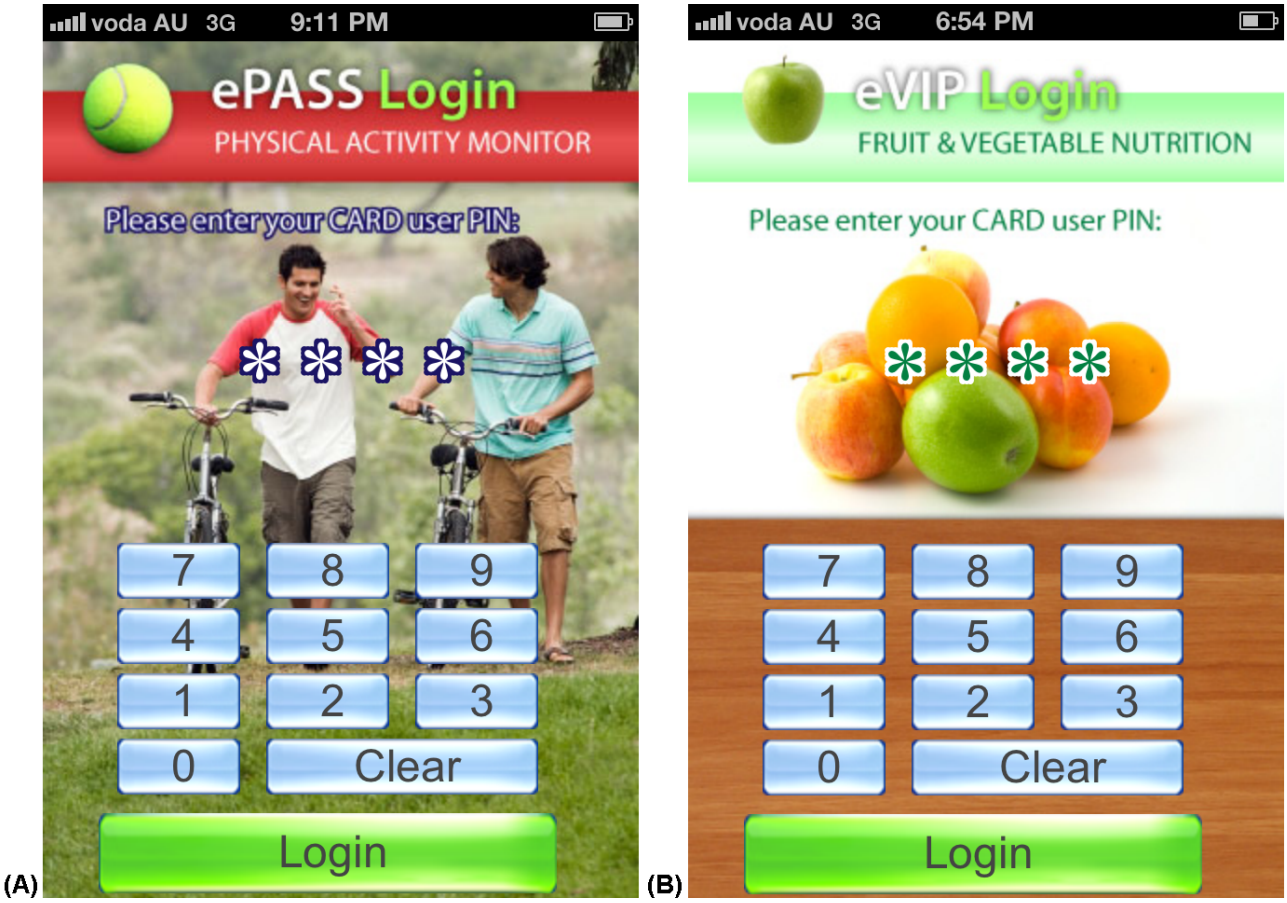


Figure 3. Screenshots taken on an iPhone device illustrating the user interface: users may record their take-out meals in eTIYP (A) or their drinks in eSIYP (B).

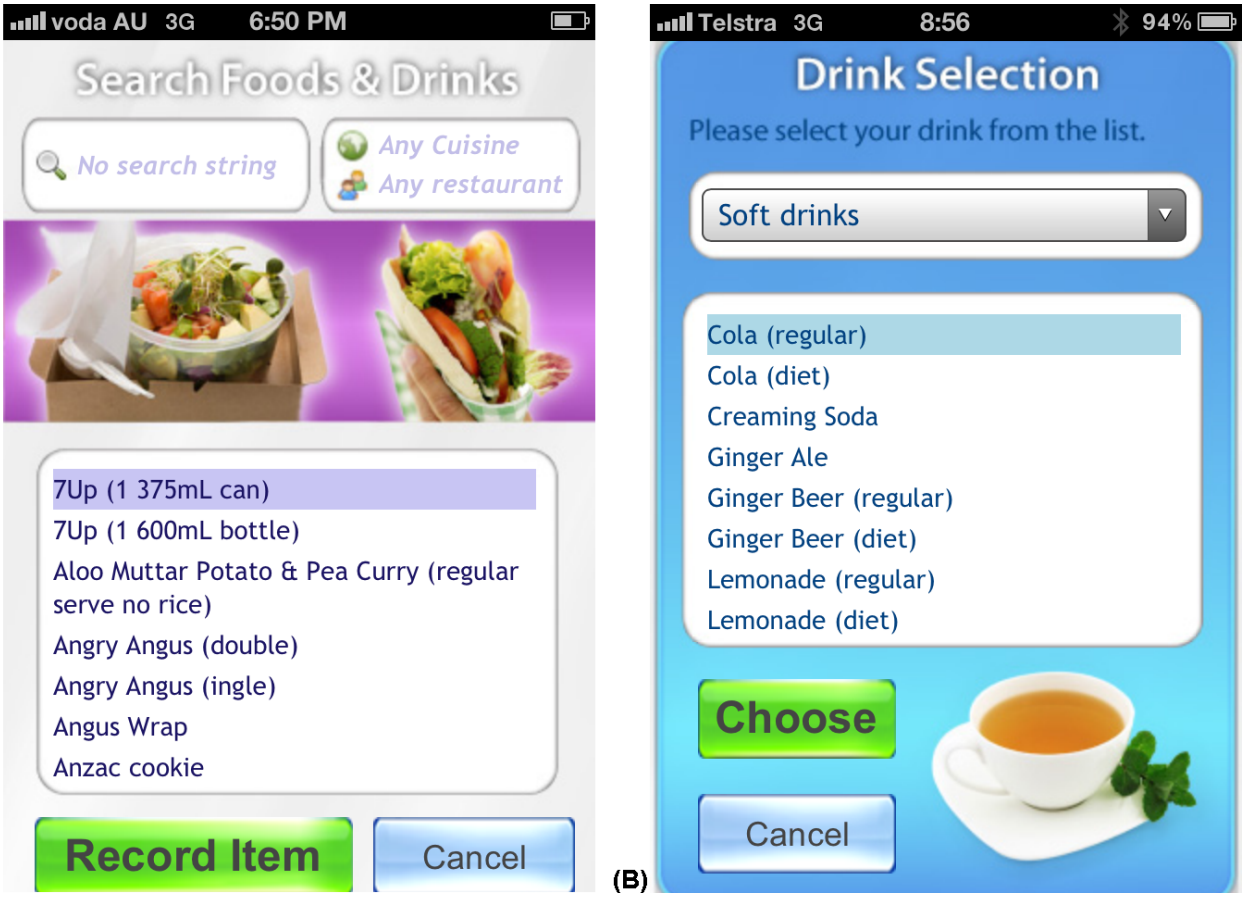


Figure 4. Screenshots taken on an iPhone device illustrating the user interface: users may review or edit their drinks in eSIYP (A) or their fruit and vegetable intake in eVIP (B).

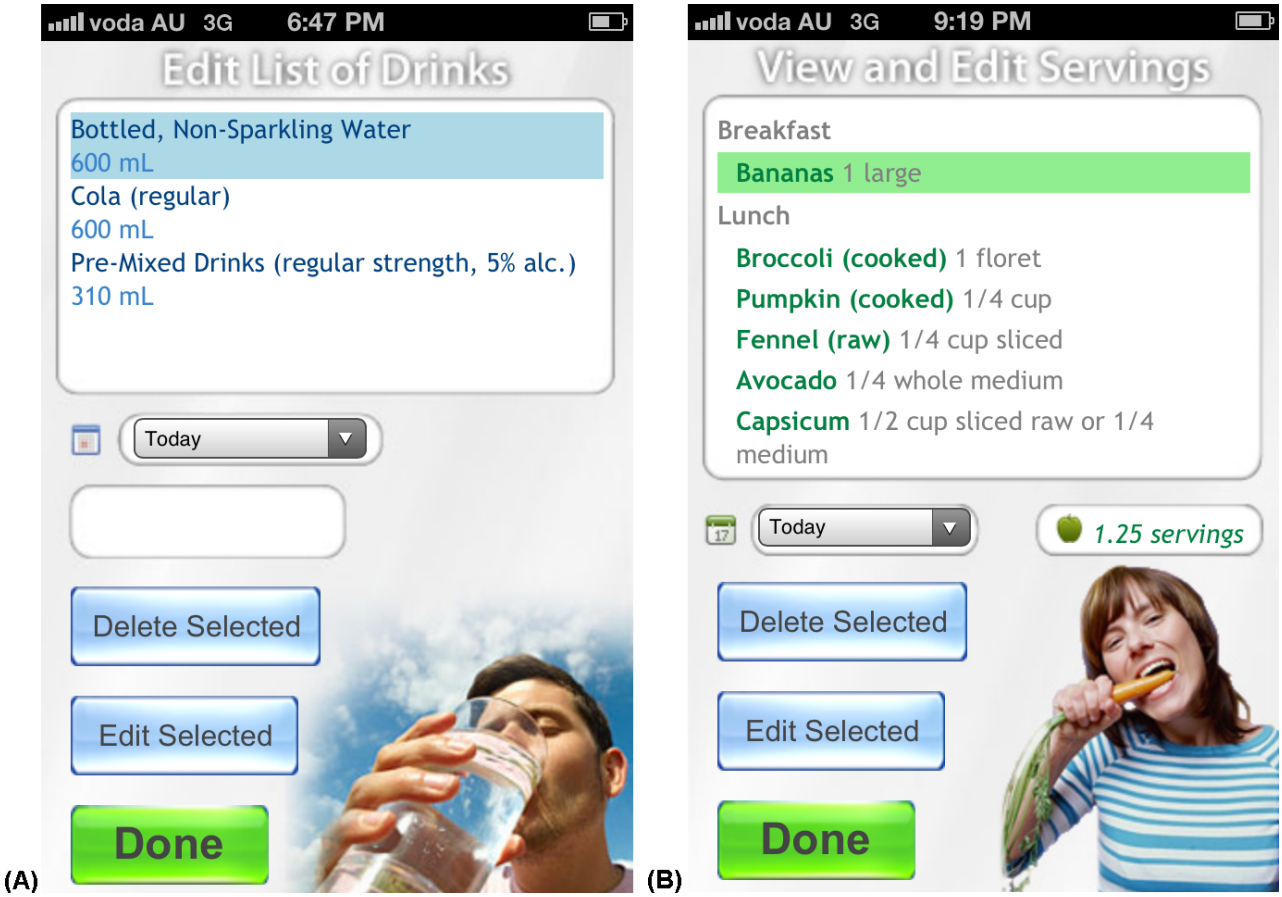
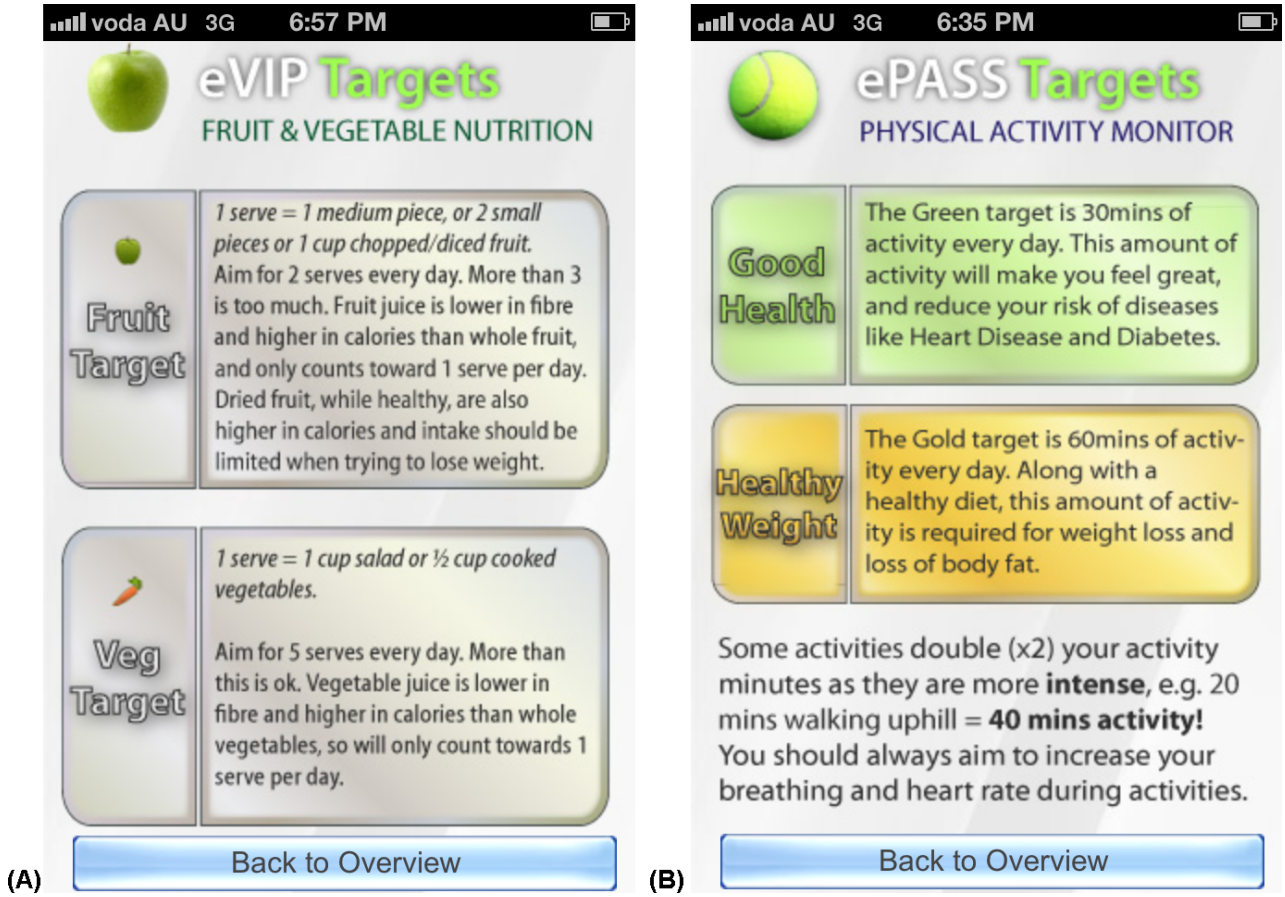


Figure 5. Screenshots taken on an iPhone device illustrating the user interface: targets screen provides the user details about the reference guidelines.



Discussion

In this paper, we have described the process of developing four smartphone apps aimed at improving nutrition and physical activity lifestyle behaviors during young adulthood. The apps were found to present precise data and to manipulate data accurately for the user. A small sample of young adults provided qualitative feedback. It was found that the slow running speed of the apps (because of their reliance on an active Internet connection) was an issue for the target audience (young adults aged 18 to 35), as was the requirement to log in to the apps. There was little suggestion for change in the information provided or graphics used in the apps, although most of the open-ended questions were posed to ask about issues or problems with the apps so that it generated negative rather than positive feedback. It is also acknowledged that the small sample size of participants testing the apps limits the validity of these findings.

Very few researchers in public health have reported on the development and use of smartphone apps for individual dietary or physical activity change. Mattila et al used a wellness diary for recording self-management of weight-related behaviors [34], Hughes et al developed an app for monitoring energy balance [35], Lee et al developed a weight loss diet game [36], while others have monitored diet or physical activity as part of a program for diabetes [37] or cardiac rehabilitation [38]. The uptake and usage of these apps has been moderate to high among adults in the intervention setting [34,36-38]. Smartphone apps have the potential to improve population health, largely because of their widespread and increasing use, dynamic technological advancements, ability to download updates, and use of existing features (eg, Internet access, geopositioning technology, as well as photo, video, and voice recording capabilities), and the potential for reducing intervention delivery costs. However, there are limitations to the use of smartphone apps, primarily because they may be expensive to develop and their use is often irregular and short-lived [34]. Therefore, if the target behaviors require commitment in the longer term, as is the case with nutrition and physical activity behaviors, additional support strategies may be required to prolong individuals' motivation to use the apps [34]. Also to consider, is the competition from new apps being developed. For this reason, an audit of existing apps is recommended to inform whether adequate apps are already available [8]. A further limitation is that other barriers to nutritional and physical activity behavior change perceived by young adults cannot be addressed, such as financial costs and aspects of their social and physical environments [39,40], although one can address personal barriers, such as time constraints [39-42] or lack of self-monitoring skills [20]. The equality of using apps as a public health strategy also remains questionable, and is likely to depend on the specific target group of interest.

Although young adults are increasingly using smartphones, use in other population groups is unclear. For this reason, formative research with the target population may be required for some groups, such as older adults, before embarking on developing apps for this demographic [43]. Future research should also examine how commercially developed apps for diet or physical

activity are being used by different population groups to improve our understanding of how this technology may be used to support behavior change.

The feedback from trialing the apps with the target population (young adults aged 18 to 35) will be used to refine the prototype versions of the developed smartphone apps. Attempts will be made to increase the speed of the apps and ensure functionality on all mobile phone operating systems popular with young adults. The revised apps will then be formally tested for their "usability," which measures the ability of a software product to be understood, learned, used, and be attractive to the user, and will involve an analysis of the number of steps or time required to complete set tasks within the software [44]. Others have extended these methods to testing the usability of mobile phone apps, suggesting additional items for evaluation [45,46].

The apps will be added as part of a multi-component randomized controlled trial in young adults, together with mobile phone text messaging and phone coaching calls, to evaluate their impact using validated measures of diet, physical activity, and anthropometrics.

Smartphone apps may be an innovative medium for delivering individual health behavior change intervention en masse. Researchers or health professionals considering developing an app in their area must give careful consideration to the target population in terms of their access, ability to adopt this form of intervention, and preferences regarding the design, the current technologies available for app development, existing commercial apps, and the possibility that their use will be irregular and short-lived.

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Authors' Contributions

LH drafted the manuscript; LH, AC, and MA-F conceptualized the apps; HvdP informed the development of the ePASS (physical activity) app; AC, HvdP, and MA-F made revisions to the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

app: smartphone application
CARDIA: Coronary Artery Risk Development in Young Adults
CSS: cascading style sheets
ePASS: physical activity smartphone app
eSIYP: sugar-sweetened drinks smartphone app
eTIYP: take-out (fast food) smartphone app
eVIP: fruit and vegetable smartphone app
HTML: HyperText Markup Language
ID: identification
MET: metabolic equivalent of task
SQL: structured query language

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Original Paper

Initial Evaluation of an Electronic Symptom Diary for Adolescents with Cancer

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Abstract

Background: The delivery of optimal care depends on accurate communication between patients and clinicians regarding untoward symptoms. Documentation of patients' symptoms necessitates reliance on memory, which is often imprecise. We developed an electronic diary (eDiary) for adolescents and young adults (AYAs) with cancer to record symptoms.

Objective: The purpose of this paper is to describe the utility of an eDiary designed for AYAs with cancer, including dependability of the mobile application, the reasons for any missing recorded data, patients' adherence rates to daily symptom queries, and patients' perceptions of the usefulness and acceptability of symptom data collection via mobile phones.

Methods: Our team developed an electronic symptom diary based on interviews conducted with AYAs with cancer and their clinicians. This diary included daily severity ratings of pain, nausea, vomiting, fatigue, and sleep. The occurrence of other selected physical sequelae was assessed daily. Additionally, patients selected descriptors of their mood. A 3-week trial of the eDiary was conducted with 10 AYA cancer patients. Mobile phones with service plans were loaned to patients who were instructed to report their symptoms daily. Patients completed a brief questionnaire and were interviewed to elicit their perceptions of the eDiary and any technical difficulties encountered.

Results: Overall adherence to daily symptom reports exceeded 90%. Young people experienced few technical difficulties and reported benefit from daily symptom reports. Symptom occurrence rates were high and considerable inter- and intra-patient variability was noted in symptom and mood reports.

Conclusions: We demonstrated the utility of an eDiary that may contribute insight into patients' symptom patterns to promote effective symptom management.

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KEYWORDS

mHealth, eHealth, patient-reported outcomes, symptom assessment, adolescent, cancer

Introduction

Adolescents and young adults (AYAs) with cancer experience numerous sequelae during treatment [1-5], which are associated with decrements in their quality of life [6]. Accurate communication between young people and their clinicians about these symptoms is crucial for the delivery of optimal supportive care. Furthermore, accurate symptom assessment during clinical

trials is needed to advance the science of supportive care in oncology.

Current practices to determine symptom occurrence in clinical trials require that patients accurately recall their symptoms during clinic visits over the prior 1 to 6 weeks and report them to their clinicians. Clinicians then record this information in the medical record and researchers abstract the information to a database for analysis. Omissions or errors at any of these steps result in an underreporting or misrepresentation of symptom occurrence. Moreover, recent data suggests that the accuracy of symptom appraisal and recall depends on the use of short recall periods [7].

Alternatively, symptom diaries in paper format that are completed daily can be used to circumvent the challenges described above. However, patient adherence with these diaries is low, ranging from 11% to 56% [8-12]. In addition, adherence with paper diary entries is markedly low when real time data entry is checked electronically (eg, with light sensors to determine when the diary was opened) against the paper submission. In one study, 90% (approximately 36/40) of patients reported temporal adherence with paper diary entries. However, the true adherence level was 11% when the actual time that diary entries were written was monitored electronically. Many patients recorded entries just prior to returning the diary, known as "parking lot entries" [11]. Data based on inaccurate symptom recall may lead to inappropriate conclusions when symptom management studies are based on poorly recalled data [13].

The collection of AYAs' symptom data in real-time using electronic diaries (eDiaries) could avoid poorly recalled data. Patients' and clinicians' interests in using eDiaries are high [14, 15]. The portability of these devices and availability of audible prompts may promote adherence with data entry. In a review of 62 studies that used electronic pain diaries [15], the overall adherence with diary entries was 83%. Factors that promoted adherence to eDiaries included the following: shorter diaries, having a user's manual, financial compensation, and reminder alarms [15].

While initial eDiary research involved the use of personal digital assistants [14, 16-20], mobile phones are now also used for collecting a variety of data. Typically, the frequency of symptom assessment using eDiaries ranges from 1 to 12 times per day [21]. Entries can be triggered by random alerts, symptom events, or at predetermined schedules. Mobile phone diaries have been used by child and adult patients to monitor symptoms, alert clinicians about severe symptoms [22], or to deliver self-care interventions based on symptom assessments [23]. The term ecological momentary assessment (EMA) is used to describe the collection of real-time data from individuals in naturalistic settings. In pediatrics, EMA has been instrumental in the study of physical activity [24-30], affective mood disorders [31-34], evaluation of alcohol and illicit drug use [35], and smoking cessation [36]. These studies included multiple evaluations per day, as frequent as every 15 minutes, among relatively healthy individuals. No such studies were conducted with hospitalized AYAs.

AYAs with cancer have unique needs related to frequent and complex exacerbations of their disease- and treatment-related symptoms that could affect their abilities to maintain eDiaries. The lack of an eDiary geared to the symptoms and developmental needs of AYAs with cancer prompted us to develop a mobile application, titled the Mobile Oncology Symptom Tracker (mOST). To do so, we assembled a multidisciplinary team of 2 nurses and 3 software developers from GoMed Solutions, one of whom is a pediatric oncologist. We elicited input from 15 AYA oncology patients from two University-affiliated children's hospitals in the inpatient or clinic settings. Semi-structured interviews were used to determine their use of technology, and ideas on the types of symptoms to monitor, frequency of reporting, and preferences for icons and graphics. In addition, clinicians and research experts were consulted during the development of the application. The symptoms selected for daily monitoring were those that occur frequently during treatment of cancer [4]. Assessment of these symptoms was done using modifications of valid and reliable instruments when possible (Multimedia Appendix 1). Considering the complex demands placed on patients undergoing cancer therapy, we designed the application to collect symptom data as a single end-of-day (EOD) entry to minimize patient burden. This single entry aims to capture the majority of the day's ratings, and the daily component circumvents issues related to poor recall associated with entries that are made on subsequent days. Entries could be made between 3 pm and midnight at the convenience of the patient. A team of researchers and developers used the application for 2 weeks to evaluate its functionality prior to clinical testing.

The purpose of this paper is to describe the utility of mOST tested on a group of 10 oncology patients, ages 13 to 21. The specific aims of this pilot study were to determine the dependability of the mobile application, the reasons for any missing entries and patients' adherence rates to daily symptom queries for multiple symptom reporting. In addition, patients' perceptions of the usefulness and acceptability of symptom data collection via mobile phones were evaluated after a 3-week trial assessment period.

Methods

Participants

In this descriptive, longitudinal study, we evaluated a mobile phone-based electronic symptom diary in a convenience sample of AYAs with cancer. Patients were eligible to participate if they were 13 to 21 years of age, could understand English, gave assent or consent to participate, had not participated in the prior application development interviews, and were receiving chemotherapy (for initial therapy, relapsed, or refractory disease). The study was approved by the Human Subjects Committee at the University of California, San Francisco.

Eligible patients were identified with assistance from pediatric oncology clinics and in-patient advanced practice nurses. Research staff approached these patients to determine interest in the study. If patients expressed interest, the research staff informed them of the study procedures, risks, and benefits. Patients 18 years of age or older and the parents/guardians of younger patients signed written, informed consent. Younger patients gave written assent. Between March and April, 2011,

11 out of 13 patients approached agreed to participate in the study (response rate of 85%). Patients who refused were too busy or too ill to participate.

Procedures

Patients completed a demographic form that included their age, race/ethnicity, primary diagnosis, date of diagnosis, number of relapses, prior mobile phone use, and approximate household income. An 8 GB iPhone 3GS, charger, and earphones were loaned to each participant during the study. The monthly service plan included: 450 minutes of peak time voice minutes, and unlimited data, text messaging, and evenings/weekend calling. The mOST application was downloaded on each phone. Patients received an instructions booklet and a tutorial on the application and phone use, expectations of the frequency of symptom reporting, and methods to notify research staff of system malfunctions. They were instructed to report their symptoms at the end of the day. A single daily report was designed to minimize patient burden. Patients could only access the system between 3 pm and midnight, as reports earlier in the day might not accurately reflect all of their experiences for the day. They could program 2 reminder messages to input daily entries with audible alerts, customizable for text choice and time selection. Data were delivered to a secure website, listed by study number only, and could be downloaded to database and statistical packages for analysis. The dates and times of data submission and data upload were coded.

Symptom Assessments

Severity ratings of 5 disease or treatment-related symptoms were assessed daily: pain, nausea, vomiting, fatigue, and sleep quality. A body diagram was used to indicate the location(s) of any pain experienced. A visual analog scale (VAS) was selected to assess pain intensity (ie, no pain or worst pain) based on a consensus statement compiled by pediatric pain researchers [37]. We selected the Color Analog Scale (CAS) as the VAS for this study due to its excellent psychometric properties [38,39]. However, pain scales that include face icons (ie, faces pain scales) were preferred by pediatric and adolescent patients in a prior study [40] and by many of the AYAs we interviewed during the software development period. We included the Faces Pain Scale-Revised (FPS-R), a valid and reliable pediatric pain measure [41], as well as a VAS to assess pain, with the consideration that no additional burden was placed on participants. The FPS-R appeared as 6 faces on the bottom of the mOST screen. When a patient tapped a face, the selection enlarged and filled most of the screen. Patients then responded to the statement, “drag the slider to show your average pain level in your <body part> since midnight”, using the CAS.

Validity of the CAS was previously evaluated by eliciting pain ratings from 30 children in an emergency department (ED) who reported pain [39]. Initial median pain ratings were higher than those obtained after analgesic administration, 6 centimeter (cm) and 3.1 cm, respectively. Median scores of 30 children without pain were 0 cm, compared to median ratings of 7.0 cm from children who reported severe pain. In addition, correlations between CAS scores and the FPS-R were positive and strong (ie, 0.89) [39]. In another study, reliability of the CAS was evaluated by obtaining 2 pain ratings on the CAS from patients in a pediatric ED, 1 minute apart. The intraclass correlation coefficient in this study was high (r=0.97, 95% CI 0.95-0.98) [38]. Previously, strong positive correlations were noted between FPS-R scores and children’s pain ratings on a VAS. The validity of the FPS-R was evaluated by eliciting pain reports from children after routine ear piercing [41]. In this study, similar correlations were noted in hospitalized children who experienced painful conditions [41]. Additional reports of the psychometric properties of the FPS-R are summarized in a review by Tomlinson and colleagues [42]

To assess nausea, we included the Pediatric Nausea Assessment Tool (PeNAT), a valid and reliable instrument to assess nausea among pediatric oncology patients [43]. In previous evaluations, PeNAT scores varied significantly among children admitted for different therapies (ie, children with cancer admitted for routine chemotherapy, children receiving conditioning therapy for hematopoietic stem cell transplants, children with cancer admitted for febrile neutropenia, and children without cancer admitted to the general pediatrics unit). Moderate correlation was noted among children’s PeNAT scores and their emetic episodes as well as with parental reports of their nausea. Test-retest reliability, measured by the collection of patient entries 1 hour apart, revealed moderate correlations between the 2 entries [43]. This tool was selected for the eDiary, with faces depicted in a similar fashion as the FPS-R. We used the PeNAT in conjunction with a VAS to assess the degree of nausea in this early stage of application development to collect correlative assessment data and to explore the optimal assessment tool for the application.

No single-item validated instruments were available to assess vomiting, fatigue, or sleep among AYA patients. The number of vomiting episodes was assessed with the single forced-choice query of: none, 1 time, or 2 or more times. Fatigue was assessed with 2 queries from the Fatigue Scale-Adolescent [44] (“my body has felt tired” and “my mind has felt worn out”) using a VAS format to collect data on physical fatigue (not tired or most tired) and mental fatigue, (not worn out or most worn out) respectively. Sleep quality was assessed with a single query in a VAS format (terrible or great) in conjunction with patient estimates of bedtime and wake time. All VAS scales on the application were in CAS format and transformed to a 0-100 scale, with higher values indicating more severe symptoms.

The occurrence of diarrhea, constipation, fever, numbness/tingling, mouth sores, dizziness, and headaches were assessed daily. These symptoms were included due to their frequent occurrence among pediatric oncology patients and their variability during treatment [4]. Patients could select symptoms from a list and highlight the text by swiping the printed text with one finger from left to right or type in other conditions. In addition, patients selected descriptors for their current mood - the choices included were angry, scared, frustrated, lonely, anxious, irritable, worried, happy, confident, and hopeful. Both positive and negative terms to describe mood were selected for inclusion based on their frequent reports in clinical encounters.

Patients received $1 credit towards a department store gift card for each diary entry. In addition, those who completed ≥ 90% of the assessments in a 21-day period were given a $50 gift

card. If patients attempted to report symptoms but experienced a system error, the attempt was also applied towards the gift card credits.

Post Use Evaluation

The principal investigator or research assistant conducted 10 to 15 minute interviews with patients at the completion of their evaluation period to obtain their perceptions about using mOST and any technical difficulties they experienced. In addition, they were asked to carry out a "think-aloud" exercise [45] where they provided the rationales for the actions they made on mOST as they did them. These interviews were audio recorded and transcribed verbatim. All patient identifiers were removed from the transcripts. A brief questionnaire was completed at the time of the interview to elicit patients' experiences with the application.

Data Analysis

Descriptive statistics were used to characterize demographic and clinical characteristics as well as rates of symptom occurrence. The total number of system errors was calculated during the 21-day study period. Data entry adherence rates were determined by calculating the number of symptom reports over the 21 days of the study. One-way analysis of variance was used to evaluate the differences in patients' weekly adherence rates. The interview transcripts were analyzed by 2 researchers, with verification by 1 of the senior investigators.

Results

Patient Characteristics

The demographic and clinical characteristics of the AYAs who participated are described in Table 1. A patient completed 2 entries just prior to being notified that her tumor had progressed. Because she required emergency surgery followed by a transfer to the pediatric intensive care unit (PICU), she was withdrawn from the study. Another patient completed 13 daily entries prior transfer to the PICU due to complications following hematopoietic stem cell transplantation. Her symptom reports are included in this analysis but she was not interviewed. All study phones were returned at the completion of the study, but several had misplaced the phone chargers or earphones.

The patients' baseline technology use is described in Table 2. All but 2 (a 15 year old male and a 20 year old male who was homeless), of the AYAs owned a mobile phone with service plans primarily paid for by their parents. Daily use of the phones for voice calls and text messaging was common but not uniform. All patients owned a computer and only 1 did not have home Internet access. Most patients (80 %) had a social networking account.

Table 1. Demographic and clinical characteristics of participants (N=10).

Characteristic[a,b]	n (%)
Gender	
Male	6 (60%)
Female	4 (40%)
Race/Ethnicity	
Hispanic White	3 (30%)
Non-Hispanic White	1 (10%)
African American	1 (10%)
Hispanic-Other or not specified	5 (50%)
Diagnosis	
Leukemia/Lymphoma	6 (60%)
Bone tumor	3 (30%)
Sarcoma-other	1 (10%)
Number of prior relapses	
None	5 (50%)
One or more	5 (50%)
Setting	
Inpatient	4 (40%)
Outpatient	4 (40%)
Both	2 (20%)

[a]Age in years (SD) = 18.2 (2.9)

[b]Time since initial diagnosis in months (SD)= 12.2 (15.3)

Table 2. Technology use among participants.

Question	Response	n (%)
Do you have a mobile phone?	Yes	8 (80%)
	No	2 (20%)
Who pays for the service?	Self	2 (20%)
	Parents	6 (60%)
	Not applicable	2 (20%)
How often do you use your phone for voice calls?	Daily	4 (40%)
	4-6 days/week	2 (20%)
	2-3 days/week	2 (20%)
	Not applicable	2 (20%)
How often do you use your phone for text messaging?	Daily	5 (50%)
	4-6 days/week	2 (20%)
	2-3 days/week	1 (10%)
	Not applicable	2 (20%)
Do you have a computer at home?	Yes	10 (100%)
	No	0 (0%)
Do you have Internet access at home?	Yes	9 (90%)
	No	1 (10%)
Is Internet access WiFi enabled?	Yes	5 (50%)
	No	2 (20%)
	Not applicable	1 (10%)
	Not sure	2 (20%)
Do you have a page on Facebook or MySpace?	Yes	8 (80%)
	No	2 (20%)

Dependability of the Mobile Application

On day 14 of our data collection period, we noted a system malfunction that occurred if patients skipped a day of diary entries. On the subsequent day, the application did not function. During the "beta-testing" period, testers skipped data entries and did not experience this malfunction. An interim solution was devised in which patients deleted the application and reloaded it from a website. Subsequently, we monitored the database daily. If patients missed an entry, we contacted them and provided instructions on how to reload the application. A total of 3 episodes of system malfunction occurred over the study period. The software malfunction was rectified by the end of the study. An error message appeared at the time of upload for 3 patients, but that the entry was transmitted the next time the application was opened.

Reasons for Missing Data

One patient missed an eDiary entry when he felt too ill to enter data. He missed the subsequent day due to the system malfunction and a third day when he went out of town and left the phone at home. Another patient missed a data entry on a day he discovered that his leukemia had relapsed. He missed 4 consecutive entries during a period when we attempted to reach him. He then reloaded the application and maintained full adherence until the end of his study period. A third patient missed 2 entries due to forgetfulness. A 4th patient reported full adherence to the data entries, but we noted missing data on 1 day with 2 entries the subsequent day, all uploaded on the third day. This finding likely represented Internet access difficulties, but we coded her data as missing a day to be conservative in adherence estimations.

Adherence

Adherence can be calculated by assessing different causation end points. When data were counted as missing only for omitted entries due to forgetfulness and illness-related concerns of mild to moderate levels (ie, giving credit for days of system error and time spent in the PICU), the overall adherence rate for daily symptom reports during the 21 day study was 97%. When days of system malfunction were included as missing data, the adherence rate was 95%. When all days of missing data were used in the calculation, including the 8 days when a patient spent was in the PICU, the adherence rate was 91%. Adherence rates did not vary among the 3 weeks ($F_{2,27}$=1.016, P =.38).

Usefulness

The data collected were used to delineate the potential utility of the eDiary to clinicians and researchers. Summaries of the

symptoms and moods reported by individual patients are listed in Tables 3 and 4, respectively. Additional physical symptoms typed in and added by patients were: jaw pain, numb chin, bloody stools, bone ache, lightheaded, tinnitus, stomachache, and itchiness. Two patients wrote in symptoms already evaluated on the application (ie, "fatigue, tiredness" and "queasy nauseous"). Additional mood descriptors reported by patients were: giggly, bored, overwhelmed, and blah. In addition, trajectories reported by one patient of the severity of mental fatigue and nausea over the 3-week course are depicted in Figure 1 along with his mean values for each symptom over the 21 day study period, as exemplars of symptom variability over time. Considerable inter-patient and intra-patient variability were noted in the symptom and mood reports. The ability to collect this variability in patients' experiences supports the usefulness of the eDiary.

Acceptability

In an exit interview, one patient with peripheral neuropathy noted that the highlighting feature was difficult to master. Others stated that the highlighting feature was simple to use. The body diagram used to describe pain locations was divided into 9 regions–head/neck, hands, arms, chest, abdomen, upper back, lower back/pelvis, legs, and feet. Difficulties with pinpointing the precise location of pain were mentioned by 4 patients (eg, the indicator to depict neck pain showed up on the head).

Patients rated the application as either "easy" (2/9, 22%) or "very easy" (7/9, 78%) to use. Daily entries were generally completed in less than 2 minutes. One patient had mild visual deficits and mentioned that the print was difficult to read at times. However, she was able to read the screens out loud during the "think-aloud" exercise. All other patients reported that the print size posed no difficulties. In the exit survey, patients were asked to select or write in adjectives to describe the application. They could select more than 1 descriptor. All of the selected words had a positive connotation (ie, 67% rewarding, 78% valuable, 78% educational, 67% interesting). No one selected challenging, frustrating, time consuming, worthless, confusing, or difficult to describe mOST. All patients who were questioned (n=7) reported that they would recommend the application to others. Selected quotations regarding why they would recommend the application to others are included in Table 5. Patients' preferences for the use of the VAS or faces scales to rate pain and nausea were fairly evenly divided. Those who preferred the VAS appreciated the opportunity to select a more precise level of pain or nausea, compared to only a few options on the faces scales. Those who preferred the faces scales commented that the diagrams depicted how they were feeling.

Table 3. Patients' reports of physical symptoms.

Symptom	Percentage of days each patient reported symptoms										Mean of symptom occurrence rates	% of patients reporting symptoms
	Patient											
	1	2	3	4	5	6	7	8	9	10		
	Inpatient				Both in and outpatient		Outpatient					
Fatigue-Physical[a]	100	100	100	86	43	21	90	62	39	5	64	100
Fatigue-Mental[a]	95	92	88	81	48	16	90	52	44	5	62	100
Nausea[b]	100	100	65	24	95	47	75	0	29	38	57	90
Headache	95	54	29	81	29	0	5	52	22	76	44	90
Pain[c]	81	69	65	43	38	0	10	0	24	33	36	80
Dizzy	52	46	24	24	29	0	30	5	17	33	26	90
Numb	62	8	100	5	0	100	0	0	0	5	10	60
Constipation	29	0	65	0	10	0	55	0	11	0	10	50
Diarrhea	29	92	6	5	5	0	0	0	0	0	14	50
Mouth sores	0	39	0	5	0	0	5	19	39	0	11	50
Fever	0	31	6	10	0	0	0	0	0	5	5	40

[a]Occurrence rate based on percentage of days that VAS score >30 on 0-100 scale

[b]Occurrence rate based on percentage of days that patients selected face 2, 3, or 4 on the Pediatric Nausea Assessment Tool (PeNAT)

[c]Occurrence rate based on percentage of days that patients selected face 2, 3, 4, 5, or 6 on the Faces Pain Scale-Revised (FPS-R)

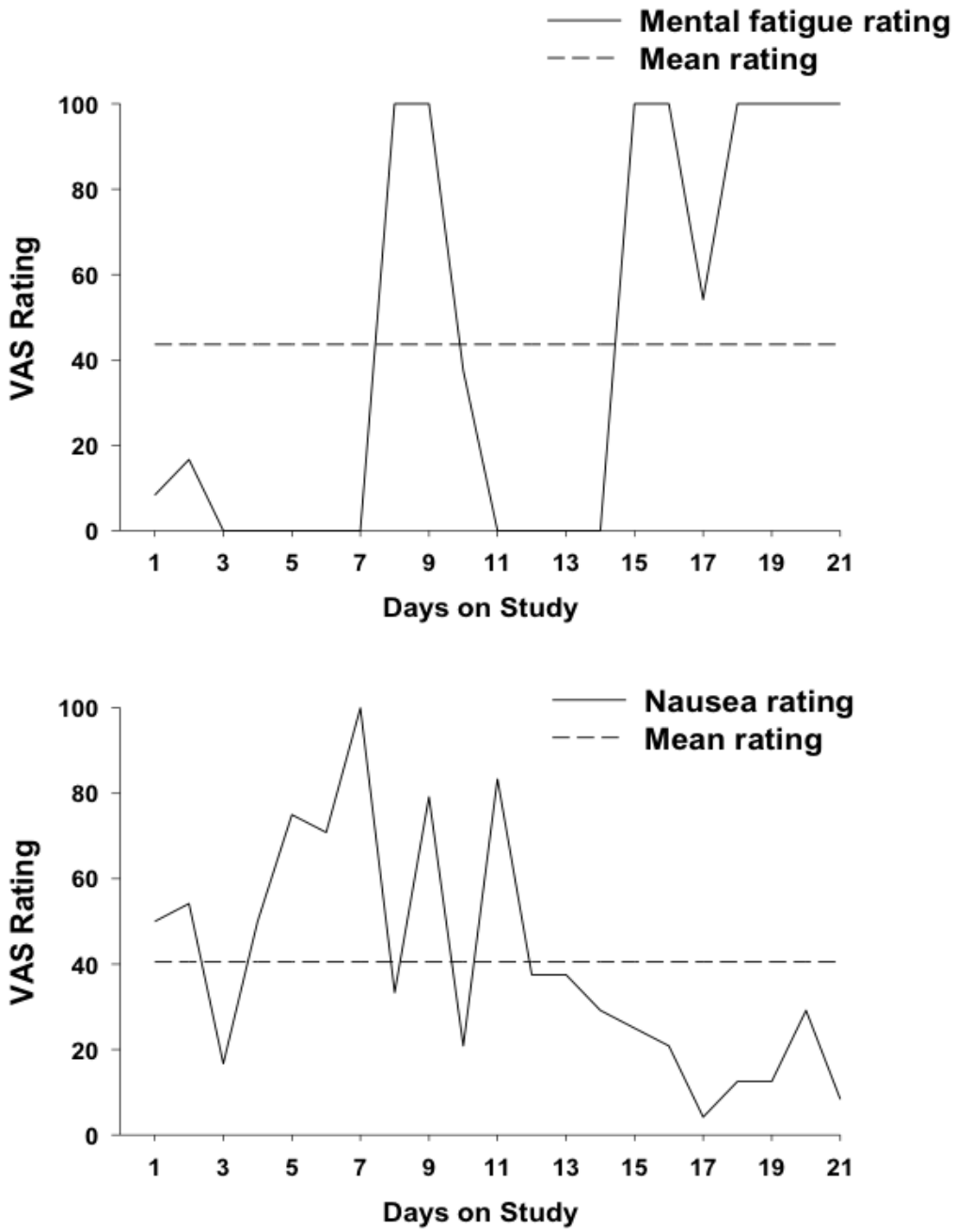
Table 4. Patients' selection of mood descriptors.

Mood descriptor	Percentage of days each patient selected mood descriptors										Mean of mood occurrence rates	% of patients reporting mood
	Patient											
	1	2	3	4	5	6	7	8	9	10		
	Inpatient				Both in and out-patient		Outpatient					
Positive mood descriptors												
Hopeful	38	0	65	86	33	26	5	43	22	91	41	100
Happy	67	15	82	0	62	26	5	52	33	24	37	90
Confident	52	15	12	86	5	37	0	10	17	86	31	90
Negative mood descriptors												
Frustrated	62	23	53	10	43	16	10	0	33	86	34	90
Irritable	0	46	12	52	38	16	15	5	56	71	31	90
Worried	0	46	59	10	19	11	40	10	0	81	28	80
Anxious	38	8	65	0	19	5	10	10	11	95	26	90
Sad	0	46	47	57	10	11	0	5	6	33	21	80
Angry	19	0	24	5	14	5	0	0	11	48	13	80
Scared	0	31	24	0	5	0	0	5	0	24	9	50
Lonely	0	0	18	33	0	0	0	0	0	0	5	20

Table 5. Participants' reasons for recommending the use of the mOST application to others.

Participant	Quotation
18 year old, Hispanic female	"…it's a good idea to keep like, to keep a list of how you're feeling"
20 year old Hispanic male	"…it kind of like channels whatever you have wrong with you like out…"
21 year old Hispanic male	"… because it really helps to see how you've been doing too actually, not just like, you know, go on day by day. But it does help you see and reflect on how you're doing. And if you did something the other day that helped, will help you make you feel better and so on. "
19 year old Hispanic female	"…because "It's a good app and it just makes you -- I know for me it makes me feel better because I can keep track of my symptoms, kind of like a self-comforting type of thing because you know what you're going through and you're not scared. And eventually if this does go to where the doctors can see it, it'd be even better because you know that your physician is seeing it and the communication's there."

Figure 1. Mental fatigue and nausea ratings for participant 5. Mental fatigue rating in response to the statement "My mind has felt worn out" on a 0-100 VAS, where higher values indicate more severe fatigue. Nausea rating is response to nausea query on a 0-100 VAS, where higher values indicate more severe nausea. Dashed line represents mean values over the 21-day study period.



Discussion

This study is the first to demonstrate that the use of an eDiary on a mobile phone platform is a feasible method to collect daily symptom data from AYAs with cancer. The adherence rates in this study (>91%) greatly exceed those associated with pen and paper diaries [8-12], and did not vary significantly over the 3-week period. Patients reported that the application was simple to use and that they would recommend its use to others. The daily collection of patients' symptom experiences may be very useful in pediatric oncology, as it opens new doors to study symptom trajectories in this population. With this technology, researchers can evaluate daily symptom reports and potentially discover patterns that may lead to a better understanding of the etiology of various symptoms. This level of assessment of symptoms may increase our ability to identify those at highest risk for unrelieved symptoms and immediately intervene to relieve suffering.

Not all diseases or treatment-related symptoms experienced by cancer patients warrant daily monitoring. However, many symptoms are labile, particularly during chemotherapy [4]. Weekly or monthly averages of such symptoms provide an incomplete picture of the patient's experience. Daily symptom reports provide clinicians with the information they need to intervene at an early stage and to encourage patients to monitor changes in symptom severity following an intervention. This variability cannot be appreciated when researchers report only group means. Mobile technology allows for the expeditious collection of daily symptom reports, avoiding the burden placed on AYAs when maintaining a paper diary.

Researchers can evaluate within-subject changes using the statistical process of multilevel modeling [46, 47]. In addition, with daily symptom reports, a more accurate evaluation of symptom clusters may be possible when temporal co-occurrence is confirmed. Through the use of an eDiary, one can evaluate changes in patients' mood descriptors to determine the relationships among a variety of mood states and physical symptoms and timing of therapies.

Daily reports may not be sufficiently frequent among a group of critically ill patients. Broderick and colleagues [13] compared symptom data collected multiple times per day with EMA to subsequent patient recall with varying recall periods. Although patients had difficulties accurately recalling events more than 2 days in the past, EOD reports were deemed sufficient. The average of the day's EMA reports strongly correlated with those recalled at the EOD [13]. However, the collection of EMA symptom ratings may be an advantageous option to evaluate symptom management strategies for some highly variable symptoms, such as novel treatments for nausea or pain.

EMA trials which involve frequent assessments throughout the day have been conducted among AYA patients with chronic pain [20], diabetes [48], and among healthy college students to assess smoking[49] and alcohol use [49]. However, to our knowledge, no studies have been done with AYA patients with cancer. One must weigh the potential for improved temporal resolution of symptom patterns with the potential for increased patient burden and subsequent decrements in adherence to monitoring. However, research on the effects of frequent monitoring on adherence with symptom reporting is lacking.

The use of mobile phones to collect symptom characteristics offers many advantages over pen-and-paper diaries for AYAs with cancer. AYAs are extremely comfortable with technology and may become more fully engaged in their care when they are empowered to track symptoms in a manner that resonates with them. AYA may prefer eDiaries to report sensitive information. In one study, adolescents reported more sexual behavior using a computer assessment compared with paper forms [50]. Thus, the use of electronic data collection may lead to more accurate and complete symptom profiles. Data collected electronically are date and time stamped to assure temporal accuracy. In contrast, reports of back filling (ie, entering data at a later date) and even forward filling (ie, entering data for future dates) of pen and paper diaries exist [51]. Electronic diaries place minimal burden on patients and clinicians can be alerted to serious concerns in real-time. In addition, eDiaries have the potential for seamless integration with web portals and electronic health records for in-depth evaluation and dissemination.

Currently our team is further evaluating the psychometrics of the mOST application. In this study, patients complete the eDiary daily over a 3-week course. On day 8 of the study they complete a series of symptom questionnaires and a quality of life measure (ie, the Pediatric Quality of Life Inventory) using a 1-week recall. Their daily eDiary responses during the first week will be compared to their recall of events reported on the symptom measures. Once the validity and reliability of the instrument are established, we plan to incorporate it into mHealth symptom intervention studies among AYA patients with cancer.

Although the use of mobile phones in research is considered an expensive endeavor, older models of phones are often available free of charge or for nominal fees. Mobile phone use among young people has been prevalent for many years and the age for acquiring smartphones is rapidly decreasing [52]. Mobile technology developers are often able to design applications that are device and platform agnostic and can be used on most phones. Thus researchers and clinicians can offer symptom assessment tools for use on patients' own devices for very little cost. In addition, direct data entry from mobile devices eliminates the potential costs of data entry and validation by staff.

The limitations of this study need to be acknowledged. These limitations include the use of a convenience sample of only 10 patients and a relatively short trial period of 21 days. The patients received a relatively high incentive of up to $71 for their participation in the study, an acceptable practice in the United States considering the patients' 3-week commitment to the study, but not standard in all countries [53]. In 2002, Institutional Review Board members were surveyed to determine their recommendations for pediatric incentives in research. The maximum allowed payment to children varied widely from $10-$1000, with a median of $100 [54]. The incentives in our study may have promoted improved adherence with daily reporting. The evaluation of the impact of study incentives on

patient adherence is an appropriate subject for future investigation, along with the investigation of non-monetary interventions to promote prolonged engagement with technology. Despite these limitations, to our knowledge, this study is the first evaluation of an eDiary on mobile phones for AYAs with cancer. The 21st century is an age in which technology is expected to revolutionize the collection of patient-reported outcomes and that may lead to important improvements in symptom management.

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Conflicts of Interest

Mr. Richard Kletter and Dr. Paul Zeltzer developed the software for GoMed Solutions, and thus declare a potential conflict of interest.

Multimedia Appendix 1

mOST screen shots.

[PDF File (Adobe PDF File), 193KB - resprot_v1i2e23_app1.pdf]

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Abbreviations

AYA: adolescent and young adult
CAS: color analog scale
ED: emergency department
eDiary: electronic diary
EMA: ecological momentary assessment
EOD: end-of-day
FPS-R: faces pain scale-revised
mOST: mobile oncology symptom tracker
PeNAT: pediatric nausea assessment tool

VAS: visual analog scale

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Original Paper

A Web-Based Intervention for Health Professionals and Patients to Decrease Cardiovascular Risk Attributable to Physical Inactivity: Development Process

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Abstract

Background: Patients with cardiovascular risk factors can reduce their risk of cardiovascular disease by increasing their physical activity and their physical fitness. According to the guidelines for cardiovascular risk management, health professionals should encourage their patients to engage in physical activity.

Objective: In this paper, we provide insight regarding the systematic development of a Web-based intervention for both health professionals and patients with cardiovascular risk factors using the development method Intervention Mapping. The different steps of Intervention Mapping are described to open up the “black box” of Web-based intervention development and to support future Web-based intervention development.

Methods: The development of the Professional and Patient Intention and Behavior Intervention (PIB2 intervention) was initiated with a needs assessment for both health professionals (ie, physiotherapy and nursing) and their patients. We formulated performance and change objectives and, subsequently, theory- and evidence-based intervention methods and strategies were selected that were thought to affect the intention and behavior of health professionals and patients. The rationale of the intervention was based on different behavioral change methods that allowed us to describe the scope and sequence of the intervention and produced the Web-based intervention components. The Web-based intervention consisted of 5 modules, including individualized messages and self-completion forms, and charts and tables.

Results: The systematic and planned development of the PIB2 intervention resulted in an Internet-delivered behavior change intervention. The intervention was not developed as a substitute for face-to-face contact between professionals and patients, but as an application to complement and optimize health services. The focus of the Web-based intervention was to extend professional behavior of health care professionals, as well as to improve the risk-reduction behavior of patients with cardiovascular risk factors.

Conclusions: The Intervention Mapping protocol provided a systematic method for developing the intervention and each intervention design choice was carefully thought-out and justified. Although it was not a rapid or an easy method for developing an intervention, the protocol guided and directed the development process. The application of evidence-based behavior change

methods used in our intervention offers insight regarding how an intervention may change intention and health behavior. The Web-based intervention appeared feasible and was implemented. Further research will test the effectiveness of the PIB2 intervention.

Trial Registration: Dutch Trial Register, Trial ID: ECP-92

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KEYWORDS

Internet intervention; Intervention Mapping; Health education; Health behaviour change; Health professionals; Cardiovascular risk

Introduction

Developing a Web-based intervention requires a well-thought idea, but also a plan of how to design, implement, and evaluate the intervention. Intervention Mapping provides a framework for building high-quality interventions that are systematically planned, theory- and evidence-based, and take perspectives of end users and intermediaries into consideration [1-6]. Intervention Mapping has been found to be effective for developing interventions [1,2,7-11]. Intervention Mapping consists of 6 planning steps in which each step has a different task and is a prerequisite for the next step. Intervention Mapping places specific emphasis on the transparency of the translation of evidence-based behavior change techniques in intervention components. This is to develop the intervention, explain its rationale, and to facilitate replication [4]. Intervention Mapping is used throughout the process of creating an intervention (from diagnosis of the problem to problem solution) and includes collaborating iteratively with priority groups, stakeholders, and experts in the fields of health education and health promotion.

In designing the intervention for this study, we focused on patients with cardiovascular risk factors. Cardiovascular risk factors increase the risk for cardiovascular disease, Type 2 diabetes, and overall mortality and morbidity [12,13]. Physical activity, particularly intense physical activity, improves cardiovascular fitness and is associated with important cardiovascular health benefits [13,14]. Lifestyle interventions directed at increasing physical activity, thereby enhancing physical fitness, may improve the cardiovascular risk profile of patients. In designing the intervention, we included health professionals, because they can—and should—encourage patients with cardiovascular risk factors to become and stay physically active.

This paper provides insight regarding the systematic development process of the Web-based Professional and Patient Intention and Behavior (PIB2) intervention to open up the “black box” of Web-based intervention development and support future development. The development of the behavioral change intervention should facilitate logic transparency, reproducibility, and diffusion of the intervention. The intervention sought to optimize behavioral coaching by health professionals and to encourage previously physically inactive patients with cardiovascular risk factors to become physically active, following cardiovascular risk management guidelines with a potential for implementation in cardiovascular inpatient and outpatient care [15].

Methods

The first step of Intervention Mapping is a needs assessment of the study population. The questions explored in the first step included: What is the problem? What are the causes? What behaviors are related to the problem? Are there detectable risk groups? The social-cognitive determinants that could explain intention and behavior were also studied [1,4]. The second step defined the performance objectives with the specification of the change objectives. The performance objectives are the anticipated behavioral outcomes of the intervention. The change objectives describe how important social-cognitive determinants that explain intention and behavior can be changed. In the third step, the performance objectives were linked to the social-cognitive determinants of intention and behavior, as explored in step 1. The theory-based intervention methods to change the determinants of intention and the (health) behavior of interest were selected [1,4]. We selected the theory-based methods, looked at the considerations for using these methods, and described conditions and strategies. Acquiring insight into behavioral change methods to be used in intervention design is essential to evaluate the effectiveness of an intervention because it reveals not only why an intervention changed intention and/or (health) behavior, but also why it may have failed [16,17]. In the fourth step, an intervention was developed based on the integration of these theory-based methods of behavior change and the intervention was pretested. During the fifth step, an adoption and implementation plan for the intervention was created to facilitate sustained implementation. In step 6, the expected results were compared to the actual results to assess the accuracy of the intervention [1,4]. See Figure 1 for an overview of the steps of Intervention Mapping, including the design, implementation, and evaluation of the intervention.

Participants were health professionals and former students of the University of Applied Sciences, Utrecht, the Netherlands. Participants with at least a Bachelor’s degree in nursing or physiotherapy and who had consultations with patients with cardiovascular risk factors were invited to participate. Patients with at least one cardiovascular risk factor (abdominal obesity, high blood pressure, low high-density lipoprotein cholesterol, elevated triglycerides, and elevated blood glucose levels) and low physical activity levels were invited [12,13]. We facilitated sustained implementation of the intervention by rewarding health professionals for extensive use of the Web-based PIB2 intervention with a certificate of 10 European credits. The implementation of the PIB2 intervention was approved by the

Ethics Committee at Maastricht University and was registered in the Dutch Trial Register (Trial ID: ECP-92).

Figure 1. Intervention Mapping steps, design, implementation, and evaluation of the Professional and Patient Intention and Behavior (PIB2) intervention.

Step			Design	Health professionals	Patients with cardiovascular risk factors
Step 1	↑	→	↓ Needs assessment	Literature search; focus-group interviews; assessment of social-cognitive determinants of intention and behavior to encourage physical activity	Literature search; small group interviews; assessment of social-cognitive determinants of intention and behavior to become physically active
Step 2	↑		↓ Definition of objectives and specification of the changes that are needed	Overall objective extending professional behavior; stating performance objectives as the anticipated outcomes of the intervention; stating change objectives	Overall objective risk-reduction behavior; stating performance objectives as the anticipated outcomes of the intervention; stating change objectives
Step 3	↑		↓ Theory-based methods and practical strategies	Identification of theoretical methods to change social-cognitive determinants of the intention to encourage patients and the corresponding behavior	Identification of theoretical methods to change social-cognitive determinants of the intention to become physically active and the corresponding behavior
Step 4	↑		↓ Intervention	Design, development, and pre-test of the Web-based intervention	Design, development, and pre-test of the Web-based intervention
Step 5	↑		↓ Adoption and implementation plan	Invited to participate via a personalized letter sent by mail; instruction meeting; telephone and email support; reward certificate	Professionals invite patients
Step 6	↑		↓ Evaluation plan	Pre- and post-test randomized controlled design	Pre- and post-test randomized controlled design
Evaluation		←	Implementation		

Results

We undertook a separate planning process for health professionals because they perform different behaviors with different social-cognitive determinants related to the intention and behavior in question than their patients with cardiovascular risk factors do [18,19].Within each step of the Intervention Mapping protocol, the application for health professionals is presented followed by the application for patients with cardiovascular risk factors.

Intervention Mapping Step 1: Needs Assessment (Health Professionals)

In the needs assessment for health professionals, we performed a literature review, held focus group interviews, and studied the social-cognitive determinants that explained intention and behavior. Focus group interviews with health professionals (n = 7) revealed that encouraging patients to become physically active was seen as an integral part of their daily practice and, although perceived as relatively easy to do, patient compliance was often a problem. In previous research, we studied through questionnaire the social-cognitive determinants of intention and behavior to encourage patients with cardiovascular risk factors to become physically active [19-28]. Input for the Intervention Mapping process showed that health professionals' encouragement of physical activity among cardiovascular patients could be predicted by high levels of intention to encourage physical activity among these patients [19].

Intervention Mapping Step 1: Needs Assessment (Patients)

In the needs assessment for patients with cardiovascular risk factors, the literature showed various guidelines explaining the recommended levels of physical activity and physical fitness. In a previous study, we investigated physical activity and physical fitness in an adult population and found that the intensity of physical activity was especially important in reducing cardiovascular risk factors [18]. Small group interviews (12 interviews with 3 patients each) revealed that patients with cardiovascular risk factors found being physically active a complex health behavior to incorporate into daily living and it was difficult to maintain. We studied through questionnaire the social-cognitive determinants of patients' physical activity intentions and the corresponding behavior [20-28]. Input for the Intervention Mapping process showed that behavior was predicted by high levels of intention [18].

Intervention Mapping Step 2: Define Objectives and Specify Changes (Health Professionals)

We defined the desired behavior of health professionals as encouraging behavior conducive to the health of patients. Health professionals should encourage patients with cardiovascular risk factors to become physically active at increasing levels of intensity as an extension of their professional behavior. This overall objective of extending professional behavior was specified in the health care professionals' performance objectives. The performance objectives were directed at monitoring their encouraging behavior, formulating explicit

plans to encourage their patients, and maintaining and habitually encouraging patients to prevent relapse (Table 1).

Table 1. Intervention Mapping step 2 performance objectives for health care professionals and patients with cardiovascular risk factors.

Target group	Performance objectives
Health professionals	Monitor the encouragement of physical activity among patients with cardiovascular risk factors as a prerequisite for a physically active patient
	Formulate explicit plans to encourage physical activity among patients with cardiovascular risk factors
	Identify solutions to diminish the barriers to encouraging physical activity among patients with cardiovascular risk factors
	Formulate explicit plans to cope with difficult situations that occur while encouraging physical activity among patients with cardiovascular risk factors
	Maintain and habitually encourage physical activity among patients with cardiovascular risk factors to prevent relapse
Patients with cardiovascular risk factors	Monitor cardiovascular risks linked to the intensity of physical activity
	Make explicit plans for physical activity
	Identify solutions to diminish barriers to physical activity
	Make explicit plans to cope with difficult situations that occur during physical activity
	Maintain a lifestyle marked by physical activity to prevent relapse

The performance objectives were linked with the social-cognitive determinants of intention and behavior as described in step 1. The link between performance objectives and social-cognitive determinants resulted in a matrix displaying the change objectives for health professionals (Tables 2 and 3). For example, the performance objective that professionals formulate explicit plans to encourage patients was related to the change objectives that health professionals know that planning is important, that they describe their personal benefits for planning, that they feel confident planning the encouragement, and they describe when, where, and how they will encourage patients to engage in physical activity.

Table 2. Intervention Mapping step 2 (change objectives) performance objectives for health professionals linked to social-cognitive determinants risk perception, attitudes, and social influence.

Performance objectives health professionals	Risk perception and knowledge	Attitude and outcome expectations	Social influence and skills
Monitors encouragement of physical activity among patients with cardiovascular risk factors as a prerequisite for a physically active patient	Describes the relationship between the professional behavior of encouraging physical activity and health outcomes for patients with cardiovascular risk factors; indicates that cardiovascular risk factors are related to the intensity of physical activity; reports relevant justifications for encouraging patients with cardiovascular risk factors to engage in physical activity	Feels positively about encouraging patients with cardiovascular risk factors to become physically active and the (health) benefits of physical activity; expects that physical activity will decrease cardiovascular risk factors	Describes others as supporting or encouraging patients with cardiovascular risk factors; asks for support; feels confident about handling negative social influence when encouraging patients with cardiovascular risk factors; performs skills necessary to encourage physical activity for cardiovascular patients
Formulates explicit plans to encourage physical activity among patients with cardiovascular risk factors	Knows planning is important for encouraging patients with cardiovascular risk factors to engage in physical activity	Describes personal benefits for planning the encouragement of patients with cardiovascular risk factors to engage in physical activity	Feels confident in planning the encouragement of patients with cardiovascular risk factors to engage in physical activity in regard significant others
Identifies solutions to diminish barriers to encourage physical activity among patients with cardiovascular risk factors	Recognizes negative feelings, thoughts, and actions regarding encouraging patients with cardiovascular risk factors to engage in physical activity that keep him/her from encouraging patients	Describes negative feelings, thoughts, and actions regarding encouraging patients with cardiovascular risk factors to engage in physical activity that keep him/her from encouraging patients	Discusses with colleagues the negative feelings, thoughts, and actions about encouraging patients with cardiovascular risk factors to engage in physical activity that keep him/her from encouraging patients
Formulates explicit plans to cope with difficult situations that occur while encouraging physical activity among patients with cardiovascular risk factors		States that he/she is convinced of the importance of encouraging patients with cardiovascular risk factors to engage in physical activity	
Maintains and habitually encourages physical activity among patients with cardiovascular risk factors to prevent relapse	Indicates that relapse is part of encouraging patients with cardiovascular risk factors to engage physical activity	States benefits of encouraging patients with cardiovascular risk factors to engage in physical activity in the short and long term; states that the best reaction to relapse is to restart	Handles negative social influence (to relapse)

Table 3. Intervention Mapping step 2 (change objectives) performance objectives for health care professionals linked to social-cognitive determinants self-efficacy and barriers.

Performance objectives for health professionals	Self-efficacy and skills	Barriers and skills to cope with barriers
Monitors that encouragement of physical activity among patients with cardiovascular risk factors is a prerequisite for a physically active patient	Is confident about encouraging patients with cardiovascular risk factors to become physically active; demonstrates the skills necessary to encourage patients with cardiovascular risk factors to become physically active; demonstrates practical skills necessary to encourage physical activity among patients with cardiovascular risk factors	
Formulates explicit plans to encourage physical activity among patients with cardiovascular risk factors	Describes when, where, and how they will encourage patients with cardiovascular risk factors to engage in physical activity	
Identifies solutions to diminish barriers to encouraging physical activity among patients with cardiovascular risk factors		Handles situations that keep them from encouraging patients with cardiovascular risk factors to engage in physical activity
Formulates explicit plans to cope with difficult situations that occur while encouraging physical activity among patients with cardiovascular risk factors	Demonstrates skills in daily planning for the encouragement of patients with cardiovascular risk factors to engage in physical activity	Incorporates difficult situations in daily planning for the encouragement of patients with cardiovascular risk factors to engage in physical activity
Maintains and habitually encourages physical activity among patients with cardiovascular risk factors to prevent relapse	Is confident in his/her ability to encourage patients with cardiovascular risk factors to engage in physical activity; demonstrates that it is best to restart after relapse; evaluates encouraging behavior	Handles incidental situations that keep him/her from encouraging patients with cardiovascular risk factors to engage in physical activity

Intervention Mapping Step 2: Define Objectives and Specify Changes (Patients)

In formulating our intervention objectives for patients, we defined the desired behavior as risk-reduction behavior assuming that if an intervention reduces the prevalence of risk factors, it can also reduce the prevalence of disease. Thus, not only should physical activity be encouraged for patients, but also the intensity of their physical activity, resulting in healthy behaviors for patients with cardiovascular risk factors [14]. This overall objective of risk-reduction behavior of the patient was specified in the performance objectives (Table 1). The performance objectives were directed at monitoring cardiovascular risk linked to physical activity, making explicit plans, and maintaining a lifestyle marked by physical activity to prevent relapse. The link between these performance objectives and social-cognitive determinants resulted in a matrix displaying the change objectives for patients with cardiovascular risk factors (Tables 4 and 5). Examples of change objectives related to the performance objective that patients maintain a lifestyle marked by physical activity to prevent relapse was related to the change objectives that patients indicate that relapse is a part of changing lifestyle physical activity, stating the health benefits of physical activity, feeling confident about handling negative social influence, and about being able to perform physical activity, demonstrating an ability to restart and evaluate the behavior, and that they can handle incidental situations that keep them from engaging in physical activity.

Table 4. Intervention mapping step 2 (change objectives) performance objectives for patients with cardiovascular risk factors linked to social-cognitive determinants risk perception, attitudes, and social influence.

Performance objectives for patients	Risk perception and knowledge	Attitude and outcome expectations	Social influence and skills
Monitors their cardiovascular risk linked to the intensity of physical activity	Describes relationship between physical activity and health; describes their personal cardiovascular risk; describes that cardiovascular risk factors are related to the intensity of physical activity; indicate relevant reasons for physical activity	Feels positively about the (health) benefits of physical activity; expects that physical activity decreases cardiovascular risk factors	Describes significant others as supporting physical activity; asks for support; feels confident about handling negative social influence; performs social skills necessary for physical activity
Makes explicit plans for physical activity	Knows planning is important for physical activity	Describes personal benefits of planning physical activity	Feels confident in planning physical activity in regard to social circumstances
Patient identifies solutions to diminish barriers to physical activity	Recognizes negative feelings, thoughts, and actions about physical activity, cardiovascular risk factors, the body or self that keep him/her from engaging in physical activity	Describes negative feelings, thoughts, and actions about physical activity, cardiovascular risk factors, the body or self that keep him/her from engaging in physical activity	Discusses negative feelings, thoughts, and actions about physical activity, cardiovascular risk factors, the body or self that keep him/her from engaging in physical activity
Makes explicit plans to cope with difficult situations that occur during physical activity		Expresses being convinced that physical activity is important	
Maintains a lifestyle marked by physical activity to prevent relapse	Indicates that relapse is part of changing lifestyle physical activity	States the health benefits of physical activity in the short and long term; states that the best reaction to relapse is to restart	Feels confident about handling negative social influence (to relapse)

Table 5. Intervention mapping step 2 (change objectives) performance objectives for patients with cardiovascular risk factors linked to social-cognitive determinants self-efficacy, and barriers.

Performance objectives for patients	Self-efficacy and skills	Barriers and skills to cope with barriers
Monitors their cardiovascular risk linked to the intensity of physical activity	Is confident about being able to perform physical activity; demonstrates the skills; shows practical skills necessary for physical activity	
Makes explicit plans for physical activity	Describes when, where, and how they will engage in physical activity	
Identifies solutions to diminish barriers to physical activity		Handles situations that keep him/her from engaging in physical activity
Makes explicit plans to cope with difficult situations that occur during physical activity	Demonstrates skills in daily planning for physical activity	Incorporates difficult situations in daily planning for physical activity
Maintains a lifestyle marked by physical activity to prevent relapse	Is confident about being able to perform physical activity; demonstrates that it is best to restart after relapse; evaluates physical activity behavior	Handles incidental situations that keep him/her from engaging in physical activity

Intervention Mapping Step 3: Theory-Based Methods and Practical Strategies

In step 3, we selected the theory-based methods (Table 6). We applied the theoretical method of risk communication and risk perception to encourage thinking about individual risk and personal vulnerability. This was followed by the generation of attitudinal change and outcome expectations by applying the method of decisional balance to list the pros and cons [29]. We applied the theoretical methods resistance to social pressure and mobilizing others for social support to encourage seeking social support [23]. Providing emotional support or supporting people with information and advice influences the performance of the behavior and is a protective factor for health outcomes [1]. Guided practice to encourage subskill enactment was also facilitated [30]. Interventions that maximize beneficial attitudes, subjective norms, and perceived behavioral control have a substantial impact on intentions [29]. We applied the theoretical method of "action and coping planning." Action planning can initiate changes in intention. Interventions that provoke alterations in intention have a greater impact on health-related behavior [30-32]. Related to action planning, formulating implementation intentions by preparatory planning when, where, and how health professionals would encourage physical activity among patients with cardiovascular risk factors, as well as determining when, where, and how patients would engage in a physical activity was added to the intervention [33]. When health professionals and patients formulate their own plans (their own implementation intentions), they are more likely to attain the goal and to perform the planned health behavior [34]. This

strategy of implementation planning was found to generate a medium-sized effect on health behaviors [35]. Coping planning was initiated to allow health professionals and patients to better cope with putting behavior change into practice [36]. Coping planning was initiated when health professionals and patients identified high-risk situations that might cause them to withdraw from the desired behavior [37]. In addition, health professionals and patients were aided to make their own explicit plans to cope with potential difficult situations that would hinder them from engaging in health behavior or relapse [38].

Table 6. Intervention mapping step 3 (theory-based methods) social-cognitive determinants linked to theoretical methods and their conditions.

Determinant	Theory-based method	Considerations for use	Conditions and strategies
Risk perception, knowledge	Risk communication, risk perception	Requires knowledge about the relationship between (health) problem and (risk vs nonencouraging) behavior	Encourage thinking about individual risk and personal vulnerability
Attitude, outcome expectations	Decisional balance	Requires consideration and evaluation of behavior	Encourage listing pro and cons of changing the behavior in the short and long term
Social influence and skills	Resistance to social pressure	Requires social-skill enactment with feedback	Encourage to resist social pressure
	Mobilizing others for social support	Requires a network that can potentially support health behavior	Encourage to seek social support
Perceived behavioral controland skills	Guided practice	Requires subskill enactment with feedback	Encourage subskills practice
	Action planning	Requires specification of when, where, and how to act	Planning behavior change, making a behavior change plan
Barriers and skills to cope	Coping planning	Requires identification of high-risk situations and the practice of coping responses	Put into practice behavior change

In a systematic review and meta-analysis, it was found that the number of behavioral change techniques applied had a positive impact on the total effect size of the intervention [6,39]. An overview of reviews on behavioral change techniques to promote behavior change found that risk communication, use of social support, and self-monitoring of behavior were all shown to be relatively effective [16]. Also, coping and action planning were found to have a sustainable effect on health behavior [6,36]. The intervention provided personalized text messages (with individuals' names in headings) that were shown to be highly effective in encouraging interaction and support of behavioral change in interventions [6,40].

Intervention Mapping Step 4: Intervention

A Web-based behavioral change intervention was considered the most appropriate intervention. The intervention aimed to motivate health care professionals to encourage physical activity among their patients and to extend their professional behavior. The intervention also aimed to improve risk-reduction behavior in patients with cardiovascular risk factors. The intervention was not developed as a substitute for face-to-face contact between the health professional and the patient, but as an additional instrument to optimize health services [41]. Research has demonstrated the favorable effects of Internet-delivered interventions, also specific for physical activity interventions [42-46]. Computer-delivered interventions can improve social-cognitive determinants and also enhance health behavior and general health maintenance [42]. An Internet-delivered intervention facilitates the delivery of the intervention to a large group of professionals and patients. Using a website is appealing to the group of interest and has the benefits of making processes visible [47].

Several tests and interviews were conducted with experts and members of the target groups (health professionals and patients) to verify the match between intervention components, the performance and change objectives, theory-based methods, conditions for use, and strategies. The PIB2 intervention embeds 5 modules, each comprising a sequential set of screens on the website (Figure 2).

In module 1, the health professionals encouraged the patient to become and stay physically active. Module 1 was designed to invite the patient to participate in the intervention (to use the intervention based on the mutual exchange of information between the health professionals and the patient) paralleling the performance and change objectives, the methods, conditions, and strategies (Figure 2). It started with the assessment of cardiovascular risk factors according to the guidelines for cardiovascular risk management [15]. Based on this assessment, the patient's cardiovascular risk factors were displayed in a pie chart and changes in the number of risk factors or risk factor levels were registered and also displayed. During the assessment step, the levels of physical activity (intensity and duration) were assessed with the short questionnaire to assess health-enhancing physical activity (SQUASH). Physical activity and the intensity (total intensity and high, medium, and low intensity) of physical activity was displayed in a bar chart; changes were registered and also displayed [48]. The social-cognitive determinants of the patient, and the intention and behavior toward physical activity, were assessed through a questionnaire and displayed

in the health spider chart of the patient; changes were registered and later shown [18].

After the assessment, the health professionals began coaching the patient with cardiovascular risk factors through a process of behavior changes to become and to stay physically active. In the process of behavior change, the 7 theory-based methods, conditions, and strategies were put into practice through 7 different website screens. The process of behavior change started with risk perception by encouraging the patient to think about individual cardiovascular risk and personal vulnerability, and the relationship between physical activity and cardiovascular risk. This was followed by listing the pros and cons of changing (or not changing) their behavior in the short and long term, and encouraging the patient to describe what his/her personal pros and cons are to becoming (or not becoming) physically active in the short and long term. After this, the patient was encouraged to resist social pressure and to seek social support, and to practice the necessary subskills. The process of behavior change ended with planning the behavior change by making a behavior change plan and putting the behavior change into practice. The patient was encouraged to specify when, where, and how to become physically active in a plan. When the patient started to put the physical active lifestyle into practice, high-risk situations should be detected and the practice of coping responses was encouraged.

A feedback system measured the progress of the patient's cardiovascular risk factors, physical activity levels, and the process of behavior change. The patient's profile was displayed while the health professional was working with the patient. The health professional provided the patient with physical activity recommendations based on research [14,49]. The physical activity recommendations were also shown in the patient's profile and could be changed by the health professional when needed.

Module 2 was the health professionals' support system. The support system was parallel to the website screens of module 1 (Figure 2). Module 2 contained background information about how to coach the patient with cardiovascular risk factors through the processes of behavior change. This module consisted of explanations of the methods, conditions, and strategies for the health professionals, scripts on how to start conversations, and so on. The health professionals could read background information for each method and select parts of this information. Once selected, the website displayed the selected background information for all subsequent consultations with this and other patients by clicking the "show suggestions" button in module 1.

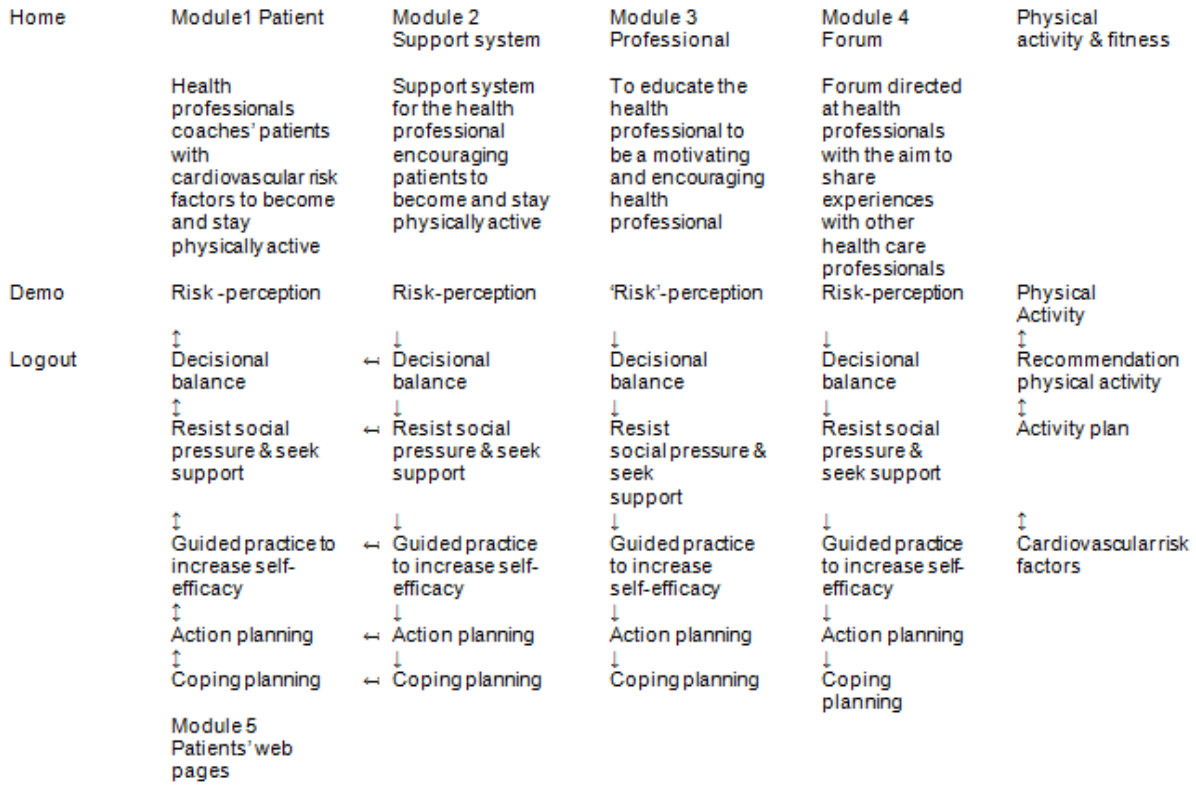
Module 3 facilitated the professional to become a motivating and encouraging health professional (Figure 2). It contained self-complete forms and was designed to educate the health professional. The process of behavior change for health professionals started with "risk" communication, thinking about encouraging patients, and thinking about compliant patients. This was followed by listing the pros and cons of encouraging (or not encouraging) patients in the short and long term. After this, the health professional was encouraged to seek social support and look at the subskills needed to be an encouraging health professional. The process of behavior change ended with planning the behavior change, making a behavior change plan, and putting the behavior change into practice. The professional was encouraged to specify in a plan when, where, and how to encourage patients. When the professional started to put his encouraging behavior into practice, the identification of high-risk situations and the practice of coping responses was encouraged. In module 3, a feedback system was incorporated to enable the professional to evaluate their progress. At the initiation of the behavior change process, the health professionals filled in a questionnaire on social-cognitive determinants, intention, and behavior to encourage patients. Progress was registered and made visible in the health professionals' coaching spider chart [19].

Module 4 consisted of a forum directed at health professionals. Health professionals could use the forum to share experiences with other health professionals who also used the PIB2 intervention and find solutions for specific problems pertaining to the coaching of patients (Figure 2). A researcher responsible for the implementation process responded to questions when other professionals did not respond or when responses were incorrect; however, the researcher refrained from interrupting online discussions.

Module 5 facilitated the patient to look back at the plans he made in conjunction with the health professionals in module 1 (Figure 2). Patients could examine the forms completed in module 1 and prepare for the next consultation with their health professional. The patient received these personalized messages underwritten with the name of their health care professional. Patients could see their progress in reducing the number of their cardiovascular risk factors, increasing physical activity levels, and implementing behavioral changes displayed in the same way as in module 1. The patient could read the physical activity recommendations provided by their health professional and practice them at home or elsewhere.

The health professionals could use all the modules of the PIB2 intervention with a log-in code. However, patients could only access module 5 with their log-in code. Health professionals could access background information on the PIB2 intervention and specific information for each module. Information on physical activity, physical fitness, general physical activity devices, making an activity plan, and cardiovascular risk factors were accessible. For patients, information about the PIB2 intervention with specific information on only module 5 was available. Background information and a response form for members of the general public visiting the website was also available.

Figure 2. Intervention Mapping step 4 (intervention) flowchart of the intervention.



Intervention Mapping Step 5: Adoption and Implementation Plan

In step 5 of Intervention Mapping we developed a plan to facilitate implementation of the intervention (Table 7). Health professionals were invited to participate via a personalized email. They were invited to attend a meeting at which the Web-based intervention was demonstrated and could be practiced. The intervention was self-explanatory, and participants could choose not to attend the meeting and use the demonstration tool on the website to familiarize themselves with the use of the website. This was followed by telephone calls, emails, and meetings [50]. Much effort was put in motivating the health professionals to use and keep using the website. The health professionals selected the patients with cardiovascular risk factors. Health professionals were strongly recommended to use the intervention for every patient suitable for intervention.

Table 7. Intervention Mapping step 5 (adoption and implementation plan) and step 6 (evaluation plan).

Group	Design				
Health professionals					
Intervention group 1	T1 Preintervention	T2 Start intervention, continuous measurement	T3 End intervention at 12 months		
Control group A	T1 Preintervention I		T2 Preintervention II	T3 Start intervention, continuous measurement	T4 End of the intervention at 24 months
Patients with cardiovascular risk factors					
Intervention group 2	T1 Preintervention	T2 Start intervention, continuous measurement	T3 End of the intervention at 12 months		
Control group B			T1 Preintervention	T2 Start intervention, continuous measurement	T3 End of the intervention at 24 months

Intervention Mapping Step 6: Evaluation Plan

The website was designed from the bottom up, beginning with determining the data needed to measure the effectiveness of the Web-based intervention [47]. The evaluation of the PIB2 intervention was designed according to the Consolidated Standards of Reporting Trials (CONSORT) criteria for reporting a randomized controlled trial [51] and will be reported in line

with the emerging CONSORT-EHEALTH guideline [52]. The intervention will be evaluated by a pretest and posttest randomized controlled trial design consisting of a health professional intervention group and a health professional waiting-list control group (Table 7). The health professionals were randomly allocated to the intervention vs the waiting-list control group. The health professionals selected the patients with cardiovascular risk factors. Continuous data collection will be part of the Web-based intervention for a follow-up period of 12 months.

The effect evaluation will be performed to verify whether the PIB2 intervention was successful in extending the encouraging behavior of health professionals (if methods, conditions, and strategies to use these methods were successfully applied to change performance and change objectives). The effect evaluation will also be performed to verify whether the intervention was successful in strengthening the physical activity behavior of patients with cardiovascular risk factors (if we attained their performance and change objectives). For patients, the main outcome measure was improvement in cardiovascular risk profiles (if patients decreased their number of cardiovascular risk factors by at least one risk factor and/or decreased their levels of cardiovascular risk factors at the end of the intervention). The process evaluation will be performed during implementation of the PIB2 intervention through the collection of data on the use and usability of the PIB2-intervention modules.

Discussion

This paper describes the systematic development process of the Web-based PIB2 intervention to disclose the black box of Web-based interventions and support future Web-based intervention development. Intervention Mapping step 1, the needs assessment for health professionals, indicated that we could state the problem that they do not always encourage patients with cardiovascular risk factors to become and/or stay physically active. The outcome measure for health care professionals was to extend their professional behavior. For patients at risk for cardiovascular disease, we could state the problem that they had low intentions toward, and inadequate levels of, physical activity and physical fitness. The outcome measure for patients with cardiovascular risk factors was to expand their risk-reduction behavior. Intervention Mapping step 2 resulted in matrices with specific performance and change objectives, for both health professionals and patients, linked with important social-cognitive determinants. Intervention mapping step 3 resulted in the linking of important social-cognitive determinants of intention and behavior, performance and change objectives with theory-based methods, and conditions and strategies to use these methods based on results of previous studies [39]. In step 4 of Intervention Mapping, we designed and pretested the website, and in step 5, the adoption and implementation plan of how to select and invite the health professionals and patients with cardiovascular risk factors to take part in the intervention was described. Step 6 Intervention Mapping resulted in the evaluation design for the intervention, consisting of a health professional intervention group and a health professional waiting-list control group. The intervention was implemented and the subgroups will be analyzed for their primary outcomes, extended professional behavior, and expanded patients' risk-reduction behavior.

Changing intentions and behavior among both health professionals and patients is a complex process with many inhibiting factors. By assessing the needs of both health professionals and patients, we defined important and changeable social-cognitive determinants. Using evidence-based behavior change techniques in the development process of the intervention was important because they provided insight regarding how social-cognitive determinants of health professionals and patients' may be changed. It proved difficult in Intervention Mapping step 3 (theory-based methods and strategies) to tune in on both groups, health professionals and patients with cardiovascular risk factors. Also in Intervention Mapping step 4, the development of the Web-based intervention made this complicated. We designed a prototype of the website, and it took many revisions, especially for the modules directed at health care professionals, before completion. The ease-of-use of the website for the selected methods proved complicated, as was the interaction between modules. Although influencing the professional behavior for health professionals and the physical activity behavior for patients with cardiovascular risk factors is difficult to achieve, the Intervention Mapping protocol provided us with tools to handle this complicated process.

Although it is easy to conclude that when you want to change the health-related behavior of patients it is a prerequisite that health professionals are able to handle the process of behavior change, this proved difficult. Choosing a Web-based intervention showed many opportunities to handle this complicated process, in our view more than any other method, but it proved difficult to make the website easy to use without having to explain everything.

Furthermore, although we carefully developed and tested the Web-based intervention in close cooperation with health professionals and patients with cardiovascular risk factors, much of its success depends on its feasibility and usefulness in the health professionals' daily practice and on whether there is sufficient time and expertise to use the intervention during the consultation period.

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Conflicts of Interest

None declared.

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
PIB2: Professional and Patient Intention and Behavior
SQUASH: short questionnaire to assess health-enhancing physical activity

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Original Paper

Technical Implementation of a Multi-Component, Text Message–Based Intervention for Persons Living with HIV

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Abstract

Background: Men who have sex with men (MSM) continue to be severely and disproportionately affected by the HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome) epidemic in the United States. Effective antiretroviral therapy has altered the HIV epidemic from being an acute disease to a chronic, manageable condition for many people living with HIV. The pervasiveness, low cost, and convenience of Short Message Service (SMS) suggests its potential suitability for supporting the treatment of conditions that must be managed over an extended period.

Objective: The purpose of this proof-of-concept study was to develop, implement, and test a tailored SMS-based intervention for HIV-positive MSM. Prior studies do not routinely provide sufficiently detailed descriptions of their technical implementations, restricting the ability of subsequent efforts to reproduce successful interventions. This article attempts to fill this gap by providing a detailed description of the implementation of an SMS-based intervention to provide tailored health communication messages for HIV-positive MSM.

Methods: We used archives from the SMS system, including participant responses to messages and questions sent via SMS, as the data sources for results reported in this article. Consistent with the purpose of this article, our analysis was limited to basic descriptive statistics, including frequency distributions, means and standard deviations.

Results: During the implementation period, we sent a total of 7,194 messages to study participants, received 705 SMS responses to our two-way SMS questions of participants, and 317 unprompted SMS message acknowledgements from participants. Ninety two percent of participants on antiretroviral therapy (ART) responded to at least one of the weekly medication adherence questions administered via SMS, and 27% of those had their medication adherence messages changed over the course of the study based on their answers to the weekly questions. Participants who responded to items administered via SMS to assess satisfaction with and use of the messages reported generally positive perceptions, although response rates were low overall.

Conclusions: Results confirm the technical feasibility of deploying a dynamically tailored, SMS-based intervention designed to provide ongoing behavioral reinforcement for HIV-positive MSM. Lessons learned related to text programming, message delivery and study logistics will be helpful to others planning and implementing similar interventions.

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KEYWORDS

short message service; SMS; text message; mobile phone; mHealth; HIV; tailored messaging

Introduction

The annual number of newly diagnosed human immunodeficiency virus (HIV) infections has remained relatively stable in the United States since the late 1990s, with more than 50,000 people becoming infected annually [1]. Meanwhile, HIV prevalence in the United States is higher than it has ever been, with more than an estimated 1 million adults and adolescents living with HIV in the United States [2]. Men who have sex with men (MSM) continue to be disproportionately affected by the HIV/acquired immune deficiency syndrome (AIDS) epidemic, accounting for just over half of all new infections in 2006 [1]. Because of advances in antiretroviral therapy, people are living with HIV for longer periods of time [3]. For people living with HIV, antiretroviral therapy has transformed HIV into a chronic health condition that can be managed via medication adherence [4]. However, adopting and maintaining healthy behaviors and a medication regimen over a lifetime is challenging and may require ongoing behavioral reinforcement [5].

Given that among American adults, more than 80% own a mobile phone [6], with no significant differences in ownership by race/ethnicity [7], health-related text messages delivered to mobile phones could have a broad reach. As of December 2010, more than 302 million wireless subscriptions were active in the United States, and these domestic users sent and received more than 187 billion text messages each month [8].

The pervasiveness, low cost, and convenience of Short Message Service (SMS, or text messaging) suggests that it may be a channel particularly well suited for supporting the treatment of diseases or conditions that must be managed over an extended period [9,10]. SMS not only facilitates more frequent communication with patients but also offers the opportunity to deliver health-related messages when and where these messages may have the greatest impact, such as medication reminders consistent with an individual's dosing schedule. Therefore, SMS may be one channel by which to provide ongoing reinforcement for people living with HIV related to medication adherence and maintenance of healthy behaviors. If effective, such an intervention may result in higher health care quality and better outcomes.

Despite the potential of SMS interventions delivered via mobile phone, a review of the literature on SMS-based interventions revealed that most prior studies have not included detailed descriptions of their technical implementation processes [11]. This gap is important because a systematic description of the technical implementation and message delivery could inform the design of future studies and strengthen the evidence base of this emerging research area. We sought to address this gap by documenting the technical implementation of our intervention. In this paper, we address the following questions:

1. How was the intervention implemented from a technical standpoint?
2. What changes to the technical implementation were made during the study?
3. Did participants respond to the messages and/or questions administered via SMS?
4. What were the participants' perceptions of the content, timing, volume, usefulness, and helpfulness of the messages?

Methods

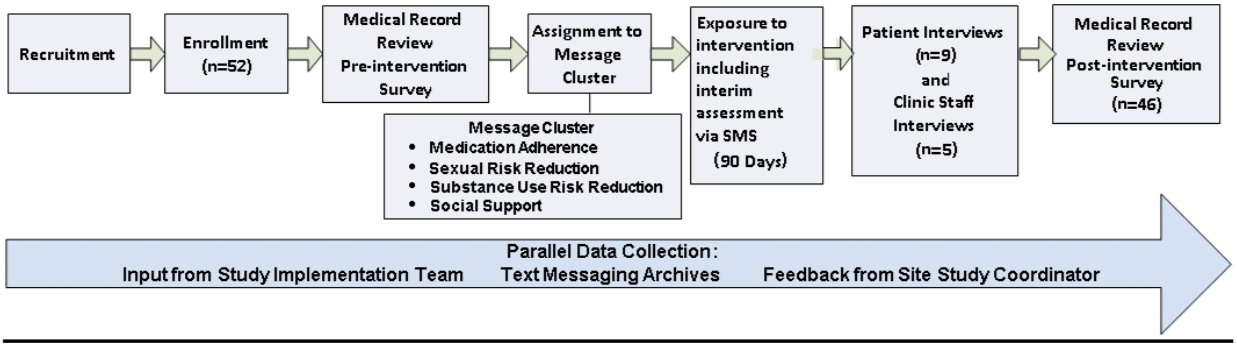
Study Design

RTI International, an independent nonprofit research organization, partnered with Howard Brown Health Center (HBHC), an ambulatory care clinic in Chicago, to implement and evaluate an SMS-based intervention for HIV positive MSM to enhance outcomes related to managing HIV. RTI also partnered with Intelecare, a company that specializes in personal notification and communication management for medication adherence and disease management, to provide the two-way text messaging gateway. The SMS platform was used not only to deliver the messaging intervention, but also as a mode of primary data collection on weekly self-reported medication adherence, sexual risk and substance use risk behaviors at 30 and 60 days, and participant satisfaction intermittently throughout the 90-day intervention period. Our study design (see Figure 1) was reviewed and approved by the Institutional Review Boards (IRBs) at both RTI and HBHC. Each participant also signed an authorization for use or disclosure of health information to be compliant with the Health Insurance Portability and Accountability Act.

Eligible participants included English-speaking, HIV-positive MSM aged 25 and older who had personal cell phones, agreed to allow us to access their medical records, and were amenable to receiving SMS messages during the 3month intervention. HBHC providers identified eligible participants during routine visits for primary care; other participants self-referred to the study after seeing posters or flyers in the clinic's waiting or examination rooms.

During initial screening, we confirmed eligibility and documented the participant's cell phone number and ability to send and receive text messages. Next, we administered informed consent. During the informed consent process, we used a message tailoring form to document each participant's preferences for receiving certain types of messages during the study or declining receipt of certain categories of messages, as required by RTI's IRB. After obtaining informed consent, we assigned each participant a personal identification number (PIN), which served to anonymize the information required to carry out the intervention as well as each participant's evaluation data. We entered the participant's PIN, cell phone number, and message cluster assignment in the SMS gateway manager. Next, we administered a comprehensive Web-based preintervention assessment survey to each participant at the clinic. We used these data to tailor specific message content for the 3-month intervention. To minimize potential attrition from loss of cell phone service, we provided each participant with a $25 incentive upon enrollment and $10 per month for the 3-month study period to offset the costs associated with monthly SMS plans.

Figure 1. Study Design.



Intervention Development

We developed the intervention implemented in our study based on a conceptual model developed by Coomes and colleagues [11]. The model integrates the communication functionality of SMS with important psychosocial factors that could mediate the impact of SMS communication on health care quality and outcomes. We developed the actual message content by beginning with a set of draft HIV prevention messages previously developed for HIV-positive individuals using a systematic formative research process [12]. We mapped each of the existing messages to the topic areas included in the current intervention (medication adherence, sexual risk reduction, substance use risk reduction, smoking cessation, general health and well-being, social support and patient involvement), identified gaps, and developed additional messages to fill those gaps. Three experts external to the project team, as well as health care providers at HBHC, reviewed and provided feedback on the draft messages. Finally, we qualitatively pretested the messages using in-depth, one-on-one interviews with 8 members of the target audience prior to disseminating them as part of the study.

We addressed each of the 8 topics below:

Medication adherence. Participants who reported a history of medication nonadherence in the week before the baseline assessment or who began antiretroviral therapy within the past 6 months received daily messages designed to complement their prescribed (Rx) regimens (e.g., “It’s going to be a great day. This is your med reminder.”). For example, patient-customized notifications were used to remind participants to take their medications, consistent with their clinical dosing schedule, which is generally 1–3 times per day. Participants who were therapeutically adherent received weekly adherence messages that encouraged them to continue taking their medications as prescribed (e.g, “He shoots! He scores! Perfect med adherence. Great job!). If at any point during the intervention therapeutically adherent patients reported missing any doses of their medication, adherence reminders were enabled and these participants received adherence reminders for the remainder of the messaging exposure.

Sexual risk reduction. Participants who reported at least one sex partner in the past 3 months received messages designed to reinforce condom use and communication with sex partners about HIV and other sexually transmitted infections (e.g., “Undetectable is respectable, but your partners are still infectable. Play safe.”). Messages regarding sexual risk reduction were sent on Saturday evenings. Sexual risk reduction was reassessed against baseline on intervention days 36 and 64 via SMS. Participants who reported at least one sex partner in the past 3 months triggered the dynamic tailoring function and those individuals began receiving the sexual risk reduction content for the remainder of the messaging exposure.

Substance use risk reduction. Considering substance use behaviors within the past 3 months, participants who reported drinking an alcoholic beverage2or more times per month, having 5or more drinks within a couple of hours at least once in the past month, or using any illicit drugs received messages to reduce use or harm (e.g., “Going out tonight? Be safe. Party smart.”). Messages regarding substance use risk reduction were sent on Friday evenings. Substance use risk reduction was reassessed against baseline on intervention days 36 and 64 via SMS. Participants who reported a history of any high-risk substance use triggered the dynamic tailoring function and those individuals began receiving the substance use risk reduction content for the remainder of the messaging exposure.

Sexual and substance use risk reduction. Because risky sex and substance use often co-occur, we developed a separate set of messages for Saturday evening delivery. Participants who reported any co-occurrence of substance use and sexual activity within the past 3 months received, in addition to the standard risk reduction messages, communications designed to reinforce the risk reduction messages and reduce harm (e.g., “No condoms? No way! Party n play the right way. Protect yourself and your partner.”). Sexual and substance use risk was reassessed against baseline on intervention days 36 and 64 via SMS. Participants who reported a history of substance use before or during sex triggered the dynamic tailoring function and those individuals began receiving the sex and substance use risk reduction content for the remainder of the messaging exposure.

Cigarette smoking. Because smoking cigarettes weakens the immune system, it can be especially harmful to persons with HIV. We included smoking cessation messages for participants who reported smoking (e.g, “There are many ways to quit smoking. Talk to your HBHC provider about the ways that would work best for you.”). Smoking cessation messages were sent every Thursday.

General health and well-being. We anticipated that all study participants would benefit from periodic messages emphasizing the value of a healthy lifestyle (e.g., "Take care of yourself today. Eat healthy foods, don't stress out, get some exercise and sleep well."). These messages were delivered to all participants every Wednesday.

Social support. In addition to general social support messages delivered every Sunday (e.g., "Worried about telling your friends and family your status? We can help you find the right words. Call HB at XXX-XXX-XXXX."), we cataloged available social support resources sponsored by HBHC. These include HIV support groups, substance abuse groups, health and well-being forums, and other meetings and events of interest. On the basis of participants' demographic and preintervention assessment survey responses, we notified participants of relevant support groups, meeting schedules and contact information for joining.

Patient involvement. All participants received messages aimed to empower themselves to be active health care consumers (e.g., "Ask your provider questions. If you don't understand the answer, keep asking until you do."). These messages were delivered to all participants on Mondays.

Appointment reminders. All participants received clinical and behavioral health appointment reminders as part of the intervention. A single appointment reminder was sent to participants at a randomly selected time within a 3 day window prior to scheduled appointments.

Data Sources

We used archives from the SMS system, including participant responses to the messages and questions sent out via SMS, as the data sources for results reported in this paper. We have reported detailed descriptions of the data sources, methodology and results from the process and outcome evaluations elsewhere [13, 14, 15].

A unique feature of our design was the use of bidirectional messaging to support interactions with study participants and to allow us to dynamically tailor content throughout the intervention. We asked questions of all participants throughout their exposure to the intervention, and their responses were used to update the content they received, when appropriate. We administered 3 types of questions via two-way SMS: weekly medication adherence assessment, participant satisfaction items, and sexual and substance use risk reduction reassessment.

Weekly Medication Adherence Assessment

Every Sunday evening, we asked participants if they have missed any antiretroviral therapy doses in the preceding week by sending the SMS message: "Over the past 7 days, on how many days did you miss a dose of medication? Please text us back the number of days you missed a dose (0–7)." We processed responses to determine whether participants had been adherent to their regimen. Every Monday, we sent participants the appropriate feedback responses based on their answers. Specifically, adherent participants received a supportive response to continue, and nonadherent participants received encouragement to comply with their regimen in the week ahead. If at any time during the program a previously adherent participant reported a missed dose, we began sending him daily medication reminders tailored to his dosing schedule for the duration of the intervention.

Interim Participant Satisfaction

We asked all participants 8 questions to assess participant satisfaction with the intervention, including feedback on the frequency of messaging and the relevance of content (see Table 1). In an effort to distribute the response burden, we sent2questions per week throughout Weeks 6–9. To manage incoming messages from participants and differentiate responses to the satisfaction questions from the sexual and substance risk assessment questions, we instructed subjects to provide responses that included number and letter combinations that corresponded to specific questions, as shown in Textbox 1.

Textbox 1. Participant Satisfaction Items (delivery Via 2-Way Sms)

How often do you read the text messages you get from HB?

Text 1A = always, 2A = usually, 3A = sometimes, 4A = never

Do you like the messages you are receiving from HB[a]?

Text 1B = yes, 2B = no

How often are the HB messages sent at the right times?

Text 1C = always, 2C = usually, 3C = sometimes, 4C = never

How do you feel about the number of text messages you get from HB?

Text 1D = too many, 2D = about right, 3D = not enough

Are the message topics you get from HB interesting to you?

Text 1E = very, 2E = somewhat, 3E = a little, 4E = not at all

How often do you use the info in the text messages from HB?

Text 1F= always, 2F = usually, 3F = sometimes, 4F = never

How helpful are the text messages you get from HB?

Text 1G = very, 2G = somewhat, 3G = a little, 4G = not at all

Do you feel like the HB messages were written for you?

Text 1H = yes, 2H = no

Sexual and Substance Use Risk Reduction Reassessment

We reassessed risk-taking behaviors related to sexual activity and substance use for all participants on days 36 and 64 of the intervention (see Textbox 2). "Yes" and "don't remember" responses were analyzed and used to initiate sending risk-reduction messages to those individuals who did not initially qualify for receiving messages in these categories.

Textbox 2. Sexual and Substance Use Reassessment Items (delivery Via 2-Way Sms)

In the past 4 weeks have you had 5 or more drinks of alcohol within a couple of hours (e.g. 2–4 hours)?

Text 1i = yes, 2i = no, 3i = don't remember

In the past 4 weeks have you used recreational drugs (e.g., pot, meth, cocaine or heroin)?

Text yes = 1J, 2J = no, 3J = don't remember

In the past 4 weeks have you had sex without a condom with any of your sex partner(s)?

Text 1K = yes, 2K = no, 3K = don't remember

In the past 4 weeks have you used alcohol or drugs before or during sex?

Text 1L = yes, 2L = no, 3L = don't remember

Analytic Methods

Messages Sent to Participants

To determine message intensity, we classified the timing of the messages on the basis of each participant's week of participation in the study, using the date the first study message was sent to the participant as the start of his study participation. We then computed the mean number of messages participants received during each of the 13 study weeks using the SAS statistical software program.

Messages Received From Participants

For each of the questions administered via SMS, except medication adherence, participants provided a number and letter response (e.g., 1D) to indicate the question to which they were responding and the appropriate response option. Responses to the medication adherence questions consisted of a number from 0 to 7. On the basis of these codes, we classified participants' text responses into the following 5categories, using the SAS software program to search the texting data for appropriate responses (1) responses to participant satisfaction questions (e.g., how helpful texts are), (2) reassessments of medication adherence and sexual and substance use behaviors, (3) acknowledgments from the participant that he received the message (e.g., "OK," "Thanks"), (4) requests to stop receiving messages, and (5) responses that did not fit into any of the other 4 categories. Given the possible differences in texting style (e.g., using zero for O, using abbreviations, leaving out spaces), we reviewed the data manually to ensure that responses were placed into the appropriate categories—for example, to ensure that a response of "2doses" was not inadvertently counted as a "2d" response to a participant satisfaction question. In the event that a participant responded more than once to the same question,

we used his last response. Finally, we computed the percentages of respondents indicating each response option.

Results

Message Delivery Schedule

The complexity of our intervention required us to design a flexible approach to tailoring the messages sent to each participant. To manage each subject's preferences for which messages they were willing to receive, we parsed the core content into 24 message classes for processing and programming purposes (see Table 1).

Table 2 illustrates the message delivery schedule by topic and by day for the 13-week SMS intervention.

Tailoring Process

We enrolled 52 participants over a 4-month period (July-October 2010). We enrolled new participants into the study every Friday throughout the 4-month recruitment phase. At the time of enrollment, we used data from the HBHC-administered screener, the message tailoring form, and the preintervention survey to create a unique text message profile for each subject. Our tailoring logic, including questions and responses that assigned participants into each message class is shown in Table 3. We used a tailoring form to code the critical values from these 3 data sources into an electronic tailoring worksheet and to manually create each participant profile.

Message content, tagged by class and day of intervention, comprised the technical script for this 90-day, automated intervention. The most significant effort in preparing for the implementation was to establish common vocabulary and a series of processes and documentation to support data exchange between RTI and Intelecare.

Both incoming and outgoing data from RTI were formatted based on the output of the tailoring process and converted to an eXtensible Markup Language (XML) "UserList" that includes the items listed in Table 4. The UserList was posted by 10:00 p.m. every Saturday throughout the implementation phase. To facilitate the transfer of the UserList, a File Transfer Protocol (FTP) site that utilized a 256-bit Advanced Encryption Standard connection was used to post the data directly to the SMS gateway. All messages were sent with the preface "<HB>" (short for "Howard Brown Health Center") so participants could identify that the messages were coming from the study.

Table 1. Message class architecture

Class Number	Text Name	Notes	Time to Send
1	Weekly adherence question	Weekly on Sunday. All participants will be set up to receive this when their accounts are created.	17:00
2	“Took all” response to #1	Will come in with Monday data. 1 message for following Tuesday. Message depends on place in cycle.	16:00
3	“Missed” response to #1	Will come in Monday data. 1 message for following Tuesday. Message depends on place in cycle.	16:00
4	Rx daily adherence	Different message each day for 7 days. Repeats weekly throughout program. A single custom message is optional. A custom time can also be defined by the participant.	15:00
5	Rx am adherence	Different message each day for 7 days. Repeats weekly throughout program. A single custom message is optional. A custom time can also be defined.	08:00
6	Rx pm adherence	Different message each day for 7 days. Repeats weekly throughout program. A single custom message is optional. A custom time can also be defined.	21:00
7	Sex risk	Different message every Saturday.	22:00
8	Substance risk	Different message every Friday.	22:00
9	Sex & substance risk	Different message every Saturday.	22:00
10	Smoking	Different message every other Thursday, starting second Thursday.	10:30
11	General health & wellness	Different message every Wednesday. All participants will be set up to receive this when their accounts are created.	10:00
12	General social support	Different message every Sunday. All participants will be set up to receive this when their accounts are created.	14:00
13	Patient involvement	Different message every Monday. All participants will be set up to receive this when their accounts are created.	09:30
14	Process question	Different questions days 38, 40, 45, 47, 52, 54, 59, & 61. All participants will be set up to receive this when their accounts are created.	12:30
15	Substance question	Question at days 36 & 64.	10:30
16	Sex question	Question at days 36 & 64.	11:30
17	Substance & sex question	Question at days 36 & 64.	12:30
18	General social support	Different messages days 9, 10, 11, & 12.	12:30
19	Tailored social support 1	Message delivered day 13.	12:30
20	Tailored social support 2	Different messages days 14 & 15.	12:30

Class Number	Text Name	Notes	Time to Send
21	Tailored social support 3	Message delivered day 16.	12:30
22	Tailored social support 4	Message delivered day 17.	12:30
23	Tailored social support 5	Message delivered day 18.	12:30
24	Tailored social support 6	Message delivered day 19.	12:30

Table 2. Message delivery schedule by topic

Topic	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Medication reminder	X	X	X	X	X	X	X
Appointment reminders	PRN[a]	PRN[a]	PRN[a]	PRN[a]	PRN[a]	PRN[a]	PRN[a]
Rx adherence assessment	X						
Rx adherence response		X					
Patient involvement		X					
Health and wellness				X			
Smoking cessation					X		
Substance risk						X	
Sexual risk							X
Sex & substance risk							X
Risk questions	Days 36 & 64						
Participant satisfaction questions			Weeks 6–9		Weeks 6–9		
Tailored social support		Days 9–19	Days 9–19	Days 9–19	Days 9–19	Days 9–19	

[a]PRN, as needed.

Table 3. Tailoring logic

Message Class	Topic	Question	Response Options	Question	Response Options	Question	Response Options
2	Response: adherent	Many people don't take their HIV medication perfectly all the time. Over the past 7 days, on how many days did you miss a dose of your HIV medication?	0				
3	Response: nonadherent	Many people don't take their HIV medication perfectly all the time. Over the past 7 days, on how many days did you miss a dose of your HIV medication?	1, 2, 3, 4, 5, 6, 7, Don't know, Refused to answer	When did you first start taking medications to treat HIV?	1–3 months ago		
4	Rx adherence daily	Are you currently taking any medications that a doctor has prescribed to treat HIV?	Yes	Many people don't take their HIV medication perfectly all the time. Over the past 7 days, on how many days did you miss a dose of your HIV medication?	1;2; 3; 4; 5; 6; 7; Don't know; Refused to answer	At what time(s) do you take your HIV medication each day?	Lunch time, dinner time, other
5	Rx adherence am	Are you currently taking any medications that a doctor has prescribed to treat HIV?	Yes	Many people don't take their HIV medication perfectly all the time. Over the past 7 days, on how many days did you miss a dose of your HIV medication?	1;2; 3; 4; 5; 6; 7; Don't know; Refused to answer	At what time(s) do you take your HIV medication each day?	Morning
6	Rx adherence pm	Are you currently taking any medications that a doctor has prescribed to treat HIV?	Yes	Many people don't take their HIV medication perfectly all the time. Over the past 7 days, on how many days did you miss a dose of your HIV medication?	1;2; 3; 4; 5; 6; 7; Don't know; Refused to answer	At what time(s) do you take your HIV medication each day?	Bedtime
7	Sex risk	Over the past 3 months, how many people did you have oral, vaginal, or anal sex with?	>1				
8	Substance risk	On average, how often in the past 3 months have you had a drink containing alcohol (e.g., a glass of beer or wine, a mixed drink, or any other kind of alcoholic beverage)?	2 or 3 times a month; Once or twice a week; 3 or 4 times a day; Nearly every day; Daily; Refuse to answer	On average, how often in the past 3 months have you had 5 or more drinks of alcohol within a couple of hours (e.g., 2–4 hours)?	Once a month; 2 or 3 times a month; Once or twice a week; 3 or 4 times a day; Nearly every day; Daily; Refuse to answer	Have you used any of the following within the past 3 months?	Marijuana; Cocaine; Heroin; Methamphetamine; MDMA[a]; GHB[b]; Ketamine
9	Sex & substance	Over the past 3 months, how often did you use alcohol or drugs before or during sex?	Rarely; Sometimes; Most of the time; Every time; Refuse to answer				
10	Smoking	Do you smoke cigarettes?	Yes; Refuse to answer				

Message Class	Topic	Question	Response Options	Question	Response Options	Question	Response Options
15	Substance question	All received					
16	Sex question	All received					
17	Sub/sex question	All received					
4	Custom time (daily)	Would you prefer to customize your own medication adherence reminder?					
5	Custom time (a.m.)	Would you prefer to customize your own medication adherence reminder?					
6	Custom time (p.m.)	Would you prefer to customize your own medication adherence reminder?					
18	General social support	All received					
19	Older adults, 50+	What is your current age?	50 or older				
20	Newly diagnosed	What month and year did you get your first positive test for HIV? If you can't remember the month or year, please give your best guess.	Calculated less than or equal to 6 months of survey date				
21	Long-time positives	What month and year did you get your first positive test for HIV? If you can't remember the month or year, please give your best guess.	Calculated greater than 6 months of survey date				
22	African American MSM	How would you describe your race?	Black or African American				
23	Latino MSM	Are you of Hispanic or Latino origin or descent?	Yes				
24	Young adults	What is your current age?	25-29 years				

[a]MDMA, 3,4-methylenedioxymethamphetamine (Ecstasy); [b]GHB, gamma hydroxybutyrate.

Table 4. UserList file format for enrollment data

Position	Example	Name
0	1234	User ID[a]
1	919-555-1234	Cell number
2	1/0	Inclusion class #2
3	1/0	Inclusion class #3
4	1/0/Custom Message	Inclusion class #4
5	1/0/Custom Message	Inclusion class #5
6	1/0/Custom Message	Inclusion class #6
7	1/0	Inclusion class #7
8	1/0	Inclusion class #8
9	1/0	Inclusion class #9
10	1/0	Inclusion class #10
11	1/0	Inclusion class #15
12	1/0	Inclusion class #16
13	1/0	Inclusion class #17
14	15:00	Custom time for #4
15	08:00	Custom time for #5
16	21:00	Custom time for #6
17	*[b]	Inclusion class #18
18	1/0	Inclusion class #19
19	1/0	Inclusion class #20
20	1/0	Inclusion class #21
21	1/0	Inclusion class #22
22	1/0	Inclusion class #23
23	1/0	Inclusion class #24

[a]ID, identification number.

[b]no variable was used for enrollment, all subjects received messages in this class.

System Testing

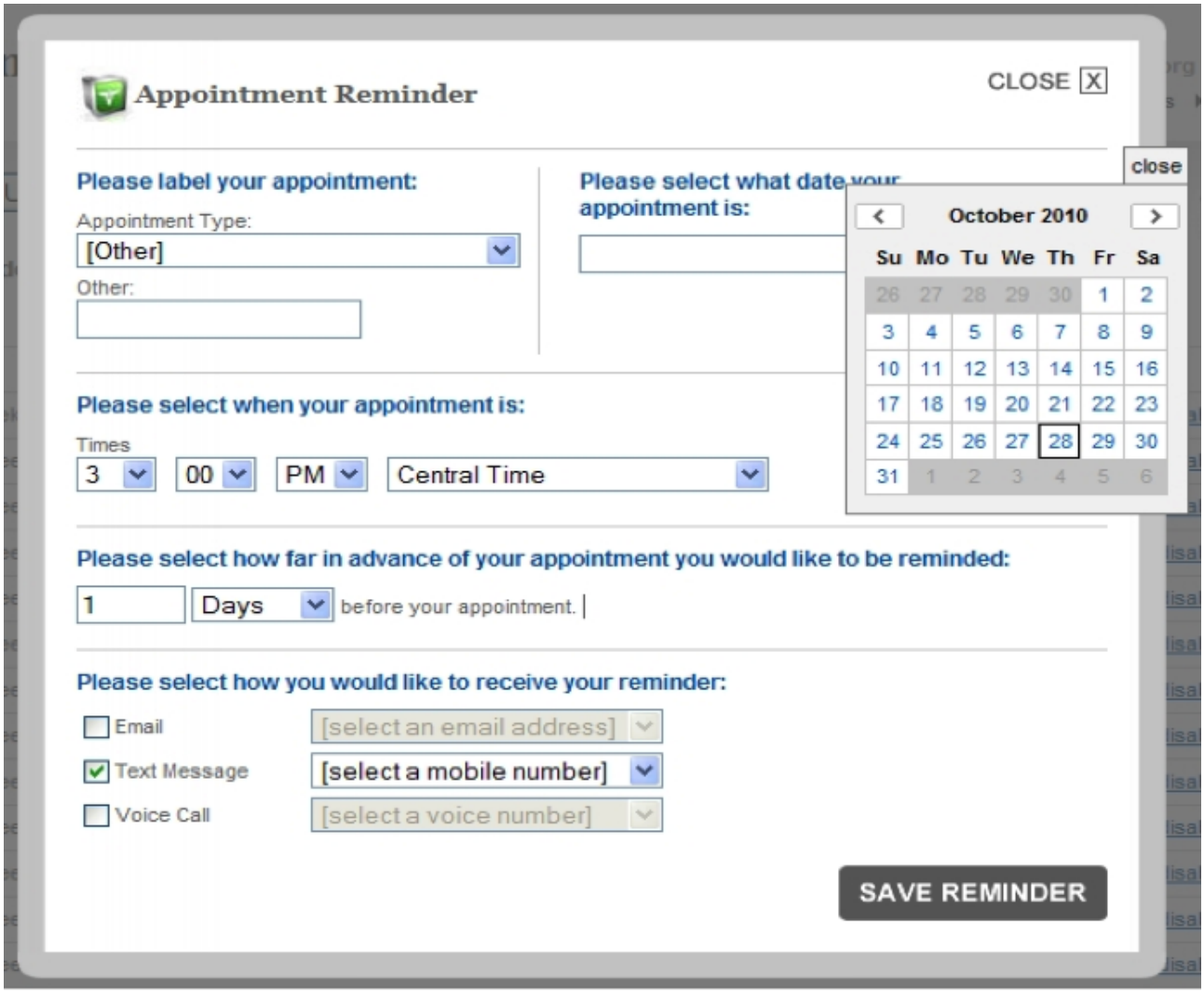
Before initiating system testing, Intelecare tested the code base and individual components of the system, as a term of their contract. After completion of their internal verification and validation process, we began system testing in July 2010 with a validation of each functional unit. First, RTI created test UserLists and transferred them from RTI to Intelecare via FTP. Once the process was deemed acceptable, Intelecare and RTI developers began testing the transmission and receipt of messages on a test schedule. Six members of the project team agreed to receive test messages based on a full implementation of the UserList, file transfer, and activation of new users in the SMS gateway. Messages were transmitted to these users on a compressed schedule over the course of 2 days. A dynamic tailoring process that automatically updated certain messages participants received, on the basis of their responses to a series of two-way SMS messages, was also developed and tested. The final step in the system process was a detailed review of the message content to be delivered by class and by day.

Intervention Monitoring

We held regular status calls every Friday with the HBHC study coordinator to review the week's recruitment strategies and progress, screening data, enrollment data, and any other relevant topics related to implementation. In addition, we held weekly status calls with the lead developer from Intelecare to discuss topics related to system performance.

Between calls, RTI staff had access to the Intelecare reminder manager, as shown in Figure 2. This password-protected, encrypted Web site permitted us to monitor the intervention in real time. The implementation task lead had full access, which enabled him to edit participant telephone numbers, disable message classes at a participant's request, and send appointment reminders as needed.

Figure 2. Intelecare Reminder Manager.



Message Intensity

Because the message content was tailored on baseline survey results, the intensity of messages, such as the average number of messages received by participants each week, varied (see Table 5). The overall distribution of message intensity over the 13-week intervention is shown in Table 5. The variation in message intensity was driven by delivery of tailored social support messages during the first few weeks of the intervention as well as by administration of participant satisfaction and risk assessment questions in Weeks 5–9. On average, participants received 9.44 (SD 9.77) messages per week.

Table 5. Mean number of texts sent to respondents, by week of participation in the study

Week	Mean (SD)
1	10.88 (6.72)
2	12.76 (7.08)
3	8.96 (6.97)
4	7.45 (6.82)
5	7.71 (6.72)
6	7.08 (7.88)
7	6.12 (6.70)
8	5.78 (7.15)
9	5.98 (7.29)
10	4.35 (7.01)
11	3.25 (5.82)
12	2.59 (5.63)
13	1.35 (3.49)

Changes to Technical Implementation Made During the Course of the Intervention

We made a few modifications to implementation that merit discussion. First, the original design did not accommodate personal preferences related to the receiving specific messages. We intended to use the responses to the preintervention survey and bidirectional messages to determine message assignment. However, the RTI IRB made their approval contingent on accommodating an individual's preference to opt out of certain message classes. For example, participants who reported high-risk sexual practices could deselect sexual risk-reduction messages.

Second, to reduce burden on project staff to coordinate configuration of the SMS platform to deliver ad hoc clinical and behavioral health appointment reminders, the study coordinator was given access to the SMS Gateway Manager midway through the implementation period. We developed a process for creating ad hoc reminders and assigned the study coordinator responsibility for these communications for the duration of the intervention. The study coordinator scheduled each participant's 3-month follow-up visits during his enrollment visit. Throughout the intervention, the study coordinator monitored the reminder schedule weekly and updated it as necessary (see Figure 2).

Third, we implemented an automated process for the initial tailoring of new enrollees in September 2010. Before the transition to an automated process, we manually evaluated multiple data inputs for each participant, and determined participants' message class assignments manually, as shown in Table 3. Our implementation and evaluation task leaders worked collaboratively to develop a process by which data from the HBHC-administered screener and the preintervention survey were imported and processed in SAS, then exported into a spreadsheet that emulated the data structure of the UserList XML file shown in Table 6. Despite this automation, some of the nonstandardized data elements captured by the HBHC study coordinator in the message tailoring form, including the customization of medication adherence reminder preferences, still required manual data entry. We tested the data output from the automated process against known tailoring outcomes from previous participants and validated it before fully implementing this process enhancement during the intervention.

Participant Response to Messages and Questions Administered via SMS

During the implementation period of July 18, 2010, to February 21, 2011, we sent a total of 7,194 messages to study participants (see Table 6).

Table 6. Number of texts sent and received

Type of Texts	Number of Texts
Texts sent by RTI	
Successfully sent	6,874
Failed	320
Total sent	7,194
Texts received by RTI	
Patient satisfaction responses	214
Sex and substance responses	101
Medication adherence responses	390
Acknowledgments	317
Other responses	69
Requests to stop receiving messages	3[a]
Total	1,094

[a]All requests to stop receiving messages were sent from a single participant.

Of these, 320 messages, or approximately 4% of messages, failed to reach the intended recipient for unknown reasons. All participants were sent messages over the entire course of the 90-day intervention.

Most messages were developed to be unidirectional and noninteractive. These messages were sent from the SMS system to participants and did not prompt recipients to post a reply or interact with the texts in any way. However, subsets of the messages sent were bidirectional texts, developed to prompt responses from participants to facilitate real-time dynamic tailoring or for data collection across a variety of topic areas. We received 705 SMS responses to our two-way SMS questions of participants during the intervention (e.g., weekly adherence assessment, patient satisfaction, and sex and substance use assessment), as well as 317 unprompted SMS message acknowledgements from participants (e.g., “thanks”). Table 7 shows the two-way process messages sent, timing, frequency, and response rates.

Table 7. Two-way SMS messages sent, timing, and frequency

Message Content	First Response n (%)	Second Response n (%)	Frequency/Schedule
In the past 4 weeks have you had 5 or more drinks of alcohol within a couple of hours (e.g., 2–4 hours)? Text 1 = Yes, 2 = No, 3 = Don't remember			Asked in baseline survey and again via text on intervention day 36.
Yes	4 (8%)		
No	13 (25%)		
Don't remember	1 (2%)		
No response	34 (65%)		
In the past 4 weeks have you had sex without a condom with any of your sex partner(s)? Text 1 = Yes, 2 = No, 3 = Don't remember			Asked in baseline survey and again via text on intervention day 36 and 64.
Yes	7 (13%)	4 (8%)	
No	14 (27%)	6 (12%)	
Don't remember	0 (0%)	0 (0%)	
No response	31 (60%)	42 (80%)	
In the past 4 weeks have you used alcohol or drugs before or during sex? Text 1 = Yes, 2 = No, 3 = Don't remember			Asked in baseline survey and again via text on intervention day 36 and 64.
Yes	6 (12%)	2 (4%)	
No	16 (30%)	12 (23%)	
Don't remember	0 (0%)	0 (0%)	
No response	30 (58%)	38 (73%)	
How often do you read the text messages you get from HB [a] ? Text 1 = Always, 2 = Usually, 3 = Sometimes, 4 = Never			Asked of all participants on intervention day 38.
Always	26 (50%)		
Usually	2 (4%)		
Sometimes	0 (0%)		
Never	0 (0%)		
No response	24 (46%)		
Do you like the messages you are receiving from HB [a] ? Text 1 = Yes, 2 = No			Asked of all participants on intervention day 40.
Yes	16 (30%)		
No	5 (10%)		
No response	31 (60%)		
How often are the messages sent at the right times? Text 1 = Always, 2 = Usually, 3 = Sometimes, 4 = Never			
Always	5 (10%)		
Usually	8 (15%)		
Sometimes	9 (17%)		
Never	3 (6%)		
No response	27 (52%)		
How do you feel about the number of text messages you get from HB [a] ? Text 1 = Too many, 2 = About right, 3 = Not enough			Asked of all participants on intervention day 47.
Too many	7 (13%)		
About right	16 (31%)		
Not enough	3 (6%)		

Message Content	First Response n (%)	Second Response n (%)	Frequency/Schedule
No response	26 (50%)		
Are the message topics you get from HB [a] interesting to you? Text 1 = Very, 2 = Somewhat, 3 = A little, 4 = Not at all			Asked of all participants on intervention day 52.
Very	5 (10%)		
Somewhat	8 (15%)		
A little	9 (17%)		
Not at all	4 (8%)		
No response	26 (50%)		
How often do you use the info in the text messages from HB [a] ? Text 1 = Always, 2 = Usually, 3 = Sometimes, 4 = Never			Asked of all participants on intervention day 54.
Always	3 (6%)		
Usually	2 (4%)		
Sometimes	15 (29%)		
Never	7 (13%)		
No response	25 (48%)		
How helpful are the text messages you get from HBHC [a] ? Text 1 = Very, 2 = Somewhat, 3 = A little, 4 = Not at all			Asked of all participants on intervention day 59.
Very	11 (21%)		
Somewhat	8 (15%)		
A little	6 (12%)		
Not at all	3 (6%)		
No response	24 (46%)		
Do you feel like the HB [a] messages were written for you? Text 1 = Yes, 2 = No			Asked of all participants on intervention day 61.
Yes	15 (29%)		
No	13 (25%)		
No response	24 (46%)		

[a] HBHC, Howard Brown Health Center.

Throughout the intervention, participant responses were used to dynamically tailor messaging for medication adherence and risk reduction.

Forty seven of the 51 participants (92%) taking antiretroviral therapy responded to at least one of the weekly medication adherence questions administered via SMS, and 14 of the 51 participants (27%) had their medication adherence messages changed over the course of the study based on their answers to the weekly medication adherence questions administered via SMS. For example, for those who changed from adherent to nonadherent, their messages changed from weekly messages reinforcing correct adherence to daily reminders to take medications at prescribed times. If participants became adherent, they would receive weekly messages reinforcing correct adherence in addition to their daily reminders.

A total of 22 participants (42%) received sex risk reduction messages, 24 participants (46%) received substance use messages, and 17 participants (33%) received the combined sex and substance risk reduction messages throughout the intervention. As described above, personal preference for messaging was taken into account at baseline for tailoring, permitting individuals to opt-out of receiving any type of message, including sex and substance risk reduction messages. Nearly all participants qualified to receive these risk reduction texts at the beginning of the study, so those who did not receive these texts from the start of the study represent the sample that opted out, rendering them ineligible for the dynamic tailoring function, and limiting our ability to evaluate this aspect of the implementation.

Participant Perceptions of Messages

Almost all (93%) of those participants who responded to a question we administered via SMS indicated that they always read the text messages they receive from the study. About three-quarters of those who responded to a question we asked

via SMS indicated that they liked the messages they received from the study.

Only about 20% of those who responded to the SMS question indicated that the messages were always sent at the right times, 30% said that they were usually sent at the right times, more than 30% said that they were sometimes sent at the right times, and only 12% said that they were never sent at the right times. Most of those who responded (62%) said that the number of messages they got from the study was "about right." About half of those who responded to the SMS question indicated that the message topics they received were either somewhat or very interesting to them. Almost one fifth said that they usually or always used the information they get in the text messages, whereas the majority (56%) said they sometimes used it, and 26% said they never used it. More than two-thirds of those who responded to the SMS question said the text messages they received from the study were either somewhat or very helpful. Participants were divided as to whether they felt the messages they received from the study were written for them.

Discussion

The complexity of the tailored messaging intervention required close monitoring and adaptations to the technical approach throughout the program's life cycle such as automating the tailoring process, investigating message send failures, and developing protocols for changing participants' mobile phone numbers during the exposure phase.

A critical component of the successful implementation of this study was the messaging platform developed by our information technology (IT) vendor, Intelecare. The Intelecare messaging platform is a well-developed, highly reliable system that is currently in use to support multiple, simultaneous text message-based interventions. The maturity of the system and the expertise of the Intelecare programmers benefitted the intervention in their support of our refinement of the messaging intervals and frequency, tests of the system, and monitoring of its status during the exposure phase. Programs considering a similar effort will need to determine whether they have the requisite IT capabilities in house or whether they need to set aside sufficient resources to contract with an outside IT vendor.

Limitations

While we recognize the limitations of this study, many are inherent in conducting and evaluating text message-based interventions. First, we observed a very low response rate to the questions administered via SMS. Of note is that this suggests participants may not be sufficiently engaged; however, this assumption is at odds with statements made by participants in which they indicated a desire for more interactivity [16]. Second, permitting individuals to opt-out of receiving certain kinds of messages even if the baseline assessment indicated that they should have received those messages weakens evaluation of this aspect of the intervention. Third, we believe that prospective evaluations of a larger scale and other text message-based interventions are required to assess the resulting longer-term behavior change.

Lessons Learned

We learned a number of things from the implementation of this intervention, including insights into text programming, message delivery, and study logistics. This knowledge will be invaluable to others embarking on a similar process and to scaling up the current intervention.

Scheduling

The dose-response relationship between texting frequency and behavioral or clinical outcomes is poorly understood [11]. Therefore, we paid particular attention to distributing messages evenly across the days of the week for this intervention. Our assumption was that, for a 3-month intervention, most participants would respond better if the daily messaging burden was limited and participants received as few messages as possible per day throughout the course of the intervention. We also considered which days of the week seemed more appropriate for certain types of messaging. For example, risk reduction messages associated with sexual and substance abuse behaviors were intentionally delivered on weekend evenings, rather than in the middle of the day or week in an effort to provide the message at a more appropriate time, when participants may be more likely to engage in higher-risk behaviors.

Message Tailoring

Although tailoring may have contributed to a high level of participant satisfaction, the process of tailoring for enrollment and dynamic tailoring during the intervention was very time-consuming and complex, and it was prone to occasional error. As such, we recommend developing tailoring protocols that automate as much data analysis and message class assignment as possible to reduce burden on project staff and minimize errant designations at enrollment. In complex longitudinal programs, allowing participants to control which message types they receive throughout the program may be a desirable feature. However, this limits ability to evaluate the effects of the program on desired outcomes.

Texting Logic

For two-way interventions that seek input from participants in response to questions, we recommend that texting systems employ computational logic that reduces the burden associated with human analysis. For example, if a participant is asked a closed-ended question, machine logic is desirable to both recognize the range of appropriate responses (yes, no, Yes, No, YES, NO, Y, N, etc) and provide an appropriate acknowledgment (either to confirm receipt if the participant's response was in the expected range or provide corrective guidance if not).

Message Receipt

Because of privacy concerns associated with the topics of sexual health, substance use, and HIV status associated with this intervention, finding ways to mask the content of the text messages is important so as to not "out" sensitive information about participants, should others see their phones.

In addition, one participant reported having received batches of messages at one time, rather than distributed throughout the

day per the message delivery schedule. Technical staff theorized that this reception behavior likely occurred when the participant's phone was not receiving a strong enough service signal (e.g., he may have been in an office or a basement for an extended period of time) and that the batches of messages arrived once the participant acquired adequate signal strength. Unfortunately, because only one participant reported this problem, technical staff members were unable to reproduce the conditions or identify any record of failed messages in the participant's log file. Because participants cannot fully control the signal strength available to them, we suggest notifying them in advance that they may sometimes receive messages in batches.

Message Fatigue

It will be important to develop ways to counter the potential for message fatigue, such as increasing the flexibility of the messaging system to alternate times and days when certain message classes are delivered. Also, keeping the content fresh by developing a wide array of messages within classes may help to stave off message fatigue. Additionally, it may be helpful to explore ways to further customize the system so that participants can have more choice about the frequency and timing of messages they receive.

For this intervention, we concentrated our effort on staggering the delivery of process questions so participants are not inundated with messages they have to respond to within a short time span.

Mobile Phone Logistics

Despite provisions to ensure wireless local number portability, some participants may switch cell numbers during the course of the study, particularly those using noncontracted, or pay-as-you-go, phones. Establishing a protocol for monitoring and updating participant contact information, documenting intervention interruption, and confirming functionality of new numbers is recommended. More specifically, proactively monitoring the failure to deliver messages to participants to prompt individual follow-up is recommended to limit the impact of intervention interruption.

Emerging evidence suggests that SMS may hold promise as a potential channel for delivering messages to effect short-term health behavior change and may help individuals manage chronic conditions [9, 10], although few studies have provided in depth descriptions on the technological implementation of an SMS-based intervention for chronic disease management and health promotion. In this paper, we provide a detailed description of our implementation so that subsequent programs can use or adapt our methods to implement similar SMS-based interventions, benefitting from our lessons learned and study participants' perspectives on the use of text messaging to support achieving better health outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

HBHC/HB: Howard Brown Health Center
HIV: human immunodeficiency virus
IRB: Institutional Review Board
MSM: men who have sex with men
SMS: short message service

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Original Paper

Telemedicine Consultations: An Alternative Model to Increase Access to Diabetes Specialist Care in Underserved Rural Communities

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Abstract

Background: Diabetes care in rural communities often suffers because of physician shortages. When patients need to see an endocrinologist, long-distance travel to urban centers can constitute a barrier to care.

Objective: To address this problem, we tested whether diabetes telemedicine consultations would be acceptable to rural patients and their primary care providers as an alternative care model.

Methods: Twenty-five patients with diabetes in a rural, medically underserved community received glycemic management recommendations via videoconferencing-based teleconsultation with an endocrinologist at an urban center. At the rural site, a nurse trained in diabetes care assisted with the visits. Outcomes measured were patient and primary care provider satisfaction (measured by structured questionnaires) and glycosylated hemoglobin (HbA1c) levels.

Results: Patients and providers uniformly reported high levels of satisfaction and acceptability. Mean HbA1c decreased from 9.6% to 8.5% ($P < .001$).

Conclusions: Teleconsultations are well accepted by users (patients and primary care physicians) and glycemic control seems to improve in patients with diabetes. This new model of care could potentially expand access to specialist care in isolated rural communities.

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KEYWORDS

Rural; teleconsultation; telemedicine; diabetes

Introduction

Rural communities in the United States suffer from a disproportionate burden of diabetes and lower quality of diabetes care than metropolitan areas [1-3]. In medically underserved rural communities, primary care providers who care for challenging cases of poorly controlled diabetes may encounter difficulties in supporting optimal diabetes care and, thus, meeting quality of care standards. Shortages of endocrinologists can complicate this problem [4]. Patients in isolated rural areas often need to travel long distances to establish care with an endocrinologist, often located in urban areas. The travel time and expense associated with transportation can be major barriers to medical care. Therefore, in order to improve the quality of

diabetes care in rural, medically underserved communities, newer models of care should take into account the problem of physical separation between specialist provider and patient.

The emerging field of telemedicine has great potential to mitigate this problem by obviating geographical barriers to care. Advances in videoconferencing now make it possible to extend diabetes expertise to rural communities, thus helping patients and primary care providers. However, diabetes mellitus has its own complexities of care requiring comprehensive patient education, especially in regards to starting and adjusting insulin therapy, education on glucose monitoring, and self-management skills. Implementation of these types of recommendations is pragmatically more difficult via videoconferencing when compared to implementation in-person at the office. Therefore, we developed a new model of care that includes teleconsultations provided by a remotely located endocrinologist combined with diabetes self-management education provided locally at the rural site by a nurse trained in diabetes care. This is a new model and acceptability has not been demonstrated yet. To our knowledge, previous studies of telemedicine have not specifically combined diabetes advice by an endocrinologist with diabetes education provided locally at the rural office. Furthermore, the acceptability of this model must be specifically demonstrated in rural communities, which have their own particular demographics and barriers to care. Likewise, acceptability by primary care providers in rural areas must be demonstrated to better understand implications for future referrals. Acceptability studies are needed before resources are committed to large-scale programs or expanding telecommunications infrastructure. To address these gaps, we conducted a study in an isolated rural community to demonstrate the acceptability of a novel diabetes teleconsultation model to optimize glycemia.

Methods

Recruitment

Protocols were approved by the University of Pittsburgh Institutional Review Board. Research participants gave written informed consent. Patients were recruited between July and October 2009. Patients (n = 25) and primary care providers (n = 7) were in a rural, medically underserved community in Pennsylvania located approximately 95 miles from the nearest endocrinology referral center. Seven primary care providers were contacted and agreed to participate, receiving no participation incentives or compensation to avoid bias. Primary care providers were notified of the study and invited to refer patients with diabetes in whom previous attempts to improve glycemic control had failed under their care. Primary care providers referred the patient participants to the study team nurse who scheduled a subsequent appointment for teleconsultation.

Procedures and Analysis

Each participant had a one-time teleconsultation (45 minutes) aimed at troubleshooting hyperglycemia. The teleconsultation videoconferencing equipment used was the Polycom HDX 4002 system (20-inch high-definition widescreen operating at 720 lines/progressive scan) located in an endocrinology office in urban Pittsburgh, Pennsylvania (hub), and in a rural clinic office (rural site). These sites were connected via a dedicated broadband Internet connection. Embedded Advanced Encryption Standard (AES) Federal Information Processing Standard (FIPS) 197, H.235v3 and H.233/234 encryption was used to protect the confidentially of the data transmission.

An endocrinologist (hub) and diabetes nurse (rural site) operated the videoconferencing equipment. The trained diabetes nurse worked as a liaison during the visit, ensuring coordination of care between sites. Teleconsultations included a medical interview and laboratory data review, followed by treatment recommendations carried out with the assistance of the nurse. Recommendations regarding the management plan (medication adjustments, lifestyle modification, self-monitoring, and laboratory tests) were forwarded to the primary care providers by letter. Glycosylated hemoglobin (HbA1c) measurements were obtained from chart review. Patient and provider program satisfaction were measured using researcher-designed satisfaction questionnaires adapted from validated satisfaction surveys in the literature [5,6]. Answers were graded on a Likert scale.

Results

Recruitment

Mean patient age was 56 years (range 35-80). Most (24/25, 96%) had Type 2 diabetes. Mean disease duration was 16 years (range 1 month to 41years). All patients (25/25, 100%) were white or Caucasian and 56% (14/25) were women. Although more than half of patients (14/25, 56%) had previously received a recommendation to consult with an endocrinologist, only 24% (6/25) had followed up on that recommendation, reflecting local underutilization of specialists. The distance between hub and rural sites was approximately 95 miles by car travel, but only 40% (10/25) of respondents were willing to travel that distance, demonstrating that travel was a barrier to care in the targeted population.

Outcomes

Patient satisfaction responses reflected uniform enthusiasm on several dimensions tested (Table 1). There were no instances of equipment or data transmission malfunction during a total of 18.8 hours of videoconferencing. Primary care provider satisfaction also was notably positive. Answers about coordination of care and the clinical value of consults were generally consistent when questions were asked in different ways.

Table 1. Patient and provider satisfaction with diabetes teleconsultations.

Questions		Responses
Access to care, n (%)		
Have you ever been told that you should see an endocrinologist (diabetes specialist)?		
	Yes	14 (56%)
	No	11 (44%)
Have you ever had a visit with an endocrinologist?		
	Yes	6 (24%)
	No	19 (76%)
If your doctor asked you to see an endocrinologist, how far would you be willing to travel to see the specialist?		
	Unable to travel	1 (4%)
	1-10 miles	7 (28%)
	10-50 miles	7 (28%)
	"Distance does not matter to me"	10 (40%)
Patient satisfaction, median (interquartile range) [a]		
How satisfied were you with your endocrinologist visit through videoconferencing, for example, were you able to communicate well and ask questions during this visit?		6 (6-6)
How satisfied were you with the videoconference method for a visit with the endocrinologist?		6 (4-6)
How satisfied were you with the technology of videoconferencing, for example, was the sound and picture clear?		6 (6-6)
Would you recommend this form of treatment to someone else with diabetes?		6 (6-6)
Would you recommend this form of treatment for other specialty care services?		6 (6-6)
Primary care provider satisfaction, median (interquartile range) [a]		
How would you rate your overall satisfaction with the diabetes telemedicine program?		5 (4-6)
I value the information from the study endocrinologist		5 (5-6)
This telemedicine service affords increased access to patient referrals to specialty areas		5 (5-6)
My patients with diabetes appreciate that I can also offer specialty services		5 (3-6)
The endocrinologist and I were able to effectively communicate a treatment plan together		5 (4-6)
I received timely information from the endocrinologist		6 (4-6)
Communication was passed between specialist and my office efficiently		6 (3-6)
I was able to know my patients' needs in the context of their diabetes		5 (4-6)
I was assured that I would provide continuity of care to my patients with diabetes		6 (5-6)
Our roles in the management of the patient were clear to me		5 (4-6)
How likely would you be to use this program again?		5 (4-6)
Would you recommend this form of program to other colleagues?		5 (4-6)
Would you recommend this form of treatment for other specialty care services?		5 (4-6)

[a] Likert score (range 0-6): 0 = very dissatisfied/do not recommend/highly disagree; 3 = neutral; and 6 = very satisfied/definitely recommend/highly agree.

Measurements of HbA1c after the teleconsultations (median 18 weeks) were available for 16 participants. In the other 9 participants, follow-up measurements were not available before the study was closed. At baseline, no participant (0/16) had an HbA1c < 7.0%, and 88% (14/16) had HbA1c ≥ 8.0% reflecting very poor glycemic control. After the teleconsultations, the proportion of patients with HbA1c ≥ 8.0% substantially decreased from 88% to 50% (P = .03, McNemar test). Mean HbA1c improved from 9.6 ± 0.4% to 8.5 ± 0.4% (P < .001, paired t test). Three-quarters of patients (75%, 12/16) experienced an absolute decrease in HbA1c of at least 0.5% from baseline.

Discussion

Main Findings

There is a disparity in diabetes care between rural and urban areas in the United States [1-3]. Although this disparity has several causes, access to physician care is an important contributor. Limited access to specialists is especially problematic [4]. Teleconsultations offer the potential to enhance the availability of diabetologist services to these communities. However, evidence that teleconsultations are well received by patients and providers in rural communities has not been demonstrated for diabetes management, which has its own complexities of care. Acceptability of this technology and care model is critical in the increasingly patient-centered environment where satisfaction and accountability take on greater importance.

Our findings demonstrate that videoconferencing-based teleconsultations specifically tailored to diabetes care are well received by both patients and primary care providers in a rural community. The direct implication of this finding is that broader adoption of this model is unlikely to be constrained by rejection of videoconferencing technology in the medical office, or primary care provider's dissatisfaction with coordinated care delivered remotely. However, since this study targeted an underserved community, it is possible that responses were influenced by the fact that teleconsultations delivered previously unavailable care. Although such potential bias cannot be ruled out, it does not detract from the value of teleconsultations as an acceptable means of delivering care to rural communities.

How generalizable are the results to other rural communities? In our sample, age and gender was representative of typical patients with Type 2 diabetes in rural communities. Reluctance and/or inability to travel was highly prevalent, supporting generalization to other rural communities. However, race was homogenous and representative of only certain US rural populations. The number of rural primary care providers in the study was modest, but not surprising since the study targeted a rural community with physician shortages; therefore, this number is typical and reflective of such shortages. In terms of referral patterns, it is possible that primary care providers might have unconsciously referred those patients who were more open-minded about teleconsultations. Nevertheless, providers make decisions about referrals based on the likelihood patients will follow their referral recommendations; therefore, our study replicates real-world clinical referral patterns.

Although this study focused primarily on satisfaction, as an exploratory analysis we thought it would be worthwhile to examine whether teleconsultations had an influence on HbA1c levels. It is difficult to answer this question with absolute certainty because there was no control group. Despite this limitation, the improvements in HbA1c in the limited dataset were quite substantial and agree with the hypothesis that teleconsultations can deliver clinically meaningful results. One limitation in our findings is that follow-up HbA1c was not available for all participants before study closure. However, the missing data should not be construed as a sign of lack of satisfaction, since suboptimal adherence to frequent testing is also affected by barriers to care. Patients in rural communities often face a number of challenges in this regard. In fact, during teleconsultation visits, participants reported economic and transportation challenges to adhere to frequent testing and medical appointments.

Comparison With Other Work

Despite the increasing attention on diabetes in our current health care environment, to our knowledge the only study examining specialist diabetes care delivered through video teleconsultation is the Informatics for Diabetes and Education Telemedicine (IDEATel) study [7]. The overall high satisfaction observed in our study is consistent with the IDEATel study, which examined a related, but different, model of telemedicine services offered by nurse case managers to patients with diabetes in urban and upstate New York. Differences between the type of telemedicine services in IDEATel and those in our study make direct comparisons inappropriate. Nonetheless, our findings complement the IDEATel study in supporting the notion that telemedicine technologies are well accepted in the context of diabetes care. Regrettably, at the time of our study, a validated questionnaire specific to diabetes telemedicine was unavailable and our sample size limited our ability to perform sound reliability testing on our survey. However, subsequent to our study, a diabetes telemedicine survey has been validated and our questions are consistent with that survey [7].

Conclusions and Future Directions

In summary, we have demonstrated that a new model combining teleconsultations by an endocrinologist and local diabetes education supported by a nurse offer a potential solution to address the needs of diabetes care expertise often lacking in rural communities. Patients and primary care providers express a high degree of satisfaction, implying that adoption of the model is unlikely to be hampered by rejection of technology in the medical office or the approach by which services are provided. However, widespread adoption of this model will require demonstration of an unequivocal impact on glycemic control and barriers to funding will need to be addressed. There is a cost to implement the telecommunication infrastructure. However, with the shortage of endocrinologists in the United States [8], the costs may be lower than those needed to attract recruitment of endocrinologists to rural communities. Ultimately, the success of teleconsultations will depend on adequate compensation systems that would motivate physicians to provide teleconsultation services. Since this study began, some states and insurers have recognized the value of telemedicine and are beginning to reimburse for teleconsultations. For instance, the Pennsylvania Medical Assistance program revisited and expanded payment to include all physician specialists. They also revised the type of telecommunications technology that can be used to provide telemedicine consultation, specifically videoconferencing. Hopefully, compensation mechanisms like these will be further developed and spark broader implementation of teleconsultations as an alternative means of delivering diabetes specialty care to underserved communities.

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Authors' Contributions

FGT and LMS designed the study, researched data, and wrote the manuscript. KR provided statistical support and reviewed/edited the manuscript. AT contributed to discussion, reviewed, and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AES: Advanced Encryption Standard
FIPS: Federal Information Processing Standard
HbA1c: glycosylated hemoglobin
IDEATel: Informatics for Diabetes and Education Telemedicine

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Original Paper

Computer-Assisted School-Based Asthma Management: A Pilot Study

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Abstract

Background: The high prevalence of asthma among children continues to be a major public health issue. In particular, low-income African-American and Hispanic children often receive asthma care in the emergency department and lack access to continuity of care.

Objective: The aim of the current study was to test the feasibility of implementing a computerized program for empowering low-income children with asthma to manage their own disease. This pilot program consisted of a guided, personalized, Web-based computer program as the main component of a school-based asthma intervention.

Methods: The Automated Live E-Health Response Tracking System (ALERTS), a computer-assisted, Web-based tracking program, was tested for implementation in a school in East Harlem, New York. The program required children with asthma, assisted by trained researchers, to routinely measure their peak flow meter readings and answer a symptom questionnaire. The program provided individualized feedback on their disease status based on peak flow meter input. The computer program sent reports to the child's physician and the nurse practitioner at the on-site school health center. The children were also encouraged to bring the reports home to their parents. A pre/post study design was employed such that each participant acted as his/her own control. Comparisons of preintervention and postintervention outcomes were calculated using the paired *t*-test and the McNemar test for dichotomous data.

Results: Twenty-four children (6 to 12 years) participated in the program over 2 to 15 months. Improvements in health outcomes showed the greatest significance among the group of participants who were enrolled for 8 months or longer. Statistically significant improvements were seen in the average physical health score of the children (from 65.64 preintervention to 76.28 postintervention, $P = .045$). There was a significant decrease in the number of participants experiencing wheezing episodes (n = 9 to n = 2, $P = .03$), and in the average number of wheezing episodes per child (1.86 to 0.43, $P = .02$). Although not statistically significant, decreases were also seen in the number of children experiencing an asthma attack and in the average number of asthma attacks among participants. There was also a significant decrease in the average number of visits to doctors' offices or clinics (1.23 to 0.38, $P = .04$). There were no overnight hospitalizations in the two-week period following the end of the pilot program, a nonsignificant reduction from an average of 0.21 per child.

Conclusion: This individualized, computer-assisted intervention resulted in improvements in some health outcomes among low-income children in an urban, public school-based setting. Consistent peak flow meter self-measurements, management of medication usage, and a computerized approach to symptom tracking resulted in fewer asthma exacerbations and improved overall physical health among this pediatric population with asthma.

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KEYWORDS

Asthma; disease management; Internet; child; underserved; Asthma Action Plan; outcomes; urban; low-income

Introduction

The high prevalence of asthma among children continues to be a major public health issue in the United States and it has both social and economic impacts [1-4]. East Harlem is a low-income, predominantly African-American and Hispanic community in New York City with one of the highest rates of asthma hospitalizations in the United States, measured at 27.6% in 2006 [5-7]. Previous research has shown that people living in low-income urban settings, such as those living in East Harlem, often receive asthma care in the emergency department, have the highest rates of hospital admission, lack access to follow-up medical care, do not receive education about their disease, and lack information to improve their self-management skills [7-13].

Researchers have determined that in order to improve health outcomes it is key to ensure that patients are educated about self-management of asthma and asthma attacks [14]. One potential pathway to reducing the burden of asthma in children is through the use of school-based programs. Children spend the majority of their day at school and are accustomed to receiving health education in this setting. Although Oruwariye et al [15] determined that school-based health centers often provided inadequate asthma care, other studies have concluded that health centers within elementary schools can produce a reduction in the rate of hospitalization and a slight decrease in absenteeism in children with asthma [16]. Moreover, school-based asthma programs have been shown to be effective regardless of whether they have a school-based health center [17-23]. Nonetheless, targeted interventions implemented in conjunction with school-based health centers could take advantage of existing health-based infrastructures while providing a personalized level of asthma education and care that could help increase children's self-management skills. A meta-analysis examining 32 educational interventions for self-management of asthma in children concluded that programs that promote self-management in the medical care of children with asthma may greatly improve their health outcomes. The analysis also showed that programs that incorporated peak flow measurements as a main component of the intervention and programs that were individually tailored to the patient (vs addressed to groups) showed the greatest success in reducing disease morbidity [24].

Some interventions in urban communities, such as East Harlem, have been implemented in conjunction with school-based health clinics. Results have been mixed, sometimes even within the same study, with some studies showing improvement in health outcomes, morbidity, and health care utilization (eg, fewer hospitalizations, emergency department visits, and follow-up visits for asthma) [25-29]. Some of the same studies have also shown positive changes in levels of asthma knowledge, self-management skills, and use of peak flow meters and inhalers, but little to no improvement in clinical outcomes [26,28,29].

The use of computers as a method to improve asthma self-management skills is a relatively new technique. It has proven successful in other studies helping children adhere to prescribed medication plans and in reducing the number of asthma exacerbations they experience, although not all of these interventions were school-based [28,30-35]. Computer-assisted asthma management programs have the potential to provide children with individualized, evidence-based feedback on their disease, including measurements of symptom severity and frequency, and can provide actual data on medication usage rather than leaving children and parents to rely on perceived or recalled medication usage information [30, 36]. We implemented a computer-assisted, Web-based, tracking pilot program that required children with asthma to routinely provide their peak flow meter readings. The program provided individualized, tailored feedback on their disease status based on this input.

Aim

The aim of the current study was to test the feasibility of implementing a computerized program for empowering children with asthma living in a low-income, urban setting to manage their own disease. This pilot study used a guided, personalized, Web-based computer program as the main component of a school-based asthma intervention.

Methods

Participants

The computer-assisted asthma management pilot program was implemented in a public elementary school in East Harlem, New York. At the time the program began, the school had enrollment of 588 students (49.1% Hispanic and 46.6% African American) in prekindergarten through grade 6. More than 95% of students qualified for the free lunch program, a surrogate measure of low socioeconomic status [37]. The school houses a health center that operates during the day, evening, and on weekends for 12 months per year to provide comprehensive community health services, including routine preventive care, chronic disease management, and treatment for minor illnesses.

Enrollment Process

The study was reviewed and approved by the Mount Sinai School of Medicine Institutional Review Board, the Mount Sinai Health Insurance Portability and Accountability Act (HIPAA) Privacy Officer, and the New York City Department of Education's Institutional Review Board. Prior to implementing the intervention, a needs assessment was conducted in the school to quantify the magnitude of the asthma problem and to identify possible gaps in asthma management plans. A questionnaire that contained standardized items on demographics, indoor environmental factors, asthma diagnosis and symptoms, and the use and access to medical care and medications for asthma was developed and distributed. The questionnaire also included items on whether children had an asthma management plan and

what details were included in that plan. Questionnaires were provided in English and Spanish. Children were instructed on the importance of their participation and were asked to bring the questionnaires home to be completed by their parents or guardians. Teachers were also encouraged to maximize class response rates; classrooms with over 80% response rates were given gift certificates for school supplies.

The needs assessment had an overall response rate of 68% and identified 101 students within the school who had active asthma (defined as a physician's diagnosis of asthma and asthma symptoms in the previous 12 months). Among these children with active asthma, over 19% did not have an asthma management plan. Most (69.3%) of the parents of children with active asthma had not been given information on when to call the doctor to assist with their child's asthma. Most of the children with asthma (59.4%) had been treated at an emergency department for their asthma in the previous 12 months. Parents of children with asthma were contacted via telephone and invited to meet with the study coordinators in a face-to-face meeting at the school to discuss their child's potential participation in the study. If a parent voluntarily agreed to the child's participation, informed consent was obtained at this time, in either English or Spanish. A total of 24 children with asthma were enrolled in the pilot study.

Once students were enrolled in the program, their asthma control was classified according to the National Heart, Lung, and Blood Institute (NHLBI) guidelines using the patient/parent responses to a baseline questionnaire. The control level of the child's asthma determined how often the child would access the program each week. Students with "mild intermittent" or "mild persistent" asthma accessed the program once per week, whereas those classified as having "moderate persistent" asthma used the program three times per week. Participants with "severe" asthma were required to use the program daily. A pre/post study design was employed, such that each participant acted as his/her own control.

Symptom Questionnaire

After inputting peak flow meter readings into the computer program, students were prompted to answer a symptom questionnaire in addition to questions about medication usage and physician and emergency department visits that occurred since their previous input. The symptom assessment questionnaire included questions regarding the frequency of symptoms (ie, shortness of breath, cough, wheezing, tightness in the chest, difficulty sleeping, and limitations to physical activity). The children were also asked to complete weekly event questionnaires that included questions about the presence or absence of a persistent cold, frequency of use of a fast-acting (rescue) inhaler, use of inhaled and oral steroids, days of school missed, and visits to the physician, emergency department, or hospital. Medication use was assessed by showing pictures of various asthma medications and prompting children to point to the one they used.

Outcomes Assessment and Data Analysis

To evaluate the effectiveness of the intervention, parents of the student participants were asked to complete the Children's Health Survey for Asthma (CHSA) at two different time points: (1) before the program began, and (2) up to 3 weeks after their child's final day of participation in the program [38]. The program was implemented over the course of 2 school years, constituting 2 phases of enrollment. Parents were asked to complete a CHSA either at the end of each school year or at the end of their child's enrollment in the program, whichever came first. Parents were given a US $20 incentive for completing the questionnaire. Children did not complete the CHSA.

The CHSA, developed and validated by the American Academy of Pediatrics, is a validated assessment questionnaire that contains questions about asthma symptoms, health care utilization, quality of life, physical activity, and family support; it has been used in numerous studies of pediatric asthma [38-40]. Numeric answers to questions in a Likert-scale format are compiled to create composite scales, ranging from 0-100, with higher scores indicating better outcomes. The five scales that can be computed from the questionnaire measure the physical health of the child, the activity level of the child, the activity level of the child's family, the emotional health of the child, and the emotional health of the child's family. The core items used to compute the physical health score are questions about symptoms due to asthma, such as tightness in the chest and wheezing, and symptoms due to use of asthma medicines, such as rapid heart rate and irritability. The core items used to compute the activity level scores are questions about how limited children were from participating in various activities, such as gym class and playing or running outside. Respondents were asked to answer questions about their children's health based on symptoms, health care utilization, and other outcomes that occurred during the 2 weeks prior to the day that respondents completed the questionnaire.

Outcomes data were analyzed using SPSS version 12 (SPSS Inc, Chicago, IL, USA). Comparisons of preintervention and postintervention outcomes were calculated using the paired *t*-test and the McNemar test for dichotomous data.

Intervention

The Automated Live E-Health Response Tracking System (ALERTS) was developed as a computer-assisted, Web-based, symptom-tracking program that allows patients with chronic disease to monitor their symptoms while reinforcing key educational lessons. Although the program was available through both a toll-free phone number and the Internet, children accessed the program only via the Internet in this study. The web-based display showed a pediatric or adult patient interface, depending on the user's profile (age ≤ 18 years displayed a pediatric interface). Researchers trained each student individually on how to use the computer program. First, the researchers demonstrated the correct way to use a peak flow meter and then coached the children on their own technique. Once the children had learned the proper technique for peak flow measurement, the researchers instructed them on the use of the computer program. Users were issued a unique personal identification number (PIN) for confidentiality and used this PIN to log in to each session. A room within the school was designated to house the computers where children accessed the program and children were coached to use the program during

their lunchtime. The computer program interface is shown in Figure 1.

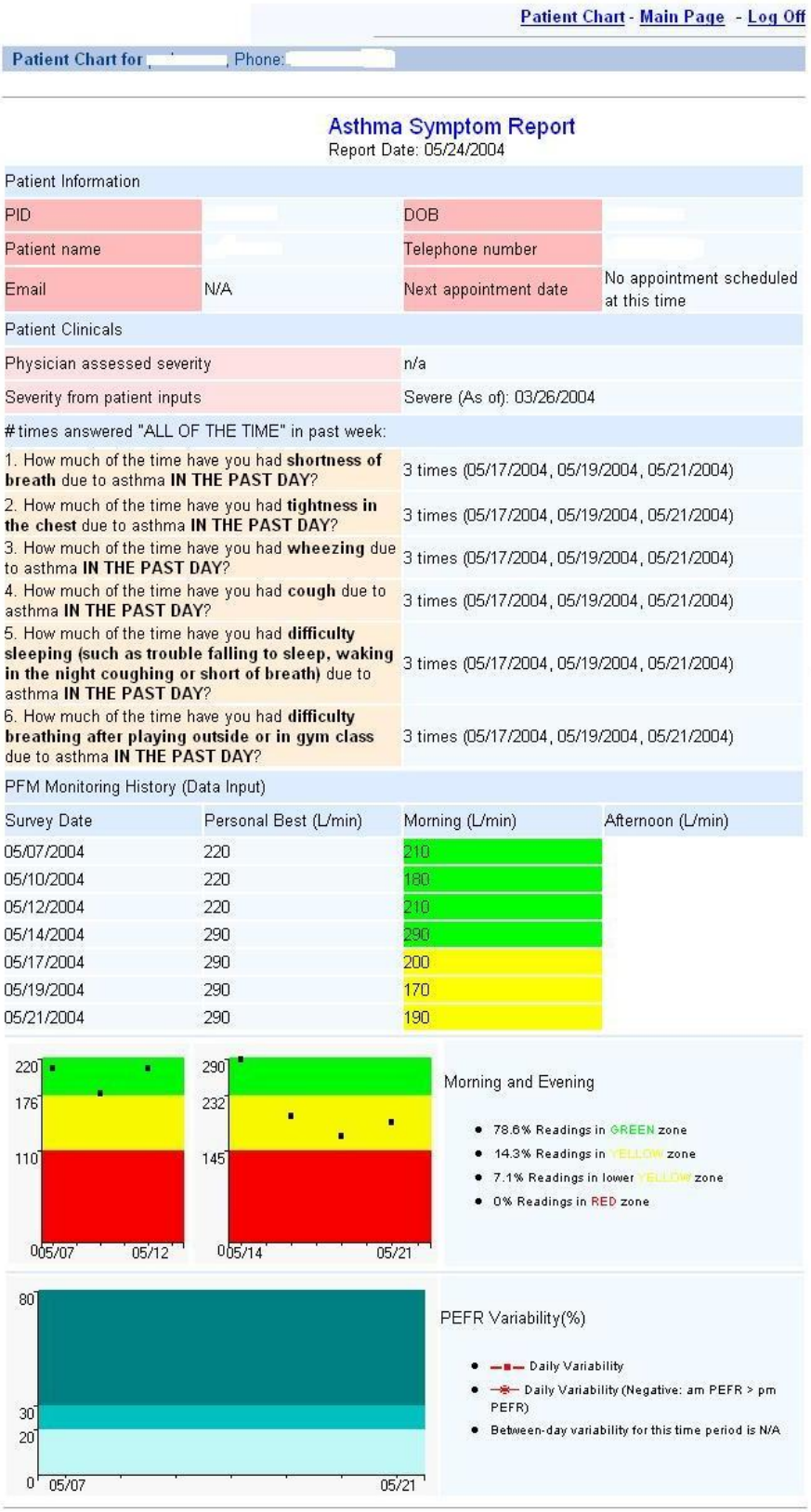
In their first session, the researchers showed the children how to enter their unique PIN and password into the interface in order to access the program and then they supervised the children as they repeated the process. Once the program interface was loaded, children were encouraged to read the screens aloud and ask the researchers any questions as they completed the program tasks and answered symptom questions. In each subsequent session, students independently logged in to their saved information settings using their individual PINs, and then inputted their current peak flow meter readings under the supervision of research staff. Children were escorted from the cafeteria to measure their peak flow meter readings during their lunch periods. To maintain consistency in the readings, the program provided an input box to be checked to indicate whether the peak flow meter reading was taken in the morning (before noon) or afternoon.

Based on the daily peak flow meter input, the program provided evidence-based feedback regarding each child's symptom zone. Specifically, when peak flow meter readings were within 80% of the child's personal best peak flow meter reading, the program let the child know they were in the "green zone;" if within 50%-80% of the child's best, they were in the "yellow zone;" and when below 50%, they were in the "red zone." The program then instructed children on how to adjust their medication use or modify activities according to their prescribed Asthma Action Plans. If a child's peak flow meter reading was not in the green zone, a report was automatically generated and brought by the child to the school health center and to research staff in the nurse's office. If a child's peak flow meter reading was in the red zone, a member of the research team escorted the child to the school health center. Children were given small toys, pencils, stickers, and other school supplies as incentives for their participation in the program.

The system was designed to send reports to the child's physician and the nurse practitioner in the on-site school-based health center. The provider received two types of reports based on questionnaires the children completed: (1) the Asthma Intervention Report (AIR) Symptom Report (Figure 2), which tabulated patients' self-reported peak flow meter readings and affiliated symptom reporting, and (2) the AIR Event Report (not shown), which tracked weekly events related to asthma, such as urgent visits to physicians or clinics and hospitalizations. Children were given real-time, evidenced-based feedback regarding their symptom zone and what to do according to their prescribed Asthma Action Plan. Program staff showed the children their peak flow meter history and symptom reports periodically and the children were encouraged to review how their peak flow meter readings had changed over time. Children were asked to identify if their readings had been increasing, decreasing, or staying the same. At the end of the program, paper copies of the peak flow meter history and symptom history were given to the parents of all participating children to share with their child's health care provider.

Figure 1. Pediatric interface of Health-e-Pal ALERTS program.

Figure 2. Asthma Intervention Report (AIR) Symptom Report.



Patient Chart - Main Page - Log Off

Patient Chart for , Phone:

Asthma Symptom Report

Report Date: 05/24/2004

Patient Information			
PID		DOB	
Patient name		Telephone number	
Email	N/A	Next appointment date	No appointment scheduled at this time

Patient Clinicals	
Physician assessed severity	n/a
Severity from patient inputs	Severe (As of): 03/26/2004
# times answered "ALL OF THE TIME" in past week:	
1. How much of the time have you had **shortness of breath** due to asthma **IN THE PAST DAY**?	3 times (05/17/2004, 05/19/2004, 05/21/2004)
2. How much of the time have you had **tightness in the chest** due to asthma **IN THE PAST DAY**?	3 times (05/17/2004, 05/19/2004, 05/21/2004)
3. How much of the time have you had **wheezing** due to asthma **IN THE PAST DAY**?	3 times (05/17/2004, 05/19/2004, 05/21/2004)
4. How much of the time have you had **cough** due to asthma **IN THE PAST DAY**?	3 times (05/17/2004, 05/19/2004, 05/21/2004)
5. How much of the time have you had **difficulty sleeping (such as trouble falling to sleep, waking in the night coughing or short of breath)** due to asthma **IN THE PAST DAY**?	3 times (05/17/2004, 05/19/2004, 05/21/2004)
6. How much of the time have you had **difficulty breathing after playing outside or in gym class** due to asthma **IN THE PAST DAY**?	3 times (05/17/2004, 05/19/2004, 05/21/2004)

PFM Monitoring History (Data Input)

Survey Date	Personal Best (L/min)	Morning (L/min)	Afternoon (L/min)
05/07/2004	220	210	
05/10/2004	220	180	
05/12/2004	220	210	
05/14/2004	290	290	
05/17/2004	290	200	
05/19/2004	290	170	
05/21/2004	290	190	

Results

Results of Needs Assessment and Population Demographics

Of the 588 students enrolled in the school, 389 returned the asthma prevalence questionnaires, a response rate of 66.2%. Half (50.9%, 198/389) of respondents identified themselves as Hispanic, 36.0% (140/389) as black or African American, 1.5% (6/389) as white, 0.7% (3/389) as Asian, 3.9% (15/389) as "other," and 6.9% (27/389) did not give an answer. The average age of students surveyed was 8.2 years. Of all responding students, 57.6% (224/389) were living in a household with a yearly gross income of less than US $20,000. A total of 38.0% (148/389) of all students had been diagnosed with asthma at some point in their lives and 26.0% (101/389) had current asthma (defined as a diagnosis with symptoms within the previous 12 months) and were identified as "current patients with asthma" (Table 1).

Table 1. Characteristics of students who completed the needs assessment questionnaires.

Characteristics		Respondents, n (%)	
		All students n = 389	Children with active asthma n= 101
Sex			
	Male	186 (47.8%)	59 (58.4%)
	Female	190 (48.8%)	38 (37.6%)
	No answer given	13 (3.3%)	4 (4.0%)
Race			
	Hispanic	198 (50.9%)	52 (51.5%)
	Black or African American	140 (36.0%)	41 (40.6%)
	White	6 (1.5%)	0 (0.0%)
	Asian	3 (0.7%)	0 (0.0%)
	Other	15 (3.9%)	4 (4.0%)
	No answer given	27 (6.9%)	4 (4.0%)
Household gross income (US $)			
	Less than $20,000	224 (57.6%)	67 (66.3%)
	$20,001-$39,999	95 (24.4%)	19 (18.8%)
	$40,000-$74,999	23 (5.9%)	5 (5.0%)
	Over $75,000	3 (0.8%)	0 (0.0%)
	No answer given	44 (11.3%)	10 (9.9%)
Students ever diagnosed with asthma		148 (38.0%)	--
Students diagnosed with current asthma		101 (26.0%)	--
Emergency department visits due to asthma in previous 12 months		N/A	60 (59.4%)
Hospitalizations due to asthma in previous 12 months		N/A	16 (15.8%)
Have a peak flow meter		N/A	36 (35.6%)
Use a peak flow meter daily		N/A	31 (30.7%)
Have a spacer		N/A	47 (46.5%)
Use a spacer regularly		N/A	26 (25.7%)

Of the 101 students identified as having current asthma, 59.4% (60/101) had visited an emergency department for urgent care due to asthma in the previous 12 months. In addition, 15.8% (16/101) of all current patients with asthma had been hospitalized due to asthma in the previous 12 months. Our needs assessment showed that of all current asthmatics, 35.6% (36/101) owned peak flow meters but only 30.7% (31/101) of them used it daily. Similarly, although 46.5% (47/101) of current asthmatics had a spacer for use with inhaled medications, only 25.7% (26/101) said they used a spacer regularly.

Computer-Assisted Intervention: Participant Demographics and Pretest and Posttest Results

Demographics

A total of 24 students were enrolled in the pilot program, ranging in age from 6-12 years at the time of enrollment. Of these, 63% (15/24) of the participants were male and 79% (19/24) were

Hispanic. Average household income for 46% (11/24) of participants was less than US $14,999. Most of the children were classified as having mild/ intermittent asthma, as defined in NHLBI guidelines (See Table 2).

Table 2. Baseline demographic characteristics of program enrollees[a](n = 24).

		n	%
Average age, mean (years)		8.6	--
Length of enrollment in program, median (months)		12	--
Sex			
	Male	15	63%
	Female	9	37%
Race			
	Black or African American	4	17%
	Hispanic	19	79%
	Other	1	4%
Student household yearly gross income (US$)			
	Less than $14,999	11	46%
	$15,000-$29,999	6	25%
	$30,000-$60,000	2	8%
	No answer	5	21%
Severity of asthma, according to NHLBI guidelines			
	Mild intermittent	15	63%
	Mild persistent	6	25%
	Moderate	2	8%
	Severe	1	4%

[a]Data from Children's Health Survey for Asthma (CHSA).

The children participated in the pilot study for 2 to 15 months over the course of 2 school years. Median enrollment time was 12 months. Nine students (38%) remained in the pilot for 7 months or less and 15 students (62%) were enrolled for 8 months or more. (Enrollment time includes only the months that school was in session and excludes summer break months.) The asthma control levels of the participants varied, with 15 having mild intermittent asthma, 6 having mild persistent, 2 having moderate, and 1 having severe asthma. Participants who remained enrolled in the program for 8 months or more tended to have more severe asthma. In contrast, children with milder symptoms tended to stop participation in the study at an earlier point.

Children's Health Survey for Asthma

Of the 24 student participants, 17 had a parent or guardian who completed the CHSA both at baseline and after completing the program. Four participants completed only one CHSA and 3 participants did not complete a CHSA and were excluded from further analysis. It is worth noting that the 3 enrollees who did not complete a CHSA were classified with the lowest level of asthma severity (mild intermittent), which may have contributed to their attrition from the program. Of the 17 participants who had paired (before and after intervention) CHSA results, improvements in health outcomes showed the greatest significance among the group of participants who were enrolled for 8 months or longer. A number of improvements in health outcomes were observed in our analysis (Table 3).

Table 3. Asthma outcomes among pilot program participants who completed preintervention and postintervention Children's Health Survey for Asthma (CHSA) surveys (n = 14).

Outcome	Prepilot (n or mean)	Postpilot (n or mean)	*P* value
Average physical health score (child)	65.64	76.28	.045[a]
Average physical activity score (child)	75.18	83.57	.24
Average physical activity score (family)	81.85	90.83	.11
Average emotional health score (child)	64.64	77.14	.17
Average emotional health score (family)	68.60	68.79	.97
Participants with asthma attacks[b], n	7	3	.13
Participants with wheezing[b], n	9	2	.02[a]
Average number of asthma attacks[b]	1.43	0.50	.10
Average number of wheezing episodes[b]	1.86	0.43	.02[a]
Average number of visits to doctor or clinic[b]	1.23	0.38	.04[a]
Average number of overnight hospitalizations[b]	0.21	0	.19
Average number of visits to the emergency department[b]	0.36	0.36	.99

[a]Event was statistically significant.

[b]Two-week recall.

There were improvements in the averages of every health scale measured by the CHSA, with statistically significant improvements shown for the average physical health score of the child (from 65.64 preintervention to 76.28 postintervention, $P = .045$). In the two-week period prior to completing the final CHSA, as compared to the two-week period prior to completion of the baseline questionnaire, there was a significant decrease in the number of participants experiencing wheezing episodes (n = 9 to n = 2, $P = .02$), and a significant decrease in the average number of wheezing episodes per child (1.86 to 0.43, $P = .02$). There was also a decrease in the number of participants experiencing an asthma attack (n = 7 to n = 3) and a decreasing trend in the average number of asthma attacks (1.43 to 0.50), although these changes were not statistically significant. Our results also showed a significant decrease in the average number of visits to doctors' offices or clinics due to asthma (1.23 to 0.38, $P = .04$). There were no overnight hospitalizations in the two-week period following the end of the pilot program, a nonsignificant reduction from an average of 0.21. In addition, prior to beginning this intervention, 5 children had never used a peak flow meter to help manage their asthma. After participating in this program, all children used a peak flow meter on a regular basis, and they also consistently reviewed their previous peak flow measurements with the program staff to see if their breathing had improved over time.

Discussion

Feasibility of a Computer-Assisted, School-Based, Intervention Program

This pilot project was intended to determine whether it was feasible to introduce a computer-based asthma self-management program in a low-income, urban, public elementary school. The pilot aimed to empower children's understanding of their disease by teaching them to use a computer program to track their asthma symptoms and provide them with evidence-based feedback on their medication usage and symptom manifestations. The pilot demonstrated that a computer-based program, when used in a school-based setting, can lead to better self-management of asthma and thereby help reduce asthma exacerbations in children living in a low-income, urban setting. After participating in the pilot, there was improvement in wheezing symptoms, number of asthma episodes, and clinic visits. Our results showed the greatest significance when we paired baselines of preintervention participants with participants who completed a CHSA at the end of their second year of enrollment, suggesting that length of enrollment in the program increased the efficacy of the program. Thirteen of the 14 participants were enrolled in the program for 8 months or longer. These results suggest that students with more severe asthma tended to stay in the program longer. Those who stayed in the program for the longer period of time showed more significant improvements in outcomes when compared to those who stayed in the program for 7 months or less. These findings are consistent with other studies where participants with more severe asthma and enrolled for longer lengths of time demonstrated the greatest improvement in outcomes [24,41,42].

Computer Programs as Tools for Asthma Self-management

The computer-based approach to asthma management has many advantages for intervening directly with children suffering from a chronic disease. This may be particularly true for lower-income populations. Low-income populations often lack regular physician supervision of their disease, leading them to receive care in emergency departments, usually when they are

experiencing an acute asthma episode. One study of urban patients with asthma in 8 major US metropolitan areas found that over half of the study participants reported that it was difficult to get adequate care for an asthma attack or follow-up visits [11,43]. Another study found that children were more likely to use anti-inflammatory medications when they had seen a health care provider in the previous 6 months, and suggested that the discontinuity of care and the absence of follow-up care between physician visits may be factors contributing to the high rates of asthma in East Harlem [44]. By using the ALERTS computer program, participants' health status is monitored on at least a weekly basis and this may help students adhere to prescribed medication plans, bridging the gap between intermittent care and the physician attention received only in situations of acute exacerbations.

Although it is not a substitute for the care and supervision by a physician, a program such as the one implemented here can help children and their families monitor medication usage and symptoms by providing personalized, real-time, evidence-based feedback on their disease status between physician visits. This information can be relayed to medically trained staff, either the school-based health center or the primary care physician, who can follow up with the patient and/or guardian if necessary. Additionally, the program generates weekly reports that are sent to the school-based health center and primary care physicians, providing a record of each patient's disease and affording this population with better continuity of health care than they might otherwise receive. This can also alert health care providers to the children's symptom history and use of medications.

Computers can be particularly effective in promoting knowledge of self-management skills among children with chronic diseases, such as asthma. Computers offer children an innovative method of monitoring symptoms that children find novel and fun. One study noted that children were more apt to use an interactive device than a written diary, for example [32]. Other studies have shown that electronic monitoring can clarify compliance among patients [36,45].

An important aspect of our pilot study was the school-based setting. Interventions similar to our pilot study have also utilized interactive technology, but were based in the home or in clinical settings, such as health clinics or doctors' offices. Our program's location within the students' school overcomes some of the barriers other researchers have found in implementing large-scale asthma interventions in the home or in clinics. For example, some researchers have found that one of the greatest barriers to implementing an asthma education program in the home was the incompatibility of the schedules of families and nurse home visitors [46,47]. Families participating in interventions based in clinics might encounter some of the same scheduling difficulties. Children with asthma followed in the school setting would not be constrained by such family scheduling conflicts.

Limitations

Limitations to our study included the fact that parents did not actually participate in any of the computer sessions (although they were involved in enrolling their children in the pilot program) and, therefore, might not have been as involved in their child's asthma monitoring as those parents who partook of interventions based in the home or in clinics in other studies [48-50]. Another limiting factor is that children cannot benefit from the program on their own if they do not have access to a computer outside of the school sessions. Many low-income children do not have computers in the home; thus, school might be their only source of computer access. Importantly, the program is also available using an interactive voice response (IVR) platform (ie, telephone) in both English and Spanish that was not accessible in the school setting. Since people are more likely to have telephones than computers in their homes, this would increase the likelihood of being able to access and use the program. Indeed, in a parallel program to this one that was implemented in a group practice setting in Connecticut and used by patients at home, where both Internet and IVR access was available, 62% of program entries were made by IVR and 38% were Web-based [48,50]. Indeed, one of the authors (RJA) was the principal investigator of such a program implemented in three large pediatric practices in New York City that showed positive preliminary results [48,50].

Conclusion

This pilot study demonstrated that an individualized, computer-assisted intervention resulted in improved health outcomes among low-income children in a public school setting. Increased awareness of the importance of regular peak flow meter measurements, provision of asthma trigger information, and a novel approach to symptom tracking resulted in fewer asthma exacerbations and improved overall physical health among a pediatric asthmatic population.

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Conflicts of Interest

None declared.

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Abbreviations

AIR: Asthma Intervention Report
ALERTS: Automated Live E-Health Response Tracking System
CHSA: Children's Health Survey for Asthma
HIPAA: Health Insurance Portability and Accountability Act
IVR: interactive voice response
NHLBI: National Heart, Lung, and Blood Institute
PIN: personal identification number

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Original Paper

Filling the Gaps in a Fragmented Health Care System: Development of the Health and Welfare Information Portal (ZWIP)

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Abstract

Background: Current health care systems are not optimally designed to meet the needs of our aging populations. First, the fragmentation of care often results in discontinuity of care that can undermine the quality of care provided. Second, patient involvement in care decisions is not sufficiently facilitated.

Objective: To describe the development and the content of a program aimed at: (1) facilitating self-management and shared decision making by frail older people and informal caregivers, and (2) reducing fragmentation of care by improving collaboration among professionals involved in the care of frail older people through a combined multidisciplinary electronic health record (EHR) and personal health record (PHR).

Methods: We used intervention mapping to systematically develop our program in six consecutive steps. Throughout this development, the target populations (ie, professionals, frail older people, and informal caregivers) were involved extensively through their participation in semi-structured interviews and working groups.

Results: We developed the Health and Welfare Information Portal (ZWIP), a personal, Internet-based conference table for multidisciplinary communication and information exchange for frail older people, their informal caregivers, and professionals. Further, we selected and developed methods for implementation of the program, which included an interdisciplinary educational course for professionals involved in the care of frail older people, and planned the evaluation of the program.

Conclusions: This paper describes the successful development and the content of the ZWIP as well as the strategies developed for its implementation. Throughout the development, representatives of future users were involved extensively. Future studies will establish the effects of the ZWIP on self-management and shared decision making by frail older people as well as on collaboration among the professionals involved.

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KEYWORDS

Self-care; cooperative behavior; interdisciplinary communication; electronic health records; frail elderly

Introduction

Current health care systems are not optimally designed to meet the needs of our aging populations [1]. First, they are characterized by fragmentation, which leads to inefficiency and can make health care efforts less effective [2,3]. Second, they do not facilitate the incorporation of patient perspectives in care decisions because they are designed according to a medical model that relies on care decisions being made by professionals with limited patient involvement [4].

Yet, the roles of patients and informal caregivers in our health care system are changing. Patients are now increasingly encouraged to become involved. There are several reasons for this. First, patients are involved in their care because it is they who make daily decisions about how they manage their disease (eg, they decide whether they take their medication or follow the lifestyle advice provided by professionals) [5]. Second, patient involvement is valued for moral and ethical reasons and considered a patient's right [6]. Third, research has shown that increased patient involvement can have favorable effects, such as improved health outcomes and improved adherence [7-9]. Therefore, increasing the involvement of patients in their own care by enabling them to participate in decision making and by supporting them to manage their disease to the best of their ability is highly recommended.

However, increased patient involvement may be difficult to achieve in a health care system that suffers from fragmentation because both patients and professionals may already be struggling to meet the complex demands placed on them by such a health care system. In a fragmented health care system, care for a single patient, especially care for a frail older patient (an older patient suffering from a range of problems in the physical, psychological, and social domain), is often provided by multiple professionals who work in a variety of settings [1,10,11]. As a consequence, continuity of care (the degree to which a series of discrete health care events is experienced as coherent, connected, and consistent with the patient's medical needs and personal context [11]), is limited. This undermines the quality of care provided [12,13]. Consequently, coordination of care across settings and services, by the sharing of accurate information between professionals and by the effective collaboration of professionals, patients, and informal caregivers, is badly needed [10,14,15].

Therefore, we developed a program aimed at: (1) facilitating self-management and shared decision making by frail older people, and (2) reducing fragmentation of care by enhancing collaboration among professionals involved in the care of frail older people through a multidisciplinary shared electronic health record (EHR) and personal health record (PHR). This paper describes the development of this program.

Methods

The program, the Health and Welfare Information Portal (ZWIP), was initiated by ZOWEL NN, a collaborative of stakeholders in health care and welfare services, located in the city of Nijmegen, the Netherlands. The two main objectives for the program were: (1) to facilitate self-management and shared decision making by frail older people and their informal caregivers, and (2) to improve collaboration among professionals by enhancing and facilitating information sharing through a multidisciplinary shared EHR and PHR. Intervention mapping, a stepwise approach for the systematic development of theory- and evidence-informed interventions [16], was chosen as the method for developing the program. In the following sections, we will discuss the steps taken in this process. An overview is provided in Table 1.

Table 1. Overview of the intervention mapping process.

Steps	Methods	Results
1. Needs assessment	Problems analysis based on literature search; semi-structured interviews with frail older people and informal caregivers (n = 22); 2 meetings of working group of professionals (n = 15); and 1 meeting of working group of older people and informal caregivers (n = 4).	Logic model for self-management (Figure 1) and interprofessional collaboration (Figure 2).
2. Preparing matrices of performance objectives and determinants	Building matrices of performance objectives, determinants and change objectives based on the needs assessment.	Matrices of performance objectives and determinants for frail older people and informal caregivers, professionals, and the organizations of professionals (Appendices 1-3).
3. Selecting theory-informed intervention methods and practical strategies	Literature search for theories and methods and their effectiveness for the target populations; selection of theories and methods.	Theories used for the program: social cognitive theory (main theory), goal-setting theory, and elements of theories of organizational change.
		Methods and strategies used for professionals: modeling, active learning, direct experience, and creating facilitating conditions.
		Methods and strategies used for frail older people and informal caregivers: tailoring, modeling, guided practice, collaborative goal setting, and action planning.
4. Producing program components and materials	Requirements for Health and Welfare Information Portal (ZWIP) were defined in 3 additional meetings of working group of professionals (n = 15) and one additional meeting of working group of older people and informal caregivers (n = 4).	Main program component: the ZWIP.
	Subsequently, development of ZWIP in parallel with reviewing by working groups: 4 meetings of working group of professionals (n = 6); 3 meetings with two working groups of frail older people (n = 4).	Target population: frail older people ≥ 70 years, informal caregivers, and their professionals.
	Small pilot study of the ZWIP.	Setting: primary care.
		Materials: the ZWIP; bubble diagram and goal-setting forms; and personalized Internet-based and paper brochures with health promotion information concerning different domains of health, functioning, and well-being.
5. Planning program adoption, implementation, and sustainability	Program initiated by network of local stakeholders in health care and welfare services; future users involved extensively in development; necessity for health care system changes for frail older people felt at several levels (government, organizations, and professionals).	Implementation strategies for professionals: involvement in development; starting with early adopters; educational program (CME credits available) and e-learning; telephonic help desk available; coaching and e-coaching available; financial compensation; publicity and flyers; and incentives.
		Implementation strategies for employing organizations: financial compensation and educational program for employees.
		Implementation strategies for frail older people and informal caregivers: involvement in development, flyers, involvement of informal caregiver, involvement of family physician, Internet-based and paper version of the ZWIP, instruction in using the ZWIP by volunteer, and telephonic help desk available.
6. Planning for evaluation	Design of an evaluation plan.	Framework for process evaluation and evaluation of effects.

Step 1: Needs Assessment

First, we assembled a planning group to develop the intervention. This planning group included the project manager, the project leader (RM), two researchers (SR and MHu), two family physicians, a geriatrician, a nurse scientist experienced in intervention mapping (MHe), an information technology consultant, and a long-term care facility physician.

This planning group analyzed the existing problems with self-management of frail older people and interprofessional collaboration in primary care. First, we performed a literature search for barriers to patient self-management and interprofessional collaboration. Second, we conducted semi-structured interviews at the homes of frail older people (n = 11) and informal caregivers (n = 11). They were invited to participate by their family physician or welfare organization and were purposively selected based on variation in living situation, socioeconomic position, and health and social problems. Interviewees were asked for their experiences with receiving information from health care and welfare professionals, informational continuity (ie, whether information concerning their health or well-being was exchanged between professionals), and interprofessional collaboration. Third, we established two working groups. The first group consisted of health care and welfare professionals (n = 15) who were involved in the care of frail older people. They were recruited through their employing organizations and were financially compensated for their time investments. Members included family physicians (n = 3), primary care nurses (n = 3), geriatricians (n = 2), municipality workers (n = 2), social workers (n = 2), a long-term care facility physician (n = 1), a pharmacist (n = 1), and a psychologist (n = 1). The second working group consisted of older people (n = 2) and informal caregivers (n = 2), who were asked to participate by older people participating in the user panel of ZOWEL NN. Both groups were asked to discuss the problems they experienced with self-management of frail older people and collaboration among professionals and they were asked to review and comment on the results from the literature search, semi-structured interviews, and the other working group.

Results of this needs assessment were integrated into a logic model. This model is derived from the Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation (PRECEDE) model [16,17] that displays behaviors, its consequences, and its determinants in a structured manner. As the problems described for each topic (self-management and collaboration) were too distinct to be compiled into one single logic model, we constructed a separate logic model for each program objective.

Step 2: Preparing Matrices of Performance Objectives and Determinants

Based on the problem analysis, we defined performance objectives (ie, the behaviors required to achieve the program objectives) for each target population. These performance objectives were then crossed in matrices with those determinants of behavior that were known to have a major influence on behavior and were amenable to change. On the crossings of performance objectives and determinants, change objectives were formulated (ie, the highly specific outcomes the program should be aiming for). We designed these matrices for all target populations involved (ie, frail older people and their informal caregivers, professionals, and their employing organizations).

Step 3: Selecting Theory-Informed Intervention Methods and Practical Strategies

We searched the literature for theories that were proven to be effective in changing the identified determinants or that were successfully used to enhance patient self-management or to promote collaboration among professionals. From these theories, we selected methods and strategies for our program. In this selection, we aimed for an optimal balance between the expected advances toward our program objectives and the investments required from the target populations.

Step 4: Producing Program Components and Materials

Requirements for the program components were defined in additional meetings of the working groups of professionals and older people and informal caregivers. Subsequently, members of the planning group started development of program components. These components were reviewed by the working group of professionals and by two additional working groups of frail older people in an iterative process involving several rounds of reviewing by the working groups, the working groups making suggestions for improvement, and members of the planning group making adjustments. In this process, development and reviewing coincided, each working group being presented with the latest version of the components at the time of their meeting. Final versions of the program components were tested in a small pilot study involving two frail older people, two informal caregivers, and seven professionals.

Step 5: Planning Program Adoption, Implementation, and Sustainability

A prerequisite for adoption and implementation of the program was met by the extensive involvement of the target population in its development and the commitment of the local collaborative of stakeholders in health care and welfare services. Further, implementation was facilitated by selecting implementation strategies that were tailored to the needs of each target population. Planning for sustainability was started early in the development of the program by searching for funding for incorporation of the program in everyday practice.

Step 6: Planning for Evaluation

In this final step, we designed a plan for the evaluation of the program. This involved an evaluation of the effects of the program as well as a process evaluation.

Results

Step 1: Results of the Needs Assessment

An overview of the results of the needs assessment for self-management of frail older people is provided in the logic model shown in Figure 1 [5,7,13,18-34]. A second logic model representing collaboration among professionals is shown in Figure 2 [4,7,10,21,23,29-31,33-49]. Each logic model describes

the problem (the last two columns), the behavioral and environmental factors that contribute to the problem (the second column), and the determinants that influence those factors (the first column). We will briefly discuss the results of the needs assessment in the following section. Knowledge of the Dutch health care system may help the interpretation of the results of this needs assessment; therefore, a summary of its characteristics is provided in Textbox 1 [50].

Textbox 1. Characteristics of the Dutch Health Care System.

- All Dutch citizens are registered with their own family physician, usually over an extended period of time. This family physician functions as a gatekeeper; hospital care and specialist care (except for emergency care) can only be accessed with a referral by a family physician.
- When patients need other health care or welfare services (eg, home care, physiotherapy, or occupational therapy), they can generally choose between many providers offering these services.
- Funding of the Dutch health care system is organized by means of a compulsory social health insurance scheme.

Figure 1. Logic model for self-management of frail older people.

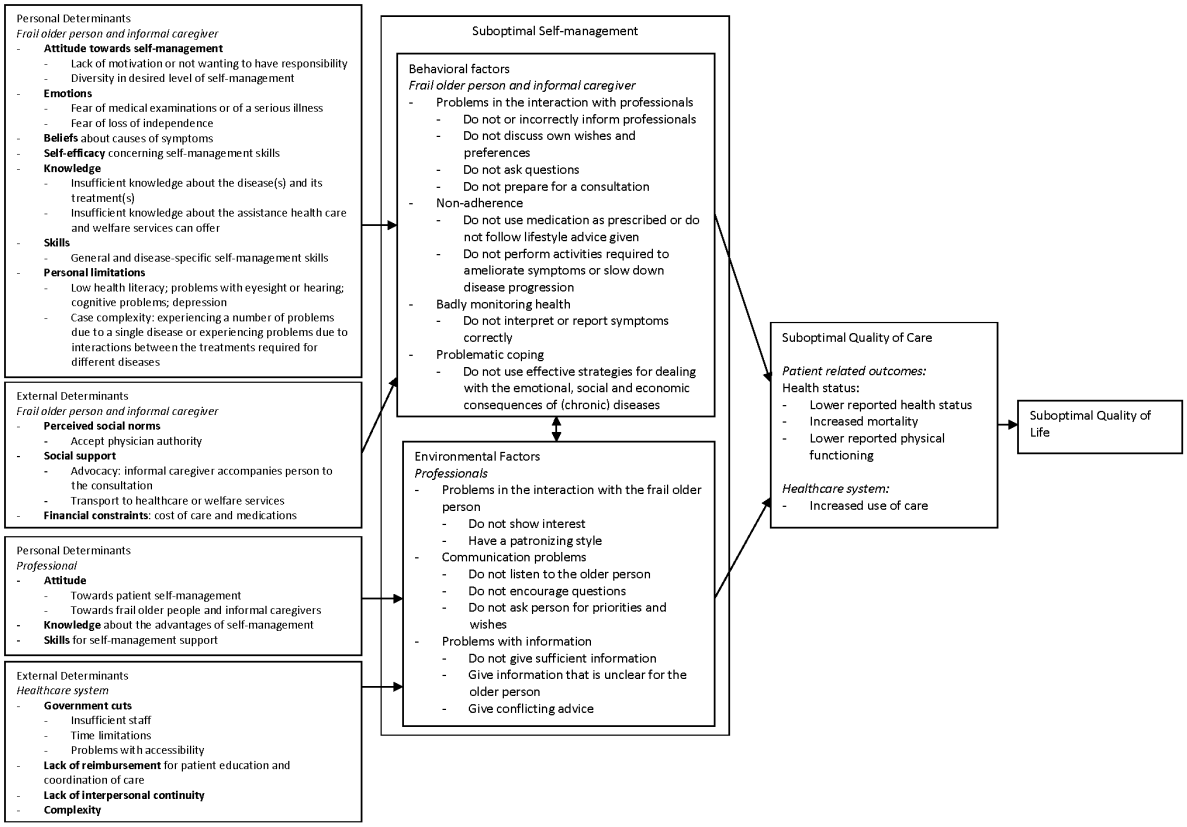
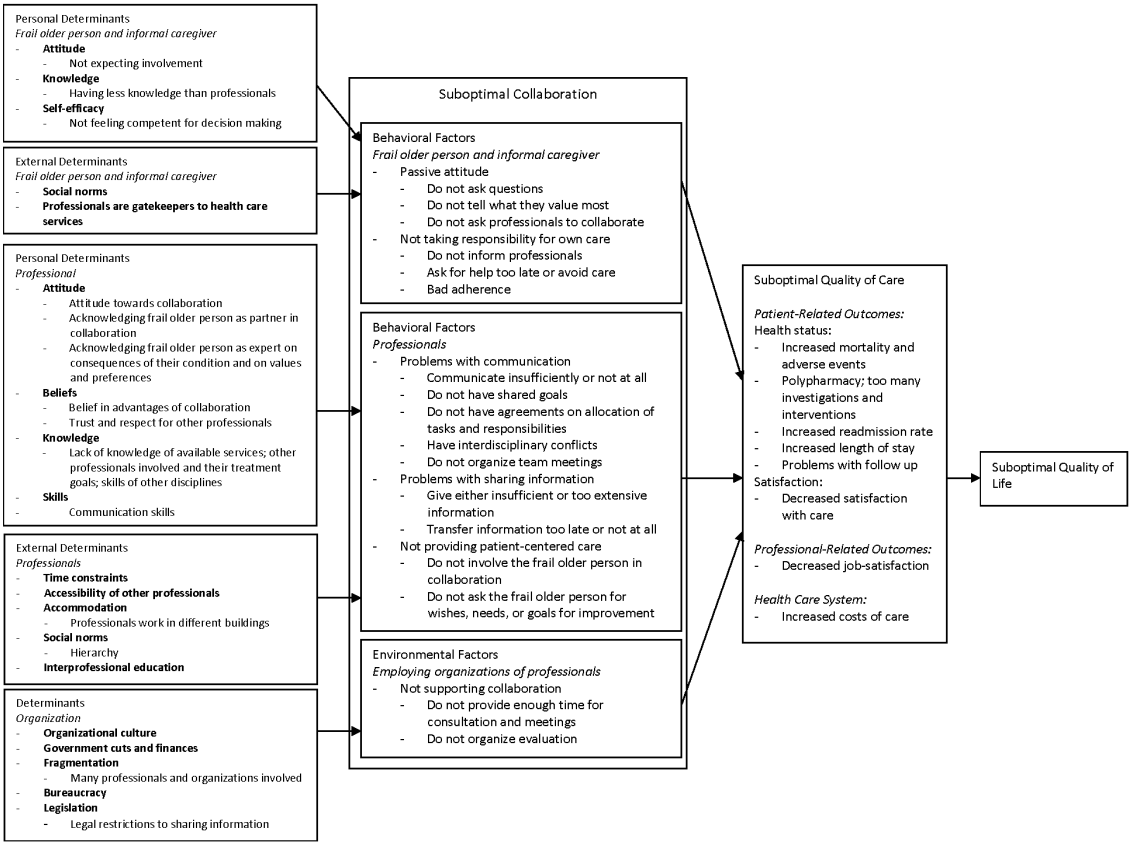


Figure 2. Logic model for collaboration among professionals.



Needs Assessment Concerning Frail Older People's Involvement in Self-management

Frail older people, informal caregivers, professionals, and previous research reported problems with patient involvement in self-management. These problems related to frail older people and informal caregivers not performing the activities required, and professionals not encouraging or facilitating involvement.

Identified behaviors of frail older people and informal caregivers that contributed to these problems included: (1) not adequately informing professionals about their health situation nor asking sufficient questions [29,30], and (2) not adhering to medications prescribed or advice given [23,29,34]. These behaviors were influenced by many determinants such as attitude toward self-management because not all frail older people want to be involved extensively [7,33]; emotions such as fear of loss of independence [7,18]; self-efficacy for self-management [5,18,26,27]; knowledge about the disease, symptoms, and treatments [18,22,26]; skills [5,27]; personal limitations (eg, cognitive problems) [7,20,26,33]; perceived social norms [7,33]; social support, such as advocacy [7,18,26,27]; financial constraints [18,25,26]; and the high complexity of the health care system [34].

Important contributing behaviors of professionals were (1) not providing the frail older person with adequate information for self-management [20,26,34], and (2) not being genuinely interested in the frail older person and not encouraging questions [25,26,29]. Important determinants affecting these behaviors were attitude toward patient self-management [22,33], knowledge [22], skills for self-management support [20,22], and determinants related to the health care system [20,33].

Needs Assessment Concerning Collaboration Among Professionals

Professionals, patients, informal caregivers, and the literature cited problems with collaboration among professionals. The main behaviors that contributed to these problems were a lack of communication or insufficient communication [35,39,47]; delays in the transfer of information or information not being transferred at all [41,44]; giving either insufficient information (eg, not giving the information required by a particular discipline) [41,44] or too extensive information that was not read by professionals with already demanding work schedules; and not involving the frail older person in the collaboration between professionals. Important determinants influencing these behaviors included attitudes toward collaboration [42,45], beliefs in the advantages of collaboration [45], knowledge about the information needed by other disciplines [45], communication skills [35,42,45], and external factors such as time constraints [35] and legal restrictions to the sharing of information [45]. However, for professionals in the working groups, more

practical determinants were the most important, such as not knowing which other professionals were involved in the care of the frail older person, not knowing them personally [39,40,42,48], and not being able to contact these professionals (eg, due to part-time work or busy telephone lines) [35,39,40].

Step 2: Results on Matrices of Performance Objectives and Determinants

Based on our needs assessment, we defined performance objectives for both program objectives and for each target population involved (Appendices 1 and 2). Also, we reviewed the determinants shown in Figures 1 [5,7,13,18-34] and 2 [4,7,10,21,23,29-31,33-49] in order to select those determinants of behavior that were considered both important to target and modifiable. For the first program objective, aimed at facilitating self-management, we developed two matrices: one for frail older people and informal caregivers and one for professionals. For frail older people and informal caregivers, targeted determinants were attitudes, skills and self-efficacy, knowledge, and social support. For professionals, targeted determinants were attitudes, knowledge, skills, and organization. For the second program objective, aimed at enhancing collaboration, we designed three matrices: one for professionals, one for their organizations, and one for frail older people and informal caregivers. For professionals, targeted determinants were attitudes and beliefs, knowledge, skills, and accessibility; for their organizations, the targeted determinant was organizational culture; and for frail older people and informal caregivers, targeted determinants were attitude, self-efficacy, knowledge, skills, social norms and social support, and accessibility. We then crossed the performance objectives with these determinants to design matrices of change objectives. For example, for the performance objective "professional communicates with other professionals involved" and the determinant "knowledge," a change objective was "professional states that problems in communication lead to adverse outcomes for frail older people." Therefore, we wanted our program to increase professionals' knowledge about the effects of communication problems. Appendix 3 provides an example of a matrix of change objectives.

Step 3: Selected Theories, Methods, and Strategies

Social cognitive theory [51] was selected as the main theory behind the program because it has been successfully used in the past for interventions aimed at improving patient self-management and in Internet-based interventions focusing on improving self-management [52-54]. A key concept of social cognitive theory is perceived self-efficacy: the beliefs people have about their capabilities to produce the effects they desire by their own actions [55]. If self-efficacy is low, people are less likely to either act or to continue trying when facing difficulties [51]. We included several methods and strategies derived from this theory in the program, based on their ability to change the targeted determinants of behavior. For professionals, we included active learning, direct experience, modeling, and facilitation. For frail older people and their informal caregivers, we included modeling, guided practice, and tailoring. Further, elements of goal-setting theory [56] (ie, goal setting and action planning) [57] were included in the program to assist frail older people and informal caregivers in describing what is most important to them, to help them to achieve their goals, and to increase their involvement in the care process. Goal-setting theory highlights the importance of setting specific, difficult goals because people who set such goals perform better that those who are merely asked to do their best [56]. Last, we incorporated elements of several theories of organizational change into the program. Methods used from these theories were providing training and coaching, and creating facilitating conditions [16,58].

Step 4: Characteristics of ZWIP

Taking the former steps of the intervention mapping process into account, we developed the main component of the program: the ZWIP. The ZWIP is a personal, Internet-based conference table for multidisciplinary communication and information exchange for frail older people, their informal caregivers, and professionals. It can be considered to be both a shared EHR and PHR. The ZWIP is aimed at frail older people identified through a specific screening method and includes: (1) a tool for multidisciplinary communication in a secure environment that enables communication through sending messages between the frail older person, informal caregiver, and the professionals involved; (2) an overview of health care and welfare professionals involved in the care of the frail older person and their contact information; (3) information about the frail older person's health, functioning, and social situation as well as the care provided; (4) the goals and action plans of the frail older person and the informal caregiver, which are formulated with them during home visits by nurses or social workers by means of a goal-setting tool; and (5) tailored educational materials for the frail older person and informal caregiver. Fundamental to the ZWIP is the central position of the frail older person, who can view the information included and who decides which professionals are granted access to his personal ZWIP. As a rule, messages that are communicated within the ZWIP are visible for all professionals with access to the ZWIP as well as for the frail older person and informal caregiver. This allows everyone concerned to remain informed about the frail older person's situation and enables everyone to bring up their own relevant observations in an ongoing conversation. However, at the request of frail older people and professionals, we also included the option of sending a private message to an individual person.

After development, as a final step before implementation, we conducted a small pilot study of the ZWIP. The most important lessons learned from this pilot were practical issues such as the need to communicate as unambiguously as possible.

Step 5: ZWIP Program Adoption and Implementation

Strategies used for the adoption and implementation of the program were tailored to the needs of each particular target population. We will describe the main strategies used in the next paragraphs; an overview of all strategies is provided in Table 1 (step 5).

For health care and welfare professionals, our most important strategy was an interdisciplinary educational program for health care and welfare professionals involved in the care of frail older people. This program consisted of 3 three-hour meetings

concerning the following subjects: (1) the concept of frailty and identification of frailty, as this was required to identify the frail older people who were the program's target population; (2) providing self-management support to frail older people by thoroughly informing them and using collaborative goal setting; (3) interdisciplinary collaboration, including information about what each discipline has to offer in the care for frail older people; and (4) working with the ZWIP. Except for its educational content, the educational program also served as a method for identifying and bringing together local health care and welfare professionals involved in the care of frail older people because the program enabled professionals to get acquainted with each other. The educational meetings were held near local family practices and all local professionals working with frail older people were invited to participate. Another important strategy was that we aimed to ensure the participation of intrinsically motivated early adopters. Further, we tailored the implementation of the program to each setting by providing family medical practices with several options for implementation, which allowed them to choose the method that would best meet their local needs and circumstances. Also, we provided financial compensation for time invested in the program, gave coaching and e-coaching in using the ZWIP, and had a telephonic help desk available.

For frail older people and informal caregivers, we had two main strategies. First, we involved their family physician in the project, who actively promoted their participation. Second, we aimed to either facilitate the use of information technology or to make the use of information technology by frail older people redundant, as we were aware that they often have low computer literacy. Hence, we provided them with an Internet-based version of the ZWIP as well as a paper version of the ZWIP, which held all information that was included in the Internet-based ZWIP except for the communication; we offered them a home visit by a volunteer, who could either demonstrate the ZWIP to inform them about its possibilities or could train them in using the ZWIP themselves; and we had a telephonic help desk available during office hours.

Step 6: Preparing for Evaluation of the ZWIP

As a final step in the intervention mapping process, we planned the evaluation of the ZWIP. This evaluation will involve both a process evaluation and an effect evaluation. In the process evaluation, we will evaluate the implementation of the intervention, exposure of the target populations to the intervention, experiences of the target populations with the intervention, and barriers and facilitators to the use of the intervention. This will be studied using a combination of quantitative and qualitative data (ie, surveys, data about both the use of the ZWIP and exposure to its implementation strategies, and semi-structured interviews). The effects of the ZWIP program will be evaluated by means of a controlled clinical trial. Outcome measures will be the effects of the program on interprofessional collaboration, patient self-management and autonomy, patient outcomes such as functioning and quality of life, and use of care. Also, cost-effectiveness of the ZWIP will be evaluated. Last, as we consider the interprofessional educational program an important part of the implementation, the effects of this program on interprofessional collaboration will be evaluated separately. This will be done in a before-and-after study using several validated questionnaires (ie, the Attitudes Toward Health Care Teams Scale [59], the Interprofessional Attitudes Questionnaire [60,61], and the Team Skills Scale [62]) followed by semi-structured interviews with purposively selected participants.

Discussion

This paper describes the successful development of a program aimed at facilitating self-management and shared decision making by frail older people and their informal caregivers and at reducing fragmentation of care through improving collaboration among professionals. For this development, the intervention mapping framework was used and future users were involved extensively. In the past, this framework has also been successfully used for the development of health promotion programs aimed at such diverse topics as leg ulcers [63], physical activity of employees in sedentary occupations [64], sexually transmitted disease, pregnancy and human immunodeficiency virus prevention [65], and asthma self-management [66]. To our knowledge, this is the first time that intervention mapping was successfully used to develop an intervention that specifically targets collaboration between professionals.

A major advantage of the use of intervention mapping was that it facilitated the systematic incorporation of the needs and preferences of the target population as well as evidence from previous research. We can exemplify this with our first program objective, which concerned self-management and shared decision making. Previous research has shown that most older people prefer a less active role in medical decision making [67], but they do want to be informed, and they want their concerns and wishes to be taken into account when decisions are made [7]. Still, there is enormous variation in the extent to which older people wish to participate in decision making [7]. Therefore, we designed our program to meet the basic level of involvement wanted by most older patients (eg, by providing information about their health and customized educational materials; by including goal setting to gain knowledge of their goals and preferences; and by educating professionals in self-management support), yet made the program flexible to more extensive patient involvement in decision making (eg, by incorporating action planning for patients willing to engage in it and by facilitating patients' communication with professionals).

Further, the program benefitted from the involvement of the target populations because they brought up a wide range of knowledge and perspectives [16]. Moreover, the target populations were able to specify which problems found in the literature were considered most pressing by members of their own population because they were highly knowledgeable of their characteristics and circumstances. For example, although we initially assumed that lack of continuity of information was an important barrier to collaboration, the involvement of the working group of professionals demonstrated that more basic obstacles to collaboration existed (ie, practical problems

concerning communication, such as not knowing which other professionals are involved or not being able to contact them due to differing working hours). Therefore, we decided to shift focus of the program to include facilitation of communication as well. This enabled designing a program that was tailored to meet their needs, thereby increasing the chances of an effective intervention and a successful implementation.

Although involvement of the target population was considered important, it also presented a challenge. First, involving frail older people proved to be difficult. For the limited number of frail participants in the working groups, problems such as not being able to attend the meetings due to health problems limited their ability to participate. Therefore, we also invited older people who were not frail to join the working groups. Also, for some of the frail older people participating in the semi-structured interviews, cognitive problems made it difficult for them to express their views about the rather abstract interview topics. Therefore, although frail older people were involved in the development process, their involvement was less than we would have preferred. Second, the evidence gathered from previous research and the different working groups did not always point in the same direction. An example was the discussion about whether or not all messages should be visible to everyone with access to the ZWIP. The working group of professionals was hesitant at first to make all messages visible, and the working groups of frail older people were divided. In the end, both groups mentioned that there were instances in which they felt a private message was absolutely required. In such cases, the planning group made a final decision. These decisions were made based on a thorough deliberation on all the arguments available from the literature and the working groups as well as arguments concerning feasibility.

Although the ZWIP is a systematically developed evidence-informed intervention, its future success depends highly on its successful implementation and its use by professionals in everyday practice. Implementation and use will be monitored and adaptations will be made whenever required. Further, future use of the ZWIP in everyday practice will have to establish the added value of the communication tool of ZWIP in relation to already existing communication methods.

In summary, this article describes the successful development of the ZWIP, a personal, Internet-based conference table for multidisciplinary communication and information exchange for frail older people, their informal caregivers, and professionals. We expect that the ZWIP will be able to increase the involvement of frail older people and informal caregivers in their care and will improve collaboration among professionals. Therefore, we expect that the ZWIP will contribute to filling the gaps in our fragmented health care systems.

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Authors' Contributions

Concept and design: SR, MHe, and RM; analysis of the data: SR, MHe, and RM; drafting of the article: SR; and critical revision of the article: MHu, TvA, SZ, MOR, HS, MHe, and RM.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Performance objectives for each target population related to self-management.

[PDF File (Adobe PDF File), 50KB - resprot_v1i2e10_app1.pdf]

Multimedia Appendix 2

Performance objectives for each target population related to collaboration.

[PDF File (Adobe PDF File), 48KB - resprot_v1i2e10_app2.pdf]

Multimedia Appendix 3

Section of matrix of change objectives on enhancing collaboration of professionals.

[PDF File (Adobe PDF File), 38KB - resprot_v1i2e10_app3.pdf]

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Abbreviations

EHR: electronic health record

PHR: personal health record
ZWIP: Health and Welfare Information Portal

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Original Paper

Electronic Problem-Solving Treatment: Description and Pilot Study of an Interactive Media Treatment for Depression

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Abstract

Background: Computer-automated depression interventions rely heavily on users reading text to receive the intervention. However, text-delivered interventions place a burden on persons with depression and convey only verbal content.

Objective: The primary aim of this project was to develop a computer-automated treatment for depression that is delivered via interactive media technology. By using branching video and audio, the program simulates the experience of being in therapy with a master clinician who provides six sessions of problem-solving therapy. A secondary objective was to conduct a pilot study of the program's usability, acceptability, and credibility, and to obtain an initial estimate of its efficacy.

Methods: The program was produced in a professional multimedia production facility and incorporates video, audio, graphics, animation, and text. Failure analyses of patient data are conducted across sessions and across problems to identify ways to help the user improve his or her problem solving. A pilot study was conducted with persons who had minor depression. An experimental group (n = 7) used the program while a waitlist control group (n = 7) was provided with no treatment for 6 weeks.

Results: All of the experimental group participants completed the trial, whereas 1 from the control was lost to follow-up. Experimental group participants rated the program high on usability, acceptability, and credibility. The study was not powered to detect clinical improvement, although these pilot data are encouraging.

Conclusions: Although the study was not powered to detect treatment effects, participants did find the program highly usable, acceptable, and credible. This suggests that the highly interactive and immersive nature of the program is beneficial. Further clinical trials are warranted.

Trial Registration: ClinicalTrials.gov NCT00906581; http://clinicaltrials.gov/ct2/show/NCT00906581 (Archived by WebCite at http://www.webcitation.org/6A5Ni5HUp)

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KEYWORDS

Depression; problem-solving therapy; computer-based therapy; interactive media; Internet intervention; problem-solving treatment; cognitive behavioral therapy

Introduction

Until now, one commonality among computer-automated depression interventions has been a heavy reliance on users reading text to receive the intervention. However, these interventions have not fully exploited the capacity of computers to deliver interactive media [1] to guide treatment. However, text-delivered interventions place a burden on persons with depression because these users may lack the literacy, concentration, or energy or motivation needed to read large quantities of text. Moreover, text conveys only verbal content, not the nonverbal cues (ie, body language and prosody) that an empathic therapist would use. Text alone cannot simulate the psychotherapy experience with high fidelity.

Programs can be designed to respond to users' inputs by playing video and audio clips, based on branching algorithms, to guide users through evidence-based treatments. Such programs could deliver some of the nonspecific aspects of therapy by conveying an on-camera therapist's warmth, personality, compassion, and ability to remain supportive when the patient experiences setbacks [2].

The purpose of this study was to explore the possibility of using interactive media—particularly video—to deliver computer-automated treatment for depression. This paper describes an interactive multimedia program that provides an automated electronic version of problem-solving therapy (*ePST*) for depression and is designed to simulate the experience of being in treatment with a master clinician. It also reports a pilot study that was conducted with 14 persons with minor depression.

Problem-Solving Treatment

The *ePST* program is directly based on a manualized, evidence-based treatment for depression known as problem-solving treatment for primary care (PST-PC). PST-PC has been demonstrated to be effective for the treatment of depression [3-5]. (For a detailed description of PST-PC, see Hegel and Arean [6].) The basis of PST-PC is that enhancing problem-solving skills and attitudes and working to solve problems in one's life can reduce depression. PST-PC involves 6 steps: (1) clarifying the problem, (2) establishing an achievable goal, (3) brainstorming alternative solutions, (4) evaluating the pros and cons of each solution and selecting one or more solutions, (5) developing an action plan to implement the solution(s), and (6) evaluating the success of the implementation and troubleshooting as needed. Each session concludes with scheduling pleasant activities.

The mechanism by which problem-solving treatment works has not yet been clearly identified [7]. PST-PC activates individuals to take steps toward changing their situation. Evidence is emerging to suggest that, along with typical predictors of improvement such as treatment adherence [8], the most important element of PST-PC for overcoming depression may be helping the patient to overcome an avoidant coping style [7,9]. Because PST-PC has strong face validity and is easy for most patients to understand, acceptance and satisfaction from patients is high, with very low dropout rates, as reported in clinical trials of PST-PC [5,10].

The ePST Program

Purpose

An interactive media program was produced to deliver *ePST*. The goal of *ePST* was to automate an empirically supported treatment and to provide it in the context of a simulated helping relationship. The *ePST* program was built for the US National Aeronautics and Space Administration (NASA) as part of a suite of self-guided programs to help astronauts manage their own psychosocial problems on long missions [11]. The system is used autonomously, confidentially, and in a self-directed manner. Although the development of *ePST* was funded by NASA, it was designed to also be evaluated among the public with a wide variety of patients. Therefore, a NASA and a general public version were produced, which differ only by a few video clips. As such, *ePST* is intended for use by both astronauts and nonastronauts.

Theoretical Underpinning

ePST is based on the Virtual Practicum Model [12,13], an approach to designing professional education programs, which is based on Boisot's "epistemological space" [14], Kolb's "learning cycles" [15], and Schon's "reflective practicums" [16]. The Virtual Practicum Model has been used to teach clinicians how to conduct counseling in prevention of human immunodeficiency virus infection [17], manage patients with human immunodeficiency virus/acquired immunodeficiency syndrome [18], and conduct genetic counseling and testing [19]. The basis of the Virtual Practicum Model is the simulation of the interactive experience of being trained one-on-one by a master clinician—a practitioner who is both a master of his or her specialty and a master teacher. The goal of the program is to provide trainees both the concrete information they need to manage clinical cases and to impart the soft skills needed to interact effectively with patients, and the case conceptualization skills needed to understand each unique case. *ePST* builds on the Virtual Practicum Model by providing persons seeking treatment for depression an opportunity to receive treatment (in a simulated fashion) from a master clinician (author MTH) who is an expert in problem-solving treatment. However, not only does the on-camera clinician walk the user through the concrete steps of problem-solving treatment, he conveys warmth and empathy—the soft skills of a skilled psychotherapist. The goal of both the VPM and *ePST* is for users to receive training or treatment from an expert in the field, and thereby to increase the number of persons who can benefit from that professional.

Program Walk-Through

ePST is a multimedia-based, video-intensive program that simulates therapy based on the PST-PC treatment manual [6]. It includes six sessions, intended to be completed once per week. In each session, users are welcomed by a therapist (author MTH) presented via audio and video, who appears in a warmly lit professional office. The user then completes the Patient Health Questionnaire-9 (PHQ-9) [20] measure of depression. Tailored feedback about his or her progress is provided by the virtual therapist, discussing the user's current level of depression and change from the previous session (see Figure 1).

The first session provides psychoeducation about depression and the process of problem-solving treatment; subsequent sessions offer decreasing guidance on the process of problem-solving treatment. During each session, the virtual therapist guides users through all steps of problem-solving treatment, plus making a list of enjoyable activities (entering their own or choosing from an extensive list of common activities) and scheduling them for the week.

Sessions 2 through 6 begin with a check-in on all active problems. The therapist provides feedback about the user's success or failure in solving problems compared with the previous session and helps him or her identify ways to improve problem solving, both on individual problems and in general.

Although the process of problem solving remains consistent throughout the program, a variety of audio and video clips are used to maintain a sense of novelty in each session and to respond to user inputs. At the end of the treatment session, the program produces a printout that summarizes the work the user has done on each problem, including his or her action plans, plus a day-by-day schedule of enjoyable activities for the coming week.

The program's interfaces are designed for ease of use: where free text entry is requested, no other options are available to the user; where menus are used, five or fewer choices are generally made available. Nonetheless, in the background a highly complex program is running, with substantial branching of video and audio, failure analysis algorithms, and data handling methods that adapt to the user's clinical status and problem-solving history within *ePST*.

Fogg and colleagues have identified factors that engender users' trust in software or websites and found that the credibility depends largely on three factors: (1) the usability of the program (especially that it does what the user expects it to do at any given moment), (2) the brand or source behind it, and (3) the professionalism of the interface and media [21,22]. If a program behaves in an unpredictable manner, is presented by an unknown entity, or looks amateurish, users are unlikely to trust it. An effort was made to enhance the credibility of *ePST* by addressing these three domains: (1) the program was designed to be simple to use and went through initial usability testing by persons who had been treated for depression, (2) familiar brands are referenced in the program (Harvard, NASA, Dartmouth), and (3) the video and audio for *ePST* were produced in a broadcast television facility, meeting industry standards for production values, and *ePST*'s interfaces were developed by professional graphic artists.

The initial version of the program was delivered via universal serial bus flash drive, which is a convenient format for astronauts, since they often train in settings without Internet access, and bandwidth on space missions is limited. However, *ePST* can readily be adapted for delivery via the Internet.

Figure 1. Virtual therapist discusses the Patient Health Questionnaire-9 (PHQ-9) results with the user. Information is provided both graphically and on video.

Unique Characteristics

ePST advances the field of computer-automated interventions for depression by (1) approximating actual treatment via the use of rich media, (2) minimizing the amount of text that a user needs to read, and (3) performing failure analyses to assist users to improve their problem-solving effectiveness.

Rich Media and the Approximation of Therapy in ePST

Information richness refers to "the potential information carrying capacity of data" [23]. Media can be ranked on richness by the number of channels of communication they employ: verbal (the words said), paraverbal (how they are said), and nonverbal (body language) communication [24]. Although some information is best conveyed by text (eg, procedures or numerical data), emotionally laden information is more effectively communicated with richer media [25]. Psychotherapy falls into the latter category. Through rich media (branching video and audio clips tailored to users' inputs), a conversation is approximated between the user and a competent, caring therapist. The intent is to make the *ePST* program feel more like interacting with a person than with a computer. *ePST* contains 148 video and 225 audio clips, although each user receives only a fraction of them, based on his or her clinical status and what he or she does in the program.

Minimization of Text in ePST

Although *ePST* was created for one of the most highly educated groups of individuals in the world—astronauts—it requires less reading skill than most self-help programs, due to the extensive use of audio and video. Text on the screen is written at a low literacy level, mainly limited to labels and occasional short sentences. The user does need to be able to input free text to write his or her own problem statement, goals, and action plan; however, proper grammar and spelling are not required. The writing skill necessary is comparable to that required for sending text messages or emails.

Failure Analyses in ePST

In in-person problem-solving treatment, a therapist guides the client and provides feedback on how he or she could improve on problem solving. However, without a therapist, the challenge of *ePST* is to guide users through the process of problem-solving treatment while simultaneously teaching them how to evaluate and improve their own work. Failure analysis is a process of examining failures, identifying reasons for them, and planning how to prevent them in the future. It is used in engineering [26], business [27], and software design [28,29]. Through failure analysis algorithms in *ePST*, the computer assists users to identify ways to improve their problem solving in general and where to revise work on specific problems, much as a live therapist would do. In this way, *ePST* tailors each session to what the user has done in the program, thus far.

Pilot Study Research Questions

The primary purpose of the pilot study was to test research methods and collect preliminary data on which to base a larger clinical trial of *ePST*. As such, we posed the following research questions, noting that the number of participants would likely not be sufficient to test hypotheses: (1) To what extent do participants find *ePST* to be usable? (2) To what extent do participants find *ePST* to be acceptable and credible? and (3) To what extent do participants who use *ePST* improve in depression, compared with those who do not use it?

Methods

We conducted a feasibility study to establish the methods to be used in a future clinical trial and to elicit initial reactions to the program. The study was conducted at the General Clinical Research Center at Beth Israel Deaconess Medical Center in Boston, MA, USA, and was approved by its institutional review board.

Participants

Because there are fewer than 100 astronauts [30] (and most do not have depression at any given point), it is necessary to study persons who bear some demographic similarities to astronauts. To support generalization from the test population to astronauts, each participant was between the ages of 30 and 60 years, had completed at least 4 years of college, used a computer at least twice per week, and read and spoke English well enough to use the program. We enrolled only persons meeting the *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition, text revision (DSM-IV-TR) [31] criteria for minor depression and scoring higher than 10 (moderate or worse depressive symptom severity) on the self-report 17-item Hamilton Depression Inventory (HDI) [32].

Exclusion criteria were a history of bipolar disorder or schizophrenia, current substance abuse or dependence, dysthymic disorder, or neurological disorders. Study participants with active suicidal ideation, self-injurious behavior, or previous suicide attempts were also excluded.

Procedures

We sent 500 email messages to persons listed on a registry of those interested in receiving information about clinical trials for depression. Of these, 104 persons responded. A total of 54 phone screening interviews (to establish age, education, computer experience, and exclusionary diagnoses obtained by history) were successfully completed. Others did not respond to messages. Of the 54 persons screened, we excluded 40 (26 lacked the required education level, 5 reported suicidal ideation or attempts, 4 were excluded for other psychiatric or medical conditions, and 5 were unavailable during the study timeframe). All persons excluded from the study were provided a list of referrals for treatment. This left 14 individuals, who were invited for in-person evaluation. All 14 met eligibility criteria and were enrolled in the study. We randomly assigned 7 participants to each condition.

We conducted the Mini-International Neuropsychiatric Interview (MINI) [33] to establish enrollment eligibility. After enrollment, a baseline assessment was administered and participants were assigned to the waitlist control or *ePST* experimental groups using block randomization to ensure equal numbers of participants in each group. Because the number of available participants was small, we made no attempt to balance groups on any variable.

Participants in the *ePST* condition were requested to use the program weekly on site at the clinic, although they were permitted to schedule sessions less frequently. However, we decided a priori that a longer than 3-week interval between sessions would be considered a protocol violation. We contacted persons in the waitlist (control) group 3 weeks after enrollment to assess depression and safety. A follow-up assessment of depression was conducted at week 6 for control group participants and at posttreatment 1 week after the final *ePST* session (nominally at 7 weeks) for *ePST* group participants. We conducted an additional follow-up with those in the *ePST* group 4 weeks after they completed *ePST*. Participants received payment based on the number of times they were required to visit the clinic: nine times for the *ePST* participants for a total of US $470 and twice for the waitlist participants for a total of US $170. Following the week 6 assessment, waitlist participants were offered off-study use of the *ePST* program.

Measures

Mini-International Neuropsychiatric Interview

The MINI is a short structured diagnostic interview for DSM-IV-TR psychiatric disorders [33]. The MINI demonstrates strong diagnostic concordance with the structured clinical interview for the *Diagnostic and Statistical Manual of Mental Disorders*, 3rd edition, revised, diagnosis of major depression, with Cohen kappa of 0.84, and sensitivity (0.96), specificity (0.88), positive predictive value (0.87), and negative predictive value (0.97) likewise strong [33]. We used the MINI in the enrollment interview only.

Hamilton Depression Inventory-17 Item

The HDI [34] is a self-report measure of 17 depressive symptoms used to assess depressive symptom severity over the previous 2 weeks. It emulates the 17-item clinician-administered Hamilton Depression Rating Scale (HDRS) [35]. The response format for individual items varies in scoring from 0 to 2 or 0 to 4 regarding frequency and severity of symptoms, and a total score algorithm is modeled after the HDRS. Scores range from 0 to 53. Consistent with the HDRS, in the HDI scores less than 7 are considered normal, 8-13 indicate mild depression, 14-18 indicate moderate depression, and scores above 18 indicate severe depression.

The HDI shows strong internal consistency (coefficient alpha = .91), strong test–retest reliability (r = .96), and strong convergent validity with the clinician-administered HDRS (r = .95) and the self-administered Beck Depression Inventory (developed by Beck and colleagues in 1961) (r = .92). Factor analysis showed an expected loading of the majority of items on one factor characterized as “depressed mood-demoralization,” which accounted for 43% of the variance in the measure [34].

System Usability Scale

The System Usability Scale (SUS) is a 10-item self-report measure of the ease of using computer programs [36,37]. Items are scored on a 5-point scale (0-4) on the strength of agreement with each of 10 statements (eg, “I found the system unnecessarily complex,” “I felt very confident using the program”). Cronbach alpha for interitem agreement is a robust .91. Factor analysis shows only one significant factor, suggesting that the overall score is the best measure of usability. The sum of the individual items (range 0-40) is multiplied by 2.5 to obtain the total score, ranging from 0 to 100, with higher scores indicating better usability. The scale was administered to *ePST* participants after session 1 and session 6 of *ePST*.

Credibility Questionnaire

The Credibility Questionnaire (Cred-Q) is a 9-item survey created for this study from several sources. It comprises questions from the research of Fogg and colleagues [22,38] used to assess the credibility of computer programs in general, plus questions about psychotherapy credibility developed by Borkovec and Nau [39]. It also includes 2 items from an in-person problem-solving treatment acceptability study by Thornett and Mynors-Wallis [40]. Examples from the scale are “How much do you believe what the program tells you?” and “How much do you trust the program to help you?”, to which the user responds on a 10-point scale (1 = not at all; 10 = completely). The Cred-Q was administered at week 7 to the *ePST* participants.

Assessment of Self-Guided Treatment

The Assessment of Self-Guided Treatment (AST) is an unpublished measure (written personal communication with C Zayfert, PhD, The Geisel School of Medicine at Dartmouth, August 2003) that we adapted for this study to assess the acceptability of the *ePST* self-guided treatment program. This instrument included 16 statements (eg, “Doing problem-solving treatment using this program was acceptable to me,” “I would feel comfortable using this program without a clinician’s supervision”) that the user responded to on a 7-point scale, which ranged from 1 (strongly disagree) to 7 (strongly agree).

Participants completed the HDI before using the *ePST* program and at 1- and 4-week follow-ups after completing *ePST*. The SUS was completed after sessions 1 and 6, the Cred-Q after session 5, and the AST after session 4.

Analyses

We recruited a sample of 14 participants, 7 per group. Because the primary aims of this evaluation were to gauge the usability and acceptability of *ePST* and refine the evaluation procedures, the number of participants was based on resources available, not on a power analysis. For the pilot study, due to the small sample size, nonparametric statistical analyses were conducted on all measures. These included the Wilcoxon signed rank test and the Mann-Whitney U test. Cronbach alpha was calculated for Cred-Q and AST. The numerical values are presented with mean (SD) or median (range), or both. We used the Statistical Analysis Software (SAS) program, version 9.3 (SAS Institute, Cary, NC, USA) for the analysis.

Results

Participants and Group Equivalence

As Figure 2 shows, 54 persons responded to an advertisement for the study and were screened by telephone. A total of 35 of them did not meet all inclusion criteria and 5 were excluded for other reasons; 14 participants were enrolled.

Mean HDI scores for the *ePST* group at pretreatment were 15.61 (SD 9.64), and the median score was 15.4 (range 3.2–31.1). For the waitlist control group, the mean HDI score was 18.71 (SD 6.65) and the median was also 15.4 (range 11.4–26). A Mann-Whitney *U* test indicated no significant difference in HDI scores between the groups (P = .62) at baseline. We did note demographic differences between the groups (see Table 1).

Figure 2. Consort diagram.

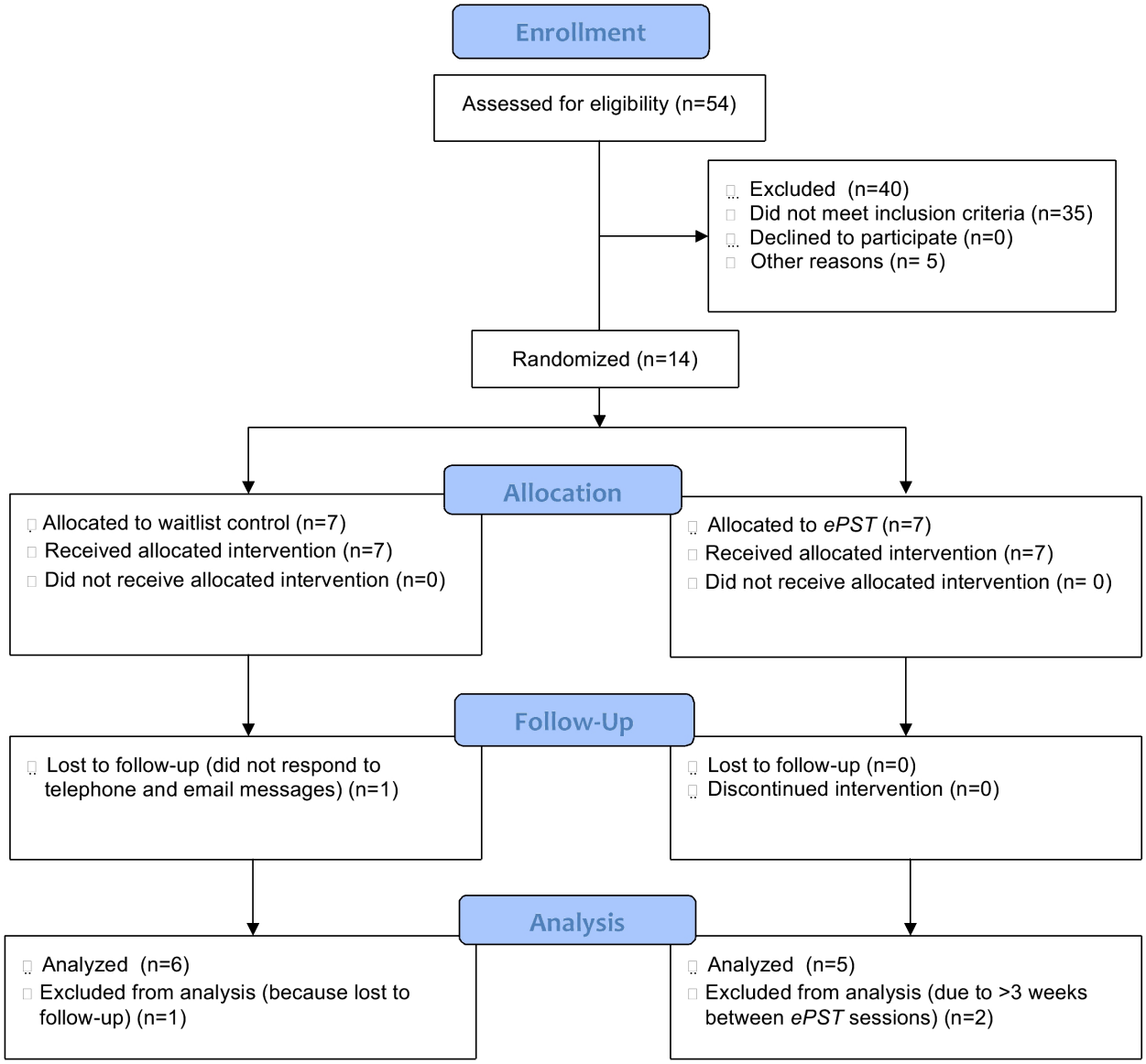


Table 1. Participant demographics.

Characteristic	Waitlist (n = 7)	*ePST*[a] (n = 7)
Age (years), mean (SD)	52.1 (7.7)	48.6 (10.2)
Female, n (%)	5 (71%)	5 (71%)
Race, n		
White	6	7
Black	1	0
Ethnicity, n		
Hispanic	2	0
Other	5	7

[a] Electronic problem-solving treatment.

Treatment Completion

One participant in the control group was lost to follow-up. All *ePST* group participants completed all *ePST* sessions and posttreatment evaluations; however, 2 persons had a gap of greater than 3 weeks between two sessions, constituting a protocol violation. They were permitted to continue using *ePST*, and we conducted separate analyses on the intent-to-treat sample (n = 13) and the subset completing treatment according to the protocol (n = 11). The mean time to complete each session was 53 (SD 31) minutes, with earlier sessions running longer than later ones.

Usability, acceptability, and Credibility

The *ePST* group completed the SUS after session 1 and session 6. On the 100-point SUS, the mean score was 80.36 (SD 19.28) and median was 85 (range 42.5–97.5) after session 1. After session 6, the mean SUS was 85.36 (SD 15.91) and median was 95 (range 57.5–100). No significant difference was found for the SUS between the two time points ($P < .09$; Wilcoxon signed rank test).

Cronbach alpha was .922 for the Cred-Q and .830 for the AST. Nonetheless, since the Cred-Q was created for this study and since data have not been previously published on the AST, an item-level analysis of those questionnaires is more appropriate than summary data. Mean and median scores for each Cred-Q item are presented in Table 2; AST scores are presented in Table 3.

Table 2. Credibility Questionnaire scores (n = 7).

Credibility item	Mean (SD)	Median (range)
How much do you believe what the program tells you?	7.71 (1.89)	8 (4–10)
How much do you trust the program to help you?	7.43 (2.23)	8 (3–10)
How competent is the program at treating depression?	7.43 (1.90)	8 (4–10)
How credible is the program?	7.71 (2.50)	8 (3–10)
How unbiased is the program?	7.57 (2.82)	8 (2–10)
How expert is the program?	7.86 (1.35)	8 (6–10)
How logical is the treatment?	8.43 (1.27)	8 (7–10)
How much do you think your depression got better?	7.14 (2.34)	8 (3–10)
How much would you recommend the treatment program to a family member or a friend?	7.86 (2.54)	8 (3–10)

Table 3. Acceptability of Self-guided Treatment Questionnaire scores (n = 7).

Item	Mean (SD)	Median (range)
I felt comfortable using the computer	6.00 (1.53)	7 (3–7)
Doing problem-solving treatment using this program was acceptable to me	6.29 (1.11)	7 (4–7)
Using the program helped me to do problem-solving treatment	6.14 (1.07)	6 (4–7)
I would rather do problem-solving treatment with a therapist than with the computer	5.00 (1.41)	4 (4–7)
I would rather use a computer to help myself privately than go to a therapist	5.00 (0.82)	5 (4–6)
Computer programs can help people with emotional problems, such as depression	5.57 (1.72)	6 (2–7)
I would feel comfortable using this program without a clinician's supervision	6.43 (0.79)	7 (5–7)
I felt safe using the program to do problem-solving treatment	5.29 (1.38)	5 (4–7)
I would feel safe doing self-guided treatment for depression on my own without a clinician's supervision	6.00 (1.00)	6 (5–7)
I would recommend this program to a friend who was also in need of treatment for depression	5.71 (0.76)	6 (5–7)
Using the program helped me to feel better	6.00 (1.29)	7 (4–7)
I believe I would feel comfortable using the program at home on my own computer	5.86 (0.90)	6 (5–7)
I felt comfortable answering questions about my depression symptoms using this program	4.14 (0.69)	4 (3–5)
Using the program helped me to cope with my depression in real life	4.86 (0.38)	5 (4–5)
I felt comfortable using this program without a clinician's assistance	5.86 (1.07)	6 (4–7)
Following the program's guidelines for in-between session tasks and homework was acceptable to me	6.14 (0.69)	6 (5–7)

Effects on Depression

At posttreatment, in the intent-to-treat analysis (n = 7), the mean HDI score for persons who received *ePST* was 8.81 (SD 5.91) and median was 6.3 (range 1.1–16.7) at posttreatment. For the *ePST* group, the mean percentage change in HDI score from baseline to posttreatment was –35.86% (SD 40.16%) (median –51.02%, range –33.87% to 79.74%). The mean HDI score for the waitlist control group at 6-week follow-up was 17.78 (SD 7.52) (median 18.55, range 8.2–28.4). The mean percentage change in depression for the control group was –11.12% (SD 18.70%) (median –17.78%, range 14.29%–28.07%; see Table 4). The difference in percentage change in depression between the two groups, using the Mann-Whitney *U* test, was not significant in the intent-to-treat analysis (P = .25). A Wilcoxon signed rank test indicated that depression scores remained stable at 4-week follow-up for the *ePST* group (P = .90), as depicted in Figure 3.

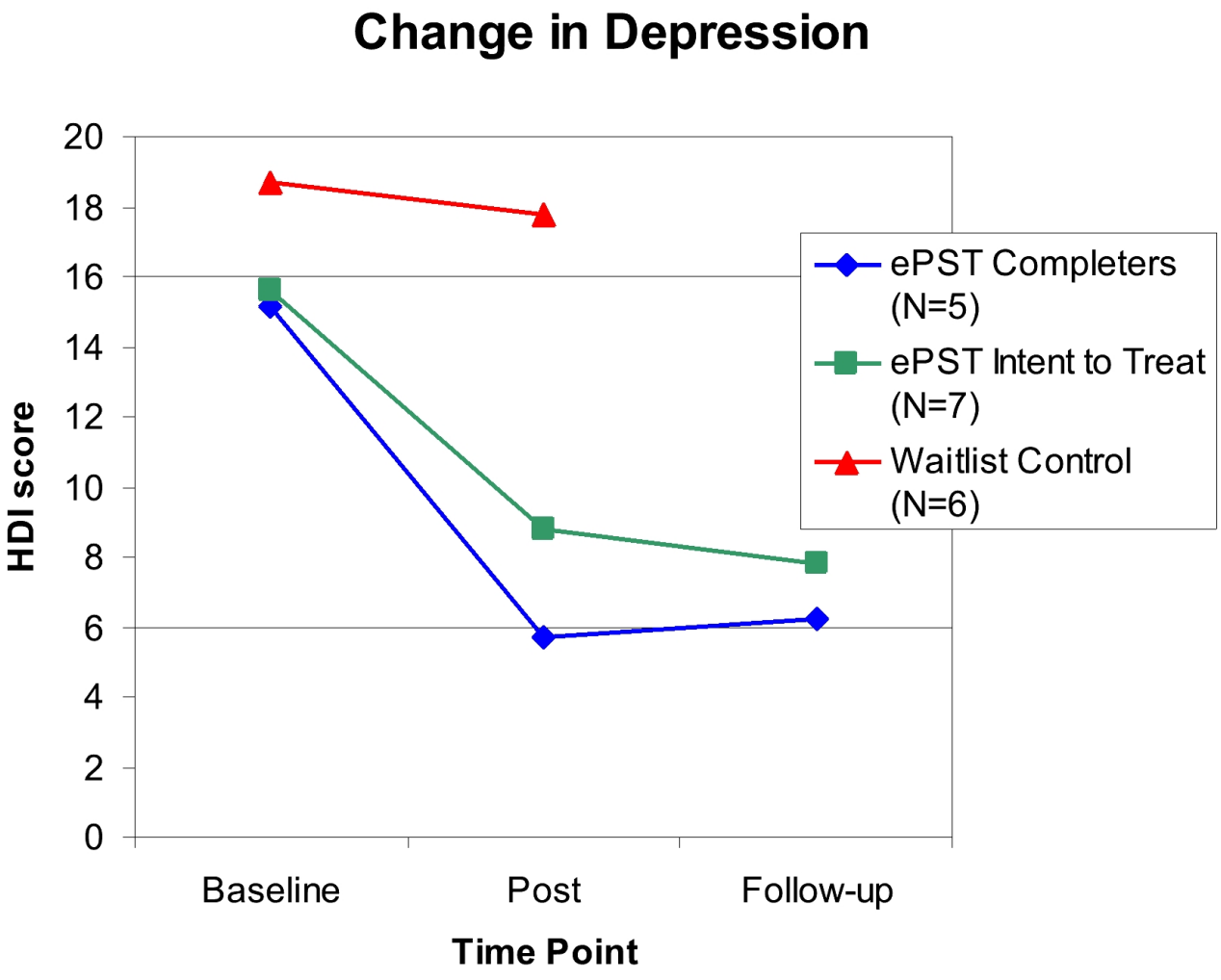
Persons who completed treatment with no more than a 3-week gap between any sessions showed a trend toward greater improvement in depression. For this subset of the *ePST* treatment group, depression decreased by an average of 52.65% (SD 28.28%) (median –61.35%, range –79.74% to –5.56%; P =.05). There was no significant difference in depression level between 1-week and 4-week follow-ups in the completer analysis (mean 6.24, SD 6.51; median 4.1, range 0.3–12.4). A Wilcoxon signed rank test indicated that depression scores remained stable at 4-week follow-up for the *ePST* group (P = .90), as depicted in Figure 3.

Table 4. Percentage change in depression as measured by the Hamilton Depression Inventory (HDI).

Group	Baseline HDI		Posttest HDI		Percentage change, baseline to posttest	
	Mean (SD)	Median (range)	Mean (SD)	Median (range)	Mean (SD)	Median (range)
ePST [a]						
*I*ntent-to-treat (n = 7)	15.61 (9.64)	15.4 (3.2–31.1)	8.81 (5.91)	6.3 (1.1–16.7)	–35.86% (40.16)	–51.02% (33.87 to –79.74)
*E*fficacy subsample (n = 5)	15.12 (11.33)	16.3 (3.2–31.1)	5.68 (3.06)	6.3 (1.1–9.6)	–52.65% (28.28)	–61.35% (–5.56 to –79.74)
Waitlist control (n = 7)	18.71 (6.65)	15.4 (11.4–26)	17.78 (7.52)	18.55 (8.2–28.4)	–11.12% (18.70)	–17.8% (14.29 to –28.07)

[a] Electronic problem-solving treatment.

Figure 3. Change in depression.



Discussion

We developed an interactive multimedia computer program to provide problem-solving treatment for depression. The program is entirely automated and does not require the involvement of a live clinician. Nonetheless, *ePST* is designed to simulate the therapy experience and to feel more like interacting with a person than with a computer. These efforts appear to have paid off, with high scores for usability, credibility, and acceptability in the pilot study. Although efficacy remains to be tested in larger studies, *ePST* appears to be a promising approach to the treatment of depression.

Usability describes the ease of use of software or other technology. In a review of 206 studies that used the SUS, the average usability score was 70.14 (SD 21.70) [37], with the upper quartile ranging from 78.51 to 93.93. The mean usability

scores in the present study were 80.4 after session 1 and 85.4 after session 6, which suggests that the program is easy to use from the outset and remains so.

Ratings on the Cred-Q suggest that participants found the program to be credible for treating their depression. In comparison, Thornett and Mynors-Wallis [40] conducted a study of problem-solving treatment and asked two of the same questions: (1) "How logical is the treatment?" and (2) "How much would you recommend the treatment to a family member or a friend?" On the 10-point scale, the median ratings for those treated by a nurse were 8 and 8, respectively, and for those treated by the general practitioner were 8 and 7, respectively. The median ratings on those questions for *ePST* were 8 and 9, respectively, which suggests similar credibility for the *ePST* program and live clinicians; however, this comparison needs to be further explored in future clinical trials.

Responses to the AST suggest that persons with depression find *ePST* to be acceptable. Of particular note were answers (on a scale of 1 to 7; strongly disagree to strongly agree) to the items "Doing problem-solving treatment using this program was acceptable to me" (mean 6.3, SD 1.1; median 7, range 4–7) and "I would feel comfortable using this program without a clinician's supervision" (mean 6.4, SD 0.8; median 7, range 5–7).

Although the pilot study was not powered to evaluate efficacy of the intervention, a decrease in depression scores was noted for persons using the *ePST* program as intended, and gains appeared to have been maintained at 1-month follow-up.

Limitations

The clinical evaluation component of this study was secondary to the technology development, in the amount of time and funding devoted to it, and was primarily intended to establish a methodology to evaluate the program in future studies. As such, the feasibility study has many limitations, including the limited sample size and unique characteristics of the sample (ie, high education and frequent computer use), inequivalent compensation and assessment time points, and lack of an active control condition. Therefore, given these limitations all conclusions must be considered to be highly preliminary, and the *ePST* program should be evaluated with a larger sample that includes an active control condition.

Although we used validated measures wherever possible, none existed for some domains of interest, and we therefore created them. The Cred-Q and AST, which were used for the first time in this study, may have been subject to response set bias. It is notable that most Cred-Q and AST item means are similar to each other, with little variability. Of note are apparently conflicting results to AST questions about preference for using a computer versus being treated by a live clinician: "I would rather do problem-solving treatment with a therapist than with the computer" (mean 5.0, SD 1.4) and "I would rather use a computer to help myself privately than go to a therapist" (mean 5.0, SD 0.8). Therefore, the Cred-Q and AST should be revised if used in subsequent studies to better detect response set. Approaches to designing Likert scales to detect and prevent response set have been advanced by Shulruf et al [41] and Barnette [42].

Future Directions and Conclusions

Future studies could directly compare the interactive media approach to delivering problem-solving treatment (which is both bandwidth intensive and costly) versus a text-based version that functions using the same logic. This could determine the merit of using interactive media, compared to the cost to produce and deliver it.

Further evaluation of the effectiveness of *ePST* is warranted; however, the question is what the best design for such as study would be. Historically, computer-automated behavioral interventions have generally been compared with a waitlist (as in this study), usual care, or live therapy. However, there are drawbacks to each of these designs. Some treatment is likely to be better than no treatment, making a waitlist control a straw man (although in many clinics patients linger on waitlists for weeks and months, making this a de facto usual care comparison). Usual care comparisons may have more real-world applicability, in which participants are randomly assigned to either use *ePST* or receive treatment as usual. But usual care varies between settings, and even within a single study group may include many interventions, such as receiving medication, intensive therapy, or nothing at all. Therefore, the usual care control is actually an amalgam of multiple types of control groups.

Randomized "John Henry" [43] (man versus machine) trials that compare *ePST* versus live problem-solving treatment clinicians following the same protocol would establish *noninferiority*. This type of data would be most useful for clinics deciding whether to deliver problem-solving treatment via computer or a live clinician (and for which patients); however, many settings do not have the resources to hire or train sufficient numbers of problem-solving treatment clinicians to meet the demand for treatment. A more useful comparison might be randomization to either *ePST* or another automated treatment of depression, now that several exist in the marketplace. Clinics that are unable to hire specialty staff may well be able to provide automated depression treatment, and few head-to-head comparisons of computer-automated depression treatments have been published.

A limitation across all of the above comparisons is that they evaluate the automated treatment as a static entity and preclude the opportunity for its improvement during the trial. The criterion-based development model proposed by Carter [44] is a cyclical model of testing and evaluating to criterion. In this model, originally for the evaluation of self-instructional interactive media programs, an a priori target level of learner performance is established, which signifies an acceptable level of mastery over a skill. Essentially, "*X*% of learners should perform skill *Y* at level *Z*." The interactive media program is then tested and revised in a spiral development model [45] until the training criteria are met. The criterion-based development model can be applied to the evaluation of self-treatment software, as well, by establishing a meaningful reduction of depression symptoms and functional impairment for users, and testing and revising the program to reach that criterion.

The advantage of the criterion-based development model over randomized trials is that evaluation data are immediately applied to the improvement of the program, maximizing the potential of the program to effect change. Rather than comparing treatment conditions, which may yield statistically, but not clinically, significant differences, evaluation group outcomes are compared with predetermined, objective standards of health and functioning. It is possible to test whether this meaningful goal is met or exceeded. Clearly there is a need for both randomized trial and criterion-based evaluations, and *ePST* should be tested using both models.

Further development of *ePST* could tailor the program to special populations, such as cancer patients, older persons, or adolescents. To increase accessibility, a range of hosts could be provided, to better match the user's demographics, including his or her language.

Although other computer-automated treatments for depression have previously been developed and shown to be effective, that does not mean work in the field should stop, any more than drug discovery should cease once an effective medication has been found for a disease. *ePST* was designed to overcome some limitations of current computer-automated therapies, such as reliance on text, limited interactivity, and little if any feeling of human connection. In doing so, it presents a model for next-generation interactive, media-based interventions.

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Conflicts of Interest

Drs Cartreine, Locke, and Hegel are co-owners of Cognitive Behavioral Technologies LLC, which owns the *ePST* program. However, this entity was created after the study was completed.

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Abbreviations

AST: Assessment of Self-guided Treatment Questionnaire
Cred-Q: Credibility Questionnaire
DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision
ePST: electronic problem-solving treatment
HDI: Hamilton Depression Inventory
HDRS: Hamilton Depression Rating Scale
MINI: Mini-International Neuropsychiatric Interview
NASA: National Aeronautics and Space Administration
PHQ-9: Patient Health Questionnaire-9
PST-PC: problem-solving treatment for primary care
SUS: System Usability Scale

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Original Paper

Decision Support and the Effectiveness of Web-based Delivery and Information Tailoring for Bowel Cancer Screening: An Exploratory Study

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Abstract

Background: Colorectal cancer (CRC) is the third most commonly diagnosed cancer in males and the second in females throughout the developed world. Population screening using fecal occult blood tests (FOBTs) facilitates early detection and greater chance of survival, but participation rates are low. We developed a Web-based decision tool to provide information tailored to an individual's decision stage for CRC screening and attitude toward screening utilizing the Preventive Health Model (PHM) and Precaution Adoption Process Model (PAPM) as theoretical frameworks for screening behavior. We describe the practical steps employed in the tool's design and the subsequent conduct of an exploratory study.

Objective: To design a decision tool for CRC screening and conduct an exploratory study among average-risk men and women to (1) test the impact of message type (tailored vs non-tailored) and message delivery modality (Web-based vs paper-based) on attitudes toward screening and screening uptake, and (2) investigate the acceptability of the decision tool and relevance of materials.

Methods: Participants (n = 100), recruited from a population sample of men and women aged 50-76 residing in urban Adelaide, Australia, were randomly assigned to a control group or one of 4 interventions: (1) Web-based and tailored information, (2) paper-based and tailored information, (3) Web-based and non-tailored (generic) information, or (4) paper-based and non-tailored information. Participation was augmented by snowball recruitment (n = 19). Questionnaires based on PHM variables were administered pre- and post-intervention. Participants were given the opportunity to request an FOBT. Following the intervention, participants discussed the acceptability of the tool.

Results: Full data were available for 87.4% (104/119) of participants. Post-intervention, perceived susceptibility scores for individuals receiving tailored information increased from mean 10.6 (SD 2.1) to mean 11.8 (SD 2.2). Scores on self-efficacy increased in the tailored group from mean 11.7 (SD 2.0) to mean 12.6 (SD 1.8). There were significant time x modality x message effects for social influence and salience and coherence, reflecting an increase in these scores for tailored Web-based participants only; social influence scores increased from mean 11.7 (SD 2.6) to mean 14.9 (SD 2.3), and salience and coherence scores increased from mean 16.0 (SD 2.2) to mean 17.7 (SD 2.1). There was no greater influence of modality or message type on movement toward a decision to screen or screening uptake, indicating that neither tailored messages nor a Web modality had superior effect. Overall, participants regarded tailored messages positively, but thought that the Web tool lacked "media richness."

Conclusions: This exploratory study confirms that tailoring on PHM predictors of CRC screening has the potential to positively address attitudes toward screening. However, tailoring on these variables did not result in significantly increased screening uptake.

Future research should consider other possible psychosocial influences. Mode of delivery did not affect outcomes, but as a delivery medium, the Web has economic and logistical advantages over paper.

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KEYWORDS

Colorectal cancer; mass screening; multimedia; communication; decision support techniques

Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed cancer in males and the second in females throughout the developed world [1]. Population screening using a fecal occult blood test (FOBT), or the second-generation fecal immunochemical test (FIT), facilitates the detection of CRC at its early stages by detecting invisible (occult) traces of blood in the feces. A recent systematic review concluded that appropriate population utilization of FOBT screening is likely to reduce death from CRC by about 1 in 6 deaths [2]. This possibility has resulted in the implementation of national pilot or population screening programs in a number of countries [3]. Effectiveness of these programs depends upon yield and participation rates—in Australia, estimates of participation in screening for colorectal cancer have been low [4]. The National Bowel Cancer Screening Program (NBCSP), which provides people turning 50, 55, and 60 years with a free FOBT, had a total participation rate over three years (June 2008 to June 2011) of 38.4% of the eligible population [5].

This paper describes the theoretical framework and practical steps we employed to design a Web-based, tailored decision tool for CRC screening, and to conduct an exploratory study to test its impact on screening attitudes and uptake prior to the design and conduct of a larger randomized trial. We examined uptake of FOBT only (versus colonoscopy or in addition to colonoscopy) because unlike other countries, such as the United States, usual CRC screening practice in Australia is by FOBT followed by colonoscopy for those with a positive result—colonoscopy is regarded as a diagnostic test rather than a screening test. We also sought to place the study in the context of the NBCSP approach, which is to encourage population-based screening using FOBT for those who do not have any obvious symptoms of bowel cancer.

Theoretical Framework

Two classes of behavioral theory are relevant to understanding uptake of new health behavior. “Stage of change” or “readiness to act” models, such as the Precaution Adoption Process Model (PAPM) [6], focus on an individual’s commitment to act. The PAPM characterizes movement toward commitment as (1) unaware of the issue, (2) heard of the issue but unconcerned, (3) considering action, (4) deciding against action, or (5) deciding to act. By contrast, “continuum” theories, such as the Preventive Health Model (PHM) [7], focus on psychosocial predictors of intention to act and on predictors of behavior. The PHM approach identifies 5 variables that affect the likelihood to act. In the context of cancer screening, these are (1) salience and coherence of the screening behavior (the perception that performing cancer screening is consistent with beliefs about how to protect and maintain health); (2) perceived susceptibility (perceptions of personal risk for developing colorectal cancer or polyps); (3) response efficacy (the belief that utilizing an FOBT will be effective in reducing disease threat); (4) cancer worries (concerns about negative consequences of undertaking cancer screening); and (5) social influence (extent to which an individual believes that those who they interact with, and whose opinions they value, support FOBT use). Research indicates that these factors are associated with the decision to screen in the United States [8], Canada [9], and Australia [10]. Two other constructs—self-efficacy and fecal aversion—are important in the context of this study. Self-efficacy, in this case the confidence to utilize the FOBT, is a significant predictor of health-related intentions [11] and behaviors [12], and fecal aversion has been demonstrated to be a predictor of FOBT uptake [13].

Research has shown that programs designed to improve screening uptake are enhanced considerably when stage theories and continuum theories are utilized together. Groups of people at a specific stage of thinking about CRC screening (PAPM) can be distinguished from people at a different stage in terms of their responses to the variables included in the PHM [14,15]. Thus, utilization of both the PAPM and PHM can enable the provision of messages that are “tailored” to individual responses with the aim of moving people to a “better” screening decision stage.

Tailored Communication

Tailored health promotion materials are “...any combination of information and behavior change strategies intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from an individual assessment” [16]. Tailored print communication is better remembered, read, and perceived as more relevant than non-tailored materials [17]. However, a recent systematic review based on two trials, found no evidence of tailored interventions on CRC screening uptake [18], although the researchers found evidence for a beneficial effect of tailored information on perception of cancer risk and knowledge of cancer. Thus, further research is required to better understand the “ingredients” of tailoring approaches on CRC screening rates.

Web Delivery of Information

Paper-based delivery of non-tailored screening messages has improved FOBT uptake [19,20] and tailoring may have the capacity to achieve further incremental improvements in uptake rates. A meta-analysis showed that computerized tailoring (feedback composed by means of computer algorithms) demonstrated improved outcomes in terms of health behaviors compared to controls [21]. Using computers to construct tailored messages can facilitate the creation of finer-grained tailored materials; without them, tailoring has been limited to few

variables because of constraints on the logistical practicality of creating a comprehensive library of messages and manipulating them to simultaneously address multiple variables [22]. Additionally, delivery via online communication channels may increase the feasibility of this individualized approach to communication through channels such as interactive feedback and simplicity of navigation to personally relevant materials. For example, a meta-analysis comparing Web-based and non-Web-based information interventions has shown enhanced outcomes among individuals using Web-based interventions, particularly in the areas of knowledge and targeted behavior change [23].

In light of the above considerations, we conducted an exploratory study to investigate whether information tailored to an individual's current decision stage for screening based on PHM variables would have a greater influence on the readiness of invitees to be screened compared with non-tailored generic information. We also sought to disentangle outcomes and investigate whether it was perceived personal relevance (through tailoring) of information, simplicity of navigation (through Web-based delivery) to access personally relevant material, or both factors that had the greater effect. The primary outcomes were (1) change in PHM scores, (2) change in PAPM decision stage, (3) intention to screen as measured by a request for an FOBT, and (4) actual uptake of screening. We were also interested in participants' opinions of the acceptability and relevance of the materials. We aimed to use results from this exploratory study to inform the design and conduct of a larger, nationwide randomized controlled trial.

Methods

Study Design

A 2 × 2 × 2 mixed model factorial design examined the influence of message type (tailored vs non-tailored) and message modality (paper vs Web) on predictors of screening (PHM variables) and stage of readiness to screen (PAPM stage) measured before and after receipt of screening messages. We planned to contact at least 750 participants to achieve a sample size deemed practical for an exploratory study (n = 125).

Pre-intervention (Time 1)

A baseline survey was taken 2 weeks before intervention. The variables measured were demographics, decision stage for screening, decisional conflict, PHM, and self-efficacy and fecal aversion variables.

Intervention

Intervention group participants received one of 4 interventions: (1) Web-based and tailored information, (2) paper-based and tailored information, (3) Web-based and non-tailored (generic) information, or (4) paper-based and non-tailored information. The factorial design is illustrated in Table 1.

Table 1. Information supplied to intervention group participants based on message type and modality.

Modality	Message	
	Tailored	Non-tailored
Web	PHM feedback and educational material	Generic information and educational material
Paper	PHM feedback and educational material	Generic information and educational material

Post-intervention (Time 2)

An endpoint survey and interviews immediately followed intervention. Variables measured were decision stage for screening, decisional conflict, relevance and navigability of the information, PHM, and self-efficacy and fecal aversion variables.

Participant Recruitment

A random subsample of 756 potential invitees aged 50-76, residing in four urban Adelaide areas, were selected (with permission) from a larger sample provided by the Australian Electoral Commission for a related study. Prior to extracting this subsample, telephone contact numbers were obtained by comparing names and addresses against information contained in the electronic White Pages telephone directory. Those persons for whom telephone contact details were not indicated were excluded, as were those whose postal code indicated they lived more than one hours' travel time from the Commonwealth Scientific and Industrial Research Organisation **(**CSIRO) laboratories. The remaining names were randomized into 4 intervention groups and 1 control group by a researcher not directly connected with the study using a computer-generated random number sequence (Microsoft Office Excel 2003).

Study Conduct

The trial commenced in August 2007 and proceeded through a number of phases.

Phase 1

A notification letter describing the study was mailed to potential participants. They were advised that they were eligible to participate if they were aged 50-76 and ineligible if they were having regular CRC screening or had ever been diagnosed with colorectal cancer or bowel polyps. Those allocated to the intervention groups were also required to have experience using a computer to search the Web and to be willing to attend the CSIRO laboratory.

Phase 2

Two weeks (+/- 48 hours) following the notification letter, attempts were made (maximum 3) to telephone individuals and recruit them to the study. A computer-assisted telephone interview (CATI) format was used to collect interview responses (Microsoft Office Access 2003). Informed consent was formally requested and recorded before commencement of the CATI. Participants answered baseline survey questions to collect background demographics and responses to other variables as described previously. Appointments were made with all but the

control group participants to visit the CSIRO laboratory and review materials concerned with CRC screening.

Phase 3

Two weeks (+/- 48 hours) later, participants attended CSIRO. They were presented with Web-based or paper-based CRC educational content, as allocated by random sampling, to work through as they wished. Additionally, one Web group and one paper group received messages tailored according to their responses to the baseline survey. The non-tailored Web and paper groups received generic information. Participants in each group were aware that the intervention might be Web- or paper-based, but those who received tailored messages were blinded to the fact that others received only generic messages. The process of developing the tailored messages and educational content is described in the Materials section. Participants were also given the opportunity to request an FOBT through either a Web link or a paper form according to intervention group.

Phase 4

Immediately following the intervention, participants were asked to complete an endpoint survey that remeasured the same variables as in the baseline survey. Control group participants were telephoned at this point (ie, approximately 2 weeks following the baseline survey) and they completed the endpoint survey through a CATI. Control group respondents whose PAPM stage was “ready to act” were regarded as having requested an FOBT kit. Those who were not ready to act were sent a letter inviting them to contact the researchers should they subsequently wish to receive an FOBT.

Phase 5

All intervention group participants completed an additional questionnaire and participated in a discussion group immediately following completion of the endpoint survey. Both the questionnaire and the discussion explored perceptions of the relevance of the information presented, ease of navigation through the materials, and satisfaction with the information they had gained. The interviews were conducted individually or as a group, depending on the number of people attending the session. The questionnaire analyses are not included here because they have been reported in a separate paper with respect to an enhanced version of the decision aid [24].

Phase 6

One day after the intervention, an FOBT was mailed to those who requested one. The remaining participants were sent a letter inviting them to contact the researchers should they subsequently wish to receive an FOBT. Receipt of completed tests was recorded by a processing center and de-identified with aggregate participation data relayed to the researchers. People who did not return their test after 6 weeks were sent a reminder letter. Those who did not return their test after 12 weeks were regarded as having not screened.

Materials

An overview of the materials developed for the study and their presentation is described subsequently, followed by specific details of the various components.

Tailored Intervention

Materials for the tailored group were a message library consisting of messages tailored to an individual user’s decision stage for screening and responses to PHM, self-efficacy, and fecal aversion variables, and generic educational content based on the NBCSP consumer information booklet. The booklet provided generalized risk information (ie, > 50 years, certain bowel conditions, and family history).

Non-tailored Intervention

Materials for the non-tailored group were a series of generic messages addressing susceptibility, response efficacy, social influence, self-efficacy and fecal aversion, and generic educational content as described above.

Web Group

Educational content was provided in hyperlink format with discrete sections. Web pages were clean and used plain language with bulleted and numbered lists, generous white space and line spacing, and large navigation indicators. Users had the ability to increase font size and to change contrast. A Web link provided the ability to order an FOBT.

Paper Group

Educational content was provided in booklet form with discrete sections prefaced with a table of contents. Pages were clean and used plain language with bulleted and numbered lists, and generous white space and line spacing. A self-complete form provided the ability to request an FOBT.

Questionnaire

A series of statements based on PHM [8,7], self-efficacy, and fecal aversion variables were prepared (Table 2). Self-efficacy was measured using 3 statements derived from previous research regarding FOBT use [7]. Fecal aversion was measured using 3 statements derived from previous research [13]. All scales had acceptable internal consistency as measured by Cronbach alpha (Table 2). All responses were measured on a 5-point Likert scale ranging from “strongly disagree” to “strongly agree.”

Table 2. Preventive health model (PHM), self-efficacy, and fecal aversion statements.

Factor	Cronbach alpha	Statements
PHM [a]		
Salience and coherence	.73	Colorectal cancer screening makes sense to me.
		Having colorectal cancer screening is an important thing for me to do.[b]
		Having colorectal cancer screening can help to protect my health.
		I will be just as healthy if I avoid having colorectal cancer screening.[c]
Social influence	.62	I want to do what members of my immediate family think I should do about colorectal cancer screening.
		Members of my immediate family think I should have colorectal cancer screening.[b]
		My doctor or health professional thinks I should have colorectal cancer screening.[b]
		I want to do what my doctor or health professional thinks I should do about colorectal cancer screening.
Cancer worries	.80	I am afraid of having an abnormal colorectal cancer screening test result.
		I am worried that colorectal cancer screening will show that I have colorectal cancer or polyps.
Perceived susceptibility	.65	The chance that I might develop colorectal cancer is high.
		Compared with other persons my age, I am at lower risk for colorectal cancer.[c]
		It is very likely that I will develop colorectal cancer or polyps.
		The chances that I will develop colorectal polyps are high.[b]
Response efficacy	.59	When colorectal polyps are found and removed, colorectal cancer can be prevented.[b]
		When colorectal cancer is found early, it can be cured.
Self-efficacy	.75	I think that doing the test would be easy for me.[b]
		Finding time to do the test would be difficult for me.[c]
		Completing the test correctly would be easy for me.
Fecal aversion	.71	Collecting feces for the purpose of bowel cancer screening is unhygienic.[c]
		Collecting feces for the purpose of bowel cancer screening is distasteful.[b,c]
		Giving a sample of feces to another person is embarrassing.[c]

[a] Preventive Health Model (PHM) construct descriptions and survey items reproduced from [8].

[b] Statements used for tailored assessment.

[c] Items were reverse coded.

Tailored Content

The steps involved in the production and presentation of tailored messages [22,25] are described subsequently.

Developing Tailoring Assessment Feedback Statements

Statements upon which tailored feedback would be based were identified. To maximize message salience and minimize message length, the item from each of the PHM factors that loaded most highly on that factor provided the message utilized [7] because previous research has established the cross-national validity of the PHM [10]. A “cancer worries” statement was not included because concern was addressed in statements derived for other variables. The fecal aversion and self-efficacy tailored feedback statements were chosen on the basis that they included aspects of all aversion or self-efficacy statements. The form of message feedback provided was determined by the strength of the rating provided by the participant. The aim was to reinforce the person when they provided feedback that was consistent with screening participation and to motivate those respondents whose ratings were inconsistent with screening participation. Progression of such messages is illustrated in Table 3; a similar series of messages was developed for each variable.

Table 3. Creating a library of tailored messages for the Preventive Health Model (PHM) factor "response efficacy" presented in order from reinforcing to motivating.

Factor	Response efficacy[a]
Tailoring statement	When colorectal polyps are found and removed, colorectal cancer can be prevented.
Strongly agree (5)	[Name], *you've told us that colon cancer screening is effective. You're absolutely right.* That is why the Australian Cancer Council recommends yearly screening for people over 50 who are of average risk. It's an important step to take to protect your health for the future, and could save your life.
Agree	[Name], *you've told us that you believe colon cancer screening is effective. You're right.* That is why the Australian Cancer Council recommends yearly screening for people over 50 who are of average risk. It's an important step to take to protect your health for the future, and could save your life.
Not sure	[Name], *you're not sure that colon cancer screening is effective. It's very effective*—that's why the Australian Cancer Council recommends yearly screening for people over 50 who are of average risk. As you are [age], it's an important step to take to protect your health for the future, and could save your life.
Disagree	[Name], *you don't think that colon cancer screening is effective. In fact it's very effective*—that's why the Australian Cancer Council recommends yearly screening for people over 50 who are of average risk. As you are [age], screening could save your life by finding early, curable cancer.
Strongly disagree (1)	[Name], *you really don't believe that colon cancer screening is effective. In fact it's very effective*—that's why the Australian Cancer Council recommends yearly screening for people over 50 who are of average risk. As you are [age], screening could save your life by finding early, curable cancer.

[a] Tailoring "fragments" shown in italics. Personalized fields indicated in square brackets.

Developing Tailoring Decision Rules

Decision rules were developed for each tailored feedback variable based on "if-then-else" logic. Messages that addressed PHM factors shown from previous research to be predictive of moving people from their current decision stage to a "better" stage [14] were given priority in the presentation of feedback to individuals, to exploit the primacy effect [26]. The two factors most strongly related to each decision stage (presented first to those in that stage) are shown in Table 4.

Table 4. Relating Preventive Health Model (PHM) factors to Precaution Adoption Process Model (PAPM) decision stage for colorectal cancer screening via fecal occult blood test (FOBT).

PAPM decision stage	PHM factors most strongly associated with decision stage[a]
Never heard of FOBT	Salience and coherence, susceptibility
Not considered FOBT	Susceptibility, response efficacy
Decided against FOBT	Susceptibility, self-efficacy
Undecided about FOBT	Salience and coherence, self-efficacy
Decided to use FOBT	Response efficacy, self-efficacy

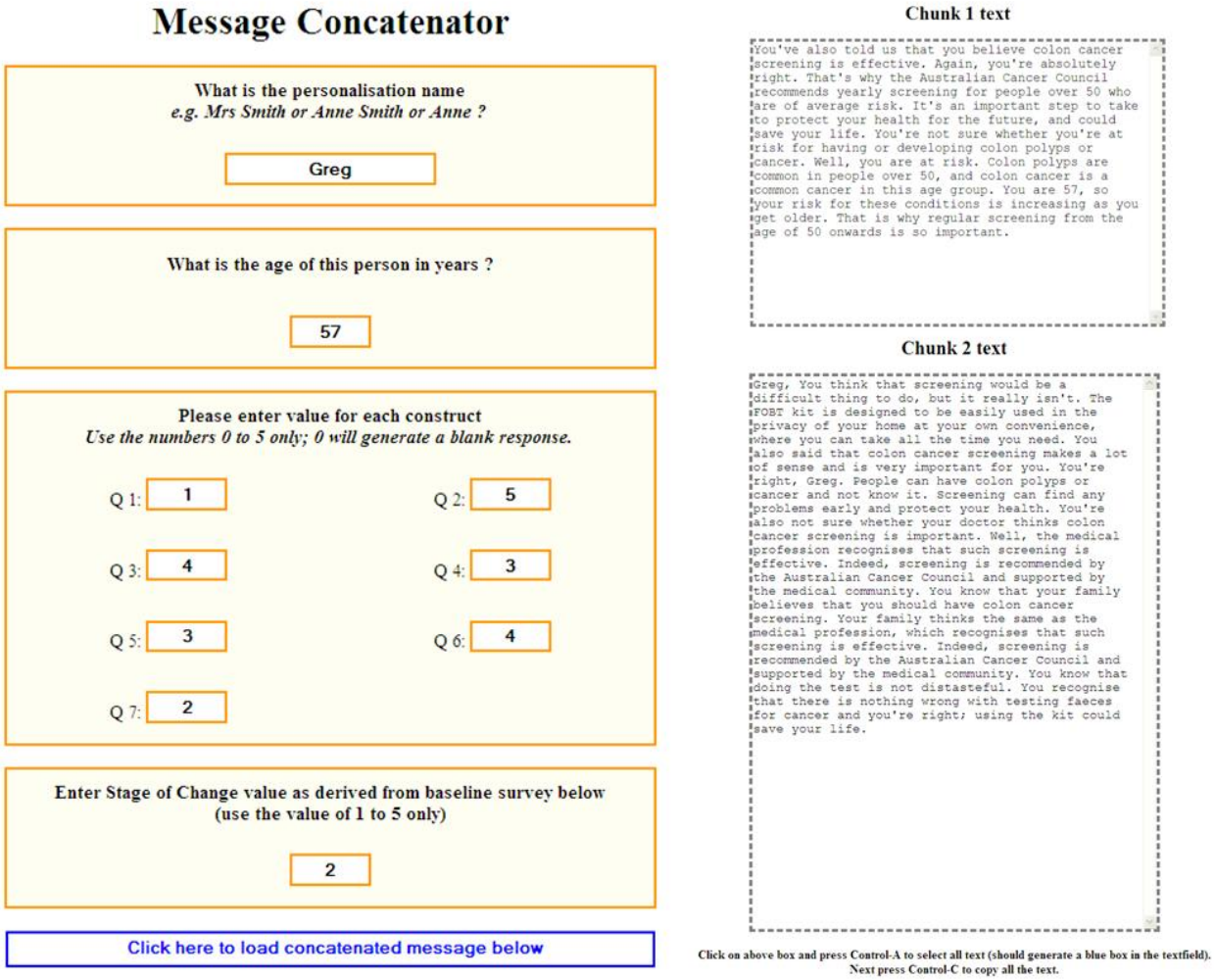
[a] Source: [14].

Preparation and Presentation of Tailored Messages

A combination of programming and manual steps ensured correct presentation of messages. From the baseline survey data, an access query obtained the participant's name, age, scores on each tailoring variable, and screening decision stage. This information was manually entered into a logic program, a "message concatenator" that accessed the message library and produced a set of personalized reinforcing or motivating messages according to scores. The messages were divided into "chunk 1" (messages addressing the factors most salient to the participant's decision stage as seen in Table 4) and "chunk 2" (messages addressing the remaining factors as seen in Table 2). The text of both sets of messages varied by individual—those at the same decision stage (having the same salient and less salient factors relating to that decision stage) may have scored those factors differently, so messages would reflect the divergence in scores. An example of a completed concatenator form and the resultant set of messages is shown in Figure 1.

As Figure 1 indicates, the underlying message–merge syntax resulted in duplication of words and phrases, concepts running together, and seemingly random placement of the personalized name and age details. These messages were subsequently edited by the first author in order to omit duplicated phrases and enhance flow between PHM factor concepts. Following is an example of a portion of the final edited message format.

Figure 1. Message concatenator entry and resulting tailored message chunks.



Chunk 1 Text, Your Information (Part 1)

Greg, you believe that colon cancer screening is effective. You're absolutely right. That's why the Australian Cancer Council recommends yearly screening for people over 50 who are of average risk. It's an important step to take to protect your health for the future, and could save your life.

However, you're not sure whether you're at risk for having or developing colon polyps or cancer. Well, you are at risk. Colon polyps are common in people over 50, and colon cancer is a common cancer in this age group. You are 57, so your risk for these conditions is increasing as you get older.

Chunk 2 Text, Your Information (Part 2)

You think that screening would be a difficult thing to do, but it really isn't. The FOBT kit is designed to be easily used in the privacy of your home at your own convenience, where you can take all the time you need.

You do think colon cancer screening makes a lot of sense. You're right, Greg. People can have colon polyps or cancer and not know it. Screening can find any problems early and protect your health.

Once edited, for the Web-based/tailored group, messages were entered into a program that displayed them on the computer screen, matched to the participant for whom they were intended. Messages bound for the paper-based/tailored group were copied and pasted into the appropriate spot in the personalized materials presented to each participant.

Generic Information and Educational Content

Generic information statements to encourage colorectal cancer screening are shown in Textbox 1.

Educational material was provided to all groups as a component of informed decision making [27]. Its content closely followed the format of information presented in the NBCSP consumer information booklet [28] and although it did not go into detail about the risks of screening (false negatives that can lead to people being wrongly assured and false positives that can result in unnecessary anxiety and diagnostic procedures), the material reproduced information that would be received by those targeted in the Australian population-based screening program. An indicative extract from the table of contents is shown in Textbox 2.

The paper group received the educational material in the form of a series of pages arranged in typical paper-based fashion (ie, with a table of contents and corresponding page numbers) and

text that progressed according to the table of contents. The Web group received the same material but as a series of headings, tabs, and hyperlinks. Web pages were designed to reflect issues of vision and cognition needs of older users; for example, the ability for text to be enlarged, contrast to be changed, and use of adequate white space [29]. A sample of the Web page is shown in Figure 2.

Textbox 1. Generic Information Statements to Encourage Colorectal Cancer Screening.

Some important messages concerning screening for colorectal cancer:

- People can have colon polyps or cancer and not even know it. Colon polyps are common in people over 50, even in those with no family history. Finding colon cancer early and removing colon polyps when they are small can prevent cancer.
- The risk for these conditions increases with age; that's why regular screening from the age of 50 onwards is so important.
- Colon cancer screening is very effective—that's why the Australian Cancer Council recommends yearly screening for people over 50 who are of average risk.
- The medical profession recognizes that such screening is effective, and supports the Australian Cancer Council recommendation for yearly screening.
- Colorectal cancer screening is easy to do. The kit is designed to be quickly and easily used in the privacy of your home at your own convenience.
- Some people may think that doing the test might be unhygienic or embarrassing, but this needn't be so. Recognizing that there is nothing wrong with testing feces for cancer and using the kit could save lives.

Textbox 2. Web- and Paper-Based Educational Content: Extract of Major Headings From the National Bowel Cancer Screening Program Consumer Information Material [28].

About bowel cancer:

- What is bowel cancer?
- How common is bowel cancer?
- What causes bowel cancer?
- What are the symptoms of bowel cancer?
- Can bowel cancer be prevented?
- Who is at risk of bowel cancer?

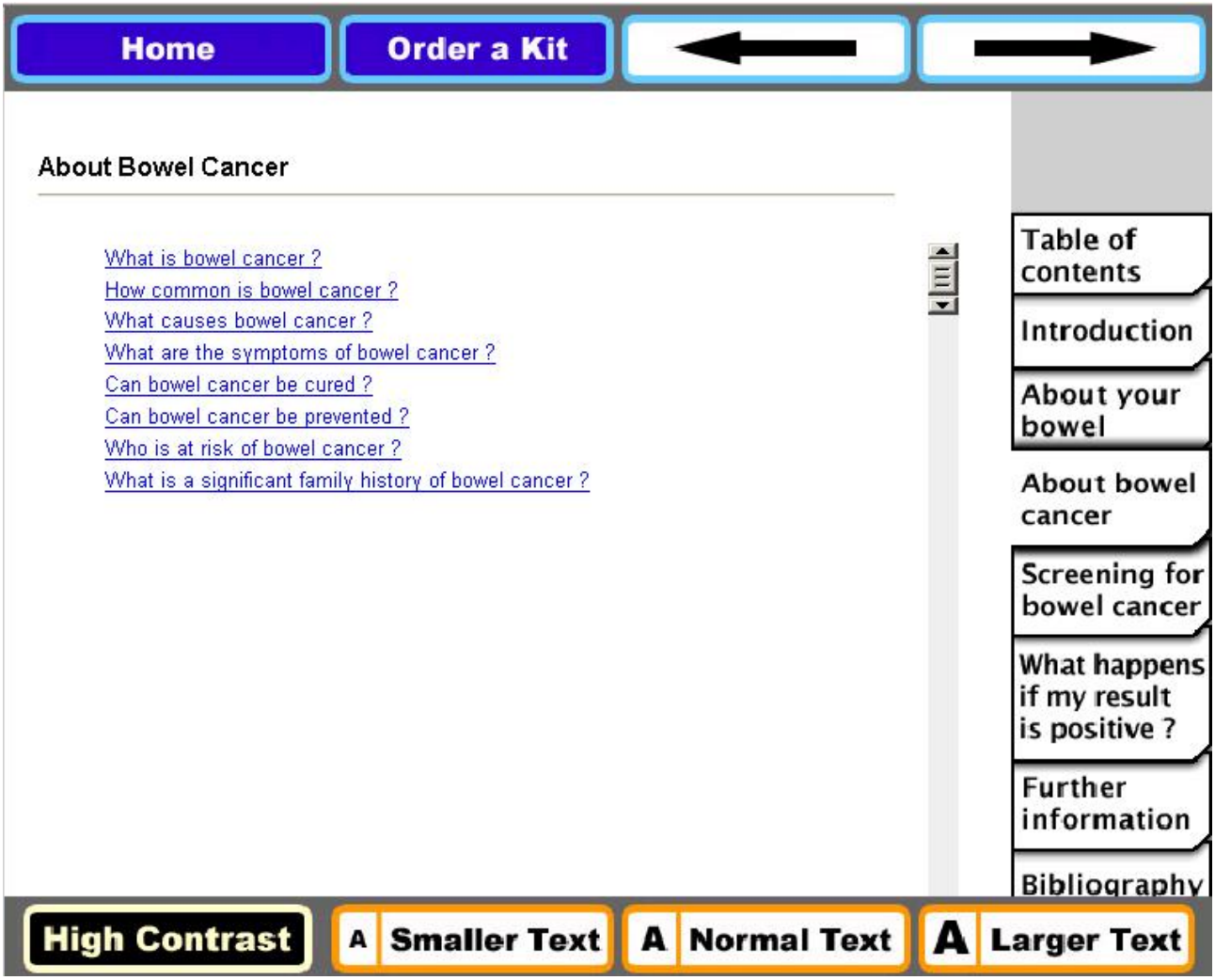
Screening for bowel cancer:

- What is screening?
- What does the FOBT involve?

What happens if my result is positive?

- What does a colonoscopy involve?
- Are there any risks from a colonoscopy?

Figure 2. Screenshot of Web-based educational content.



Screening Offer

An FOBT order form accompanied the print and Web material. Participants had the option of completing the form immediately after viewing the material and leaving the completed form with the researchers (paper group) or using a hyperlink to email their details (Web group). The screening kit included (1) a bowel cancer screening information pamphlet; (2) an immunochemical FOBT (InSure, Enterix Australia) that does not require dietary or drug restrictions; (3) a combined participant details and consent form confirming personal details, nominating a preferred doctor for follow-up, and consent to obtain clinical follow-up reports if required; and (4) a reply-paid return envelope addressed to the processing laboratory. The processing laboratory provided the researchers with de-identified FOBT receipt information.

Data Analysis

Chi-square analyses (χ^2) and one-way analyses of variances (ANOVAs) were initially undertaken to confirm group comparability at baseline. A mixed-group design ANOVA with two between-group factors—message delivery modality (Web or paper) and message type (tailored or non-tailored)—and one within-subject factor, time of measurement (baseline–time 1 and endpoint–time 2), was undertaken to examine for main effects from message, modality, and time of measurement, and their interaction on the main outcome variables. These main effects and interaction terms were examined in order to test whether attitudes and beliefs, as reflected in scores on the PHM variables and self-efficacy and fecal aversion, improved over time, and were influenced by the message delivery modality and the nature of the message. It was hypothesized that tailored messages delivered via Web modality would be associated with greatest improvement. The effect of modality and message type on categorical outcome variables (ie, decision stage movement, FOBT request, and uptake) was examined using Chi-square analyses. Participation rates were defined as “early” or “late” at a cut-off point of 6 weeks following dispatch of FOBT, and “non-return” at a cut-off point of 12 weeks. All analyses were conducted using a two-sided alpha level of .05.

Results

From a sampling frame of 756 people, 532 people were contacted at baseline. Of these, 298/532 (56.0%) declined to participate and 134/532 (25.2%) were ineligible. In total, 100/756 (13.2%) agreed to participate in the study. There was no significant difference in gender distribution (the only demographic variable obtained from non-participants) between those who declined to participate and participants ($\chi^2_1 = 0.2$, *P*

= .68). Because the numbers in the intervention groups were lower than anticipated, we resorted to "snowball" [30] recruitment (n = 19) to increase the number of participants to within approximately equal numbers in each group. "Snowballing" is a chain-referral method whereby a study participant who fits the eligibility criteria uses their social networks to recruit participants with similar characteristics. Those participants then recruit others, resulting in a process analogous to a snowball rolling down a hill. Subsequently, 15 participants (2 in the paper/non-tailored, 5 in the paper/tailored, 6 in the Web/non-tailored, and 2 in the Web/tailored groups) did not attend the laboratory for the intervention. Therefore, full data were available for 95.7% (104/119) of participants. Although "snowball" recruits comprised 17.3% (18/104) of the final sample and varied between groups, there were no significant differences between groups for gender, mean age, education, Australian birth, marital status, and awareness of FOBT (Table 5).

Table 5. Comparison of groups across conditions.

Demographic	Condition					χ^2 (df)	*F* (df)	*P*
	Paper		Web		Control (n = 20)			
	Non-tailored (n = 22[a])	Tailored (n = 21[b])	Non-tailored (n = 20[c])	Tailored (n = 21[d])				
Gender, n (%)						4.34 (4)		.36
Male	15 (68)	10 (48)	10 (50)	8 (38)	9 (45)			
Female	7 (32)	11 (52)	10 (50)	13 (62)	11 (55)			
Education level, n (%)						8.53 (8)		.38
Some high school	6 (27.3)	7 (33.3)	4 (20)	7 (33.3)	10 (50)			
Completed high school/trade	6 (27.3)	6 (28.6)	8 (40)	7 (33.3)	8 (40)			
University	10 (45.4)	8 (38.1)	8 (40)	7 (33.3)	2 (10)			
Place of birth, n (%)						7.01 (4)		.13
Within Australia	18 (81.8)	15 (71.4)	13 (65)	18 (85.7)	19 (95)			
Outside Australia	4 (18.2)	6 (28.6)	7 (35)	3 (14.3)	1 (5)			
Relationship status, n (%)						1.79 (4)		.77
With partner	18 (81.8)	15 (71.4)	17 (85)	15 (71.4)	15 (75)			
Single	4 (18.2)	6 (28.6)	3 (15)	6 (28.6)	5 (25)			
Heard of FOBT, n (%)						2.32 (4)		.68
Never heard of FOBT	11 (50)	9 (42.9)	10 (50)	12 (57.1)	13 (65)			
Heard of FOBT	11 (50%)	12 (57.1)	10 (50)	9 (42.9)	7 (35)			
Age, mean (SD)	61 (7.0)	62 (6.4)	60 (6.2)	59 (7.9)	62 (6.8)		0.75 (4.99)	.56

[a] Snowball (n = 1).

[b] Snowball (n = 6).

[c] Snowball (n = 6).

[d] Snowball (n = 5).

Change in PHM Scores

Initial examination of movement in attitudes and beliefs of the control group across time were examined using related samples *t* tests. No significant changes were observed, suggesting that scores on PHM variables and fecal aversion and self-efficacy, without intervention, were all stable and reliable across time.

Descriptive statistics for intervention groups according to condition (ie, 2 × 2 × 2) are presented in Table 6, and the results of the repeated measures ANOVAs are presented in Table 7. Overall, there was a significant change in scores pre- and post-intervention for all variables. However, there were no significant time × modality interactions, indicating no difference

between groups due to receiving paper versus Web-based information. There were significant time × message interactions for both perceived susceptibility and self-efficacy. Perceived susceptibility scores for individuals receiving tailored information increased from mean 10.6 (SD 2.1) to mean 11.8 (SD 2.2). Scores on self-efficacy increased in the tailored group from mean 11.7 (SD 2.0) to mean 12.6 (SD 1.8). There were significant time × modality × message effects for social influence and salience and coherence, reflecting an increase in these scores for tailored Web-based participants only: social influence scores increased from mean 11.7 (SD 2.6) to mean 14.9 (SD 2.3) and salience and coherence scores increased from mean 16.0 (SD 2.2) to mean 17.7 (SD 2.1).

Table 6. Means and standard deviations on all PHM, fecal aversion, and self-efficacy outcome variables according to condition.

Outcome variable	Message type	Pre-intervention modality		Post-intervention modality	
		Paper mean (SD)	Web mean (SD)	Paper mean (SD)	Web mean (SD)
Salience and coherence	Tailored	16.4 (2.5)	16.0 (2.2)	16.6 (2.3)	17.7 (2.1)
	Non-tailored	17.0 (2.3)	15.8 (2.4)	17.6 (1.8)	16.1 (2.5)
Cancer worries	Tailored	6.3 (1.6)	5.2 (2.1)	5.9 (1.9)	4.3 (2.1)
	Non-tailored	4.5 (2.1)	5.0 (1.9)	4.4 (1.8)	5.0 (1.9)
Perceived Susceptibility	Tailored	10.4 (2.1)	10.8 (2.1)	11.4 (2.1)	12.3 (2.3)
	Non-tailored	10.9 (1.6)	10.8 (2.3)	11.0 (2.2)	10.9 (2.1)
Response efficacy	Tailored	7.5 (1.1)	7.7 (1.1)	8.0 (1.2)	8.1 (1.1)
	Non-tailored	7.4 (1.0)	7.7 (1.3)	8.1 (1.3)	8.2 (1.0)
Social influence	Tailored	13.5 (1.9)	11.7 (2.6)	14.5 (2.0)	14.9 (2.3)
	Non-tailored	12.7 (2.7)	12.9 (2.6)	14.9 (2.5)	14.1 (2.9)
Self-efficacy	Tailored	11.7 (2.2)	11.7 (1.9)	12.1 (1.6)	13.0 (1.9)
	Non-tailored	12.5 (1.3)	11.9 (1.4)	12.4 (1.4)	12.2 (1.5)
Fecal aversion	Tailored	9.5 (2.5)	10.4 (3.0)	10.4 (2.6)	11.4 (2.8)
	Non-tailored	11.2 (2.0)	10.3 (2.1)	11.9 (2.2)	10.6 (2.7)

Table 7. Repeated measures ANOVAs comparing pre- and post-intervention group scores.

Outcome variable	Time[a]		Time × Modality		Time × Message		Time × Modality × Message	
	$F_{1,80}$ [b]	*P*	$F_{1,80}$ [b]	*P*	$F_{1,80}$ [b]	*P*	$F_{1,80}$ [b]	*P*
Salience and coherence	10.28	< *.001*	1.62	.20	1.04	.31	4.25	*.04*
Cancer worries	5.86	*.02*	0.28	.59	2.90	.09	0.88	.35
Perceived susceptibility	11.15	< *.001*	0.27	.60	7.11	*.01*	0.52	.47
Response efficacy	14.49	< *.001*	0.15	.69	0.41	.52	0.31	.57
Social influence	65.80	< *.001*	1.54	.22	0.50	.48	11.03	< *.001*
Self-efficacy	8.62	< *.001*	3.21	.08	4.74	*.03*	0.58	.45
Fecal aversion	16.60	< *.001*	0.15	.70	1.27	.26	0.42	.52

[a] Time effect refers to pre- and post-intervention scores.

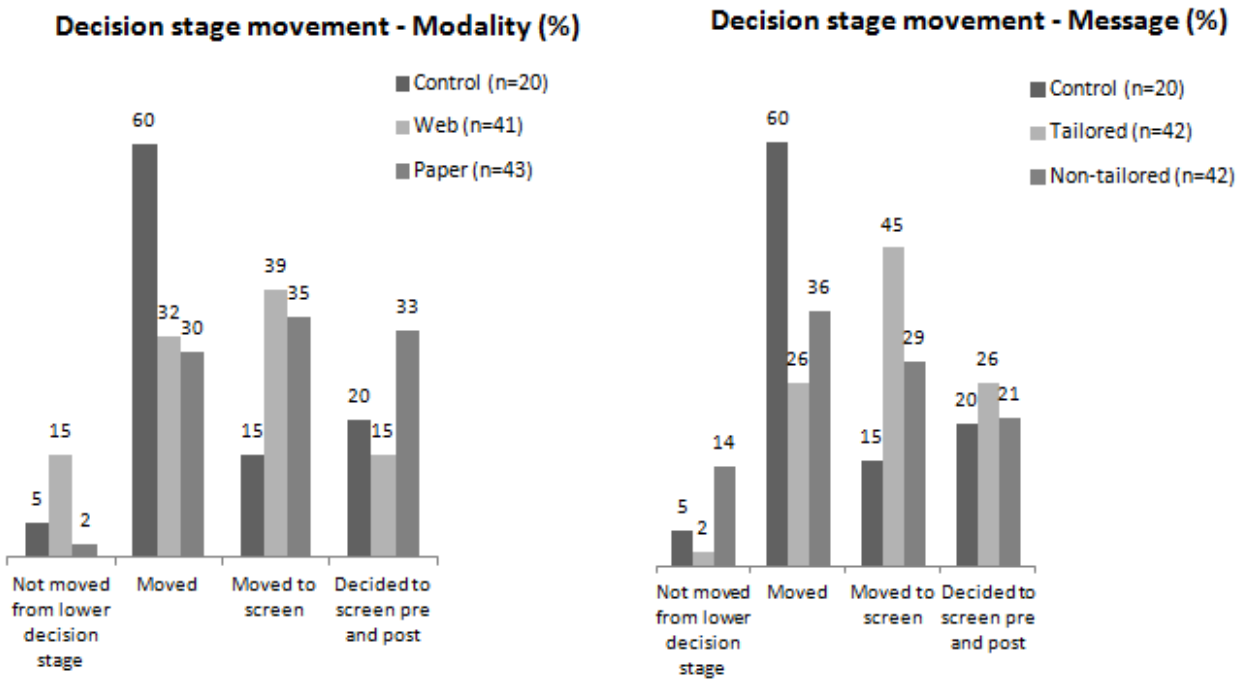
[b] *F* test for statistical difference between > 2 groups.

Movement in PAPM Decision Stage

Movement in the PAPM decision stage from pre- to post-intervention was measured for modality and message separately, and included the control group (Figure 3, shown as a percentage of group). A greater percentage of the control group "moved" compared to intervention groups; however, they moved from "unaware of the issue" to only "heard of the issue but unconcerned." Although a similar percentage of Web- or paper-based participants moved to deciding to screen, a greater percentage of those receiving tailored (vs non-tailored) messages moved to deciding to screen. Post-intervention movement of intervention groups was further dichotomized as "moved to screen" versus "other movement type" and excluded those who had decided to screen pre- and post-intervention (n = 20). A Chi-square (with Yates continuity correction) analysis indicated no significant difference for either modality ($\chi^2_1 = 0.2$, $P = .62$) or message ($\chi^2_1 = 2.3$, $P = .13$), indicating that Web or tailored

delivery was no more effective than paper or non-tailored delivery in moving people toward a decision to screen.

Figure 3. Movement in decision stage post intervention.



FOBT Participation

Including the control group, FOBTs were requested by 58.7% (61/104) of participants at the interview and by another 9 participants following the interview (overall request rate 67.3%, 70/104). Completed FOBTs were returned by 58.6% (41/70) of participants over a period of 14.1 weeks (mean 4.9 weeks). Of the kits returned, 65.9% (27/41) were received within 6 weeks ("early"). For the intervention groups, there was no significant difference in modality (Web vs paper) or message (tailored vs non-tailored) for FOBTs requested or returned (Table 8).

Table 8. Request and return of fecal occult blood tests (FOBTs) by intervention group.

	Modality				Message				Control
	Web n = 41	Paper n = 43	χ^2_1	*P*	Tailored n = 42	Non-tailored n = 42	χ^2_1	*P*	n = 20
FOBTs requested	28	34	0.8	.38	34	28	1.5	.21	8
FOBTs returned	18	18	0.0	.99	22	14	2.4	.12	5

Participant Interviews

Interviews were conducted with all intervention group participants by IF and EH, in groups or alone according to number of participants at each session. They discussed issues relating to acceptability of the information, particularly the tailored messages, and acceptability of the website.

Impact of Tailored Message

Respondents who received tailored information had a positive impression overall. The tailored information was viewed as an acceptable substitute for a one-on-one conversation:

> *It was really in response to the information I had given, and, it wasn't patronizing but it was really just confirming...Yes, I think that approach is beneficial. It drags you in; it's like having a conversation.* [male, Web/tailored group]

The fact that the tailored information addressed an individual's specific responses was positively regarded:

> *I think it reinforced things for me...I'd made one comment that I perhaps agreed or disagreed, but this was actually telling me why it was different...So for me it's a more direct approach and I found that very useful.* [female, Web/tailored group]

Although some participants did experience the receipt of tailored information as somewhat confronting:

> *I sort of didn't realize what I had said. Well, I think probably I've thought about it since, and thought well that was a stupid statement to make...it was just a bit*

> *strange seeing things that I'd said.* [female, paper/tailored group]

Acceptability of the Website

The presentation of the Web tool was described as requiring improvement:

I'd be looking for clear indication on the site that gave me very quickly, very clearly without a lot of words, what I've gotta [sic] *look for and what I can do to find out. It was a bit long and a bit wordy—trying to put too much information. You can do more with pictures than you can do with words.* [male, Web/non-tailored group]

> *...it wasn't very exciting. It was very boring...there weren't any pretty pictures, it was sort of, you know—very basic.* [female, Web/non-tailored group]
>
> *I think beige would be more exciting!* [male, Web/non-tailored group]

Impact of Educational Content

Some male participants were surprised to learn that CRC and prostate cancer incidence rates are similar. This suggested some men were more aware of prostate cancer screening and considered themselves more at risk for prostate cancer than CRC:

It rose [sic] *my awareness. I'm now aware that that's a test that I should be looking for. And put it in the same bracket as prostate cancer, whereas it was not even on my radar.* [male, paper/tailored group]

When I saw the graph and I saw prostrate [sic] *cancer and I saw bowel cancer and they were almost identical, can't remember the exact numbers, but they were almost identical in terms of amount.* [male, Web/tailored group]

Discussion

This exploratory study tested the relative efficacy of Web-delivered, tailored messages about CRC screening and FOBT use on beliefs about and attitudes toward screening in comparison to paper-delivered tailored messages and non-tailored messages delivered by both paper and Web. In addition to changes in PHM variable scores, outcomes included changes in decision stage for screening, FOBT requests, and participation.

After the interventions, there was an improvement in PHM variable scores for all groups except the control group, who received no information. For the intervention groups, all mean scores significantly moved in the desired direction (eg, decreased cancer worries or increased support for cancer screening identified in all other psychological variables). Although not influencing every factor, receipt of tailored messages increased perceived susceptibility and self-efficacy and increased both salience and coherence and social influence when combined with Web delivery. Perceived susceptibility has been shown to be a predictor of intention to screen [31,32]. Similarly, a person's confidence in their capacity to act (self-efficacy) is widely reported as a predictor of actual health behavior participation [33] and has been shown to moderate the relationship between intention, planning, and action [34,35]. Thus, it appears that messages tailored to individual levels of these important factors have a greater likelihood of beneficially influencing screening behavior than more generic messages. Salience and coherence and social influence are also important behavioral determinants of screening [8]; it is unclear how Web delivery interacted with tailoring to improve these scores.

Overall, there was no indication of a modality effect for PHM factors; the delivery channel alone (paper or Web) had no direct influence on score changes. Web delivery enables a shift from the use of static material to a dynamic interactive resource [36] that could be expected to provide more sophisticated and effective decision support. Qualitative data suggests that the site may not have fulfilled expectations with regard to "media richness." "Rich" media are generally characterized by the capacity for immediate feedback, the capacity to transmit multiple cues, the use of language variety, and capacity of the medium to have a personal focus [37,38]. The Web-based educational content of the decision support tool was designed to be comparable with the paper version, with only the presence of hyperlinks differentiating the modes of transmission (Figure 2). Interview feedback suggested participants found the information "boring" and "dry" in comparison to other websites and this may have affected their level of engagement. This result highlights the need to ensure that Web-based information is presented in media-rich format that users have come to expect, albeit with due consideration of the needs of the target age group (eg, issues of cognition, readability, vision, and disability) [29].

Regarding movement in decision stage, more people in the control group moved from "never heard of FOBT" to no further than "not considering" FOBT. This result corresponds with the control group's lack of movement in PHM scores and clarifies that the act of being asked to just think about the factors associated with screening without accompanying more specific information is unlikely to encourage screening uptake. Although there was greater movement toward a decision to screen in the intervention groups, no one modality or message type was more effective than the other. The lack of effect of Web versus paper delivery could be ascribed to the previously mentioned lack of expected Web-based richness of information. However, receipt of tailored messages, compared to non-tailored material, had a beneficial effect on several PHM factors and could be expected to increase intention to screen.

Despite a growing evidence base showing that tailored messages are superior to generic messages in their ability to influence health behavior [39], the mechanisms by which tailoring works is still unclear [40]. Tailored feedback can take different forms—descriptive, comparative, evaluative, or a combination [25,41]—and their relative effectiveness may differ between individuals. For example, some study participants found our descriptive approach (providing feedback on what is known about the recipient based upon their PHM responses) confronting (eg, it was a "...bit strange seeing things that I'd said") and the language may have lacked empathy. Message framing may also have an influence. For example, Akl and colleagues [42] in their systematic review noted that loss messages (vs gain messages) led to more positive perception of effectiveness for screening messages. Others have found that differing presentation of risk

factors (absolute vs comparative) had an impact on intention to screen [43], and message order was found to influence responses to breast cancer information [44]. Further research to test the effects of different types of message feedback, framing, and presentation order using both behavioral and communication theories [45,46] in the CRC screening context would help "unpack" the mechanisms through which tailoring has an influence.

The FOBT request and uptake rates, although greater than the control, were no different for modality or message type. Only slightly more than half of the FOBTs requested were returned. Although it is generally accepted that intention to screen is a necessary precursor of action, other variables amenable to tailoring may exert a greater influence on screening uptake. For example, in a group of people committed to screening we found that, in conjunction with self-efficacy, commitment explained only 8.0% of variance [47], and others have found that life difficulty variables were better predictors of action than intention [48]. Other researchers have approached the choice of tailoring variables in other ways (eg, by targeting the most important barriers identified by participants themselves [49]).

We did not test whether knowledge of bowel cancer and screening was enhanced through provision of the educational material, or whether such knowledge helped participants decide whether or not to screen. Knowledge is a critical component of informed decision making; however, as Jepson and colleagues [50] point out, a tension exists between the need of a screening program to attain high rates of uptake and the promotion of informed choice—an individual with whom information about the explicit risks and benefits has been shared may choose not to undertake screening (as in the case of prostate cancer screening [51]). Although acknowledging the ethical imperative of being able to make an informed choice, it is unclear whether increased knowledge alone actually influences uptake. Increased knowledge does not necessarily translate into action. This fact has been demonstrated with respect to bowel cancer screening [52,53], other screening behaviors [50,54-56], and organ donation [57].

Regardless of the relative lack of effect of Web-based delivery, from a practical perspective, using the Web as a delivery medium for tailored information has significant advantages over tailoring via paper. Material and decision rules can be created and updated more easily and economically, thus maintaining currency for a longer period, and the interaction required for obtaining relevant information and providing tailored feedback can occur in the one session. This creates a "real time" interaction that can be linked to immediate behavior activation (eg, ordering an FOBT online). Older people are increasingly using the Internet. An earlier study we conducted found that more than half the population over 50 years in South Australia had access to the Internet at some location [58]. Others have found that in South Australia the proportion of people aged 45 to over 65 years seeking Internet health information significantly increased between 2001 and 2008 [59]. These data are likely to be representative of greater Australia and other developed countries.

Limitations and Strengths

There are some limitations with this study. First, our sample was small, but it was consistent with that typically used in exploratory studies. Second, those who did participate were likely to have had greater focus on their health status and, therefore, not necessarily representative of the external population. Participants and non-participants did not differ in gender, although we acknowledge that they may have differed on other variables. It was not possible to measure the extent of any potential bias without detailed information on those who did not participate, which was inherently unavailable. We also had a lower than expected initial uptake rate, necessitating snowball recruitment and the associated loss of randomization.

Nevertheless, by means of this exploratory study we gained sufficient indication of the beneficial effect of tailored material on FOBT screening attitudes and participation to justify the formulation of feasible hypotheses upon which to expand our research. We also gained a participant perspective of the usability and the content of the website. These results will be incorporated into the design of a larger, truly randomized trial using an improved Web interface. The process of producing and presenting tailored messages from survey responses was labor-intensive and not readily transferable to population settings. Going through the process, however, highlighted the potential for the development of more sophisticated, fully automated message libraries and the use of natural language generation systems, for example [60,61].

Despite that randomization was broken, strengths of the study included the majority of participants (although self-selected) were randomly sampled from a population frame, thereby providing a stronger indication of generalizability of results. We used behavioral constructs that had been validated as predictors of CRC screening, and FOBT participation was not measured by self-report alone.

Conclusions

This exploratory study has confirmed that the provision of tailored messages that address attitudes and perceptions of screening that are amenable to change are more likely to result in increased readiness to screen for CRC compared to provision of generic information alone. However, despite increased PHM scores and generally positive qualitative feedback, tailored messages did not result in significantly increased requests for an FOBT or its actual use. Future research should address optimal message framing and construction, and consideration of other possible psychosocial influences on screening uptake. Mode of delivery did not affect outcomes, but this may have been due to Web design deficiencies. From a public health promotion perspective, the Web has economic and logistical advantages over paper as a delivery medium.

We are currently undertaking a large-scale, randomized population trial using a redesigned Internet decision aid [62] to construct and deliver tailored messages in real time. Based on the results of this exploratory study, we have been able to improve the quality and precision of our intervention. We ensured that the initial sample approached would be large enough, after allowing for attrition through non-eligibility and

non-participation, to retain sufficient power to detect statistically significant group differences for the primary outcomes. This study also highlighted that the steps involved in gaining responses to PHM variables upon which to base tailored messages, and the process of preparing the messages for presentation in a coherent manner, was labor-intensive and not compatible with a population-based screening program. Therefore, in the larger trial [62], baseline survey responses will be collected in real time and participants in the tailored information group will receive immediate tailored feedback. Additionally, an automated tailored message library using sophisticated algorithms [61] will be used to ensure that messages are united with natural language so that they can be read in a coherent, logical manner without the need for further "editing."

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Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
CATI: computer-assisted telephone interview
CRC: colorectal cancer
CSIRO: Commonwealth Scientific and Industrial Research Organisation
FIT: fecal immunochemical test
FOBT: fecal occult blood test
iFOBT: immunochemical fecal occult blood test
NBCSP: National Bowel Cancer Screening Program

PAPM: Precaution Adoption Process Model
PHM: Preventive Health Model

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Original Paper

Usability Study of a Computer-Based Self-Management System for Older Adults with Chronic Diseases

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Abstract

Background: Usability can influence patients' acceptance and adoption of a health information technology. However, little research has been conducted to study the usability of a self-management health care system, especially one geared toward elderly patients.

Objective: This usability study evaluated a new computer-based self-management system interface for older adults with chronic diseases, using a paper prototype approach.

Methods: Fifty older adults with different chronic diseases participated. Two usability evaluation methods were involved: (1) a heuristics evaluation and (2) end-user testing with a think-aloud testing method, audio recording, videotaping, and interviewing. A set of usability metrics was employed to determine the overall system usability, including task incompletion rate, task completion time, frequency of error, frequency of help, satisfaction, perceived usefulness, and perceived ease of use. Interviews were used to elicit participants' comments on the system design. The quantitative data were analyzed using descriptive statistics and the qualitative data were analyzed for content.

Results: The participants were able to perform the predesigned self-management tasks with the current system design and they expressed mostly positive responses about the perceived usability measures regarding the system interface. However, the heuristics evaluation, performance measures, and interviews revealed a number of usability problems related to system navigation, information search and interpretation, information presentation, and readability. Design recommendations for further system interface modifications were discussed.

Conclusions: This study verified the usability of the self-management system developed for older adults with chronic diseases. Also, we demonstrated that our usability evaluation approach could be used to quickly and effectively identify usability problems in a health care information system at an early stage of the system development process using a paper prototype. Conducting a usability evaluation is an essential step in system development to ensure that the system features match the users' true needs, expectations, and characteristics, and also to minimize the likelihood of the users committing user errors and having difficulties using the system.

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KEYWORDS

Usability evaluation; self-management; patient participation; chronic disease

Introduction

With the advent of advanced technology, a number of health information systems have been developed and employed to increase support for patient self-management of chronic disease. However, many of those innovations are not regularly used in care management and some have been abandoned. This non-adoption issue is significant and can largely be attributed to problems with the usability of the technology, such as

ineffective system design, lack of ease of use and convenience of access, and a mismatch between the system features and the needs, expectations, and characteristics of the users [1,2]. Even when a technology is adopted, these usability barriers are likely to result in frustration and irritation for the user, in inefficiency and disruption in the care management process, and in a higher likelihood of committing errors [3].

To avoid these negative outcomes, designers should evaluate and verify system usability during the early stages of system development [4]. This is especially important for health care technologies because their usability can have implications for quality and effectiveness of health care [5-7]. In fact, researchers have directed their efforts at improving the usability of their new health information technology (IT) applications to avoid unintended consequences at rollout [8-14]. For example, Tang and colleagues [12] applied the heuristics evaluation, a usability engineering method, to examine the usability of a digital emergency medical service system designed for paramedics to input patient data. They uncovered a number of heuristic violations in the user interface design. In another health care IT project, Rose and colleagues [11] conducted a qualitative study to assess the usability of a Web-based electronic medical record and used the findings to recommend design changes to the system. Similarly, Yen and Bakken [13] performed a heuristics evaluation and think-aloud test to study the usability of a Web-based communication system for nurse scheduling. They demonstrated that their study was effective in identifying system design problems and obstacles to task performance.

Usability is also important for elderly and disabled people for the following reasons. First, most older adults and others with disabilities are experiencing a decline in their physical and cognitive abilities [15,16]; as a result, they may have more difficulty interacting with technology [17,18]. Second, many technologies are not made to be accessible for these people, making it difficult to use them [18,19]. Third, many of the design guidelines are established for developing products for people with no functional limitations; thus, it is necessary to pay special attention to the usability of the products that are specifically designed for the elderly and disabled. Indeed, a number of researchers who are interested in aging, disability, and technology demonstrate the effectiveness of usability evaluation in technology development [20-25].

Most of these previous works cover either Web sites or health care provider technology, but our study focuses on the usability evaluation of a patient-centered interactive self-management system for older adults with chronic illnesses. We focus on this because we acknowledge the high prevalence of chronic diseases among the elderly [26] and the potential for using health IT to improve disease self-management and health outcomes of elderly patients [27,28].

Usability evaluation includes a set of techniques for improving the usability of a system through the identification of potential difficulties and problems in using the system [4,29]. Among the various techniques, end-user testing and heuristics evaluation are prevalent and prominent [30,31]. End-user testing examines how effective and efficient a task or process is carried out using the system and explores users' opinions based on their experience with the system. Heuristics evaluation is performed by usability specialists and focuses on the assessment of the system against a set of human factors design guidelines and heuristics [4,32]. These two methods can be implemented together in a usability evaluation to increase the likelihood of uncovering more design problems [30,33].

Conducting a usability evaluation during the early stages of the development process for a new design is highly recommended [29]. In addition, using paper prototypes to study usability is practical due to their low cost and comparable effectiveness with computer-based prototypes in identifying usability problems [34-38]. This study, which was part of a larger project to develop a computer-based self-management system for older adults with chronic diseases, evaluated the usability problems and weaknesses of the system using a paper prototype test. We first conducted a heuristics evaluation and then end-user testing using the think-aloud method. The objective of the heuristics evaluation was to determine whether the system design characteristics met the human factors design guidelines and principles. The aim of end-user testing was to examine use performance and satisfaction with the system interface among a group of elderly patients with chronic diseases. This usability study analytically discovered design weaknesses in the self-management system and provided directions for system design modifications and for conducting future system analyses.

Materials and Methods

Self-management System Paper Prototype

Our research team has been working on the development of a computer-based, interactive, touchscreen self-management system designed for patient use in their homes. The system allows patients to assess, record, and track their vital signs, including weight, blood pressure, blood glucose level, temperature, and oxygen saturation (SpO_2). The assessment records can be saved in the system and retrieved for review. The system can also remind the patients to take their prescribed medications at predetermined times. Figure 1 describes the measurement page for blood pressure. The page displays the blood pressure readings and includes the history data page button. By pressing the button, the users can access the history page and retrieve past blood pressure values from the two-dimensional line chart (see Figure 2). The design of the interface and functions of the other measurement modules (eg, blood glucose and weight) is similar to that of the blood pressure module. The intended users of the system are older adults with common chronic illnesses, such as diabetes, hypertension, and heart disease. The creation of the system interfaces was guided by a set of human factors design principles [4,39-41]. Examples of the principles are (1) match the system to the real world [4], (2) use recognition rather than recall [4], (3) reduce short-term memory load [39], (4) strive for consistency [39], (5) use compatibility of proximity principle [40], (6) conceptual compatibility [40], (7) avoid sound effects [41], (8) eliminate distracting features [41], and (9) have a clear and simple page [41]. In this study, we used a paper prototype that consisted of a collection of color-printed screenshots of the system interface to conduct our usability evaluation. This study protocol received

the approval of the institutional review board of the University of Hong Kong. Informed consent was obtained from all of the participants.

Figure 1. The blood pressure measurement page of the self-management system.

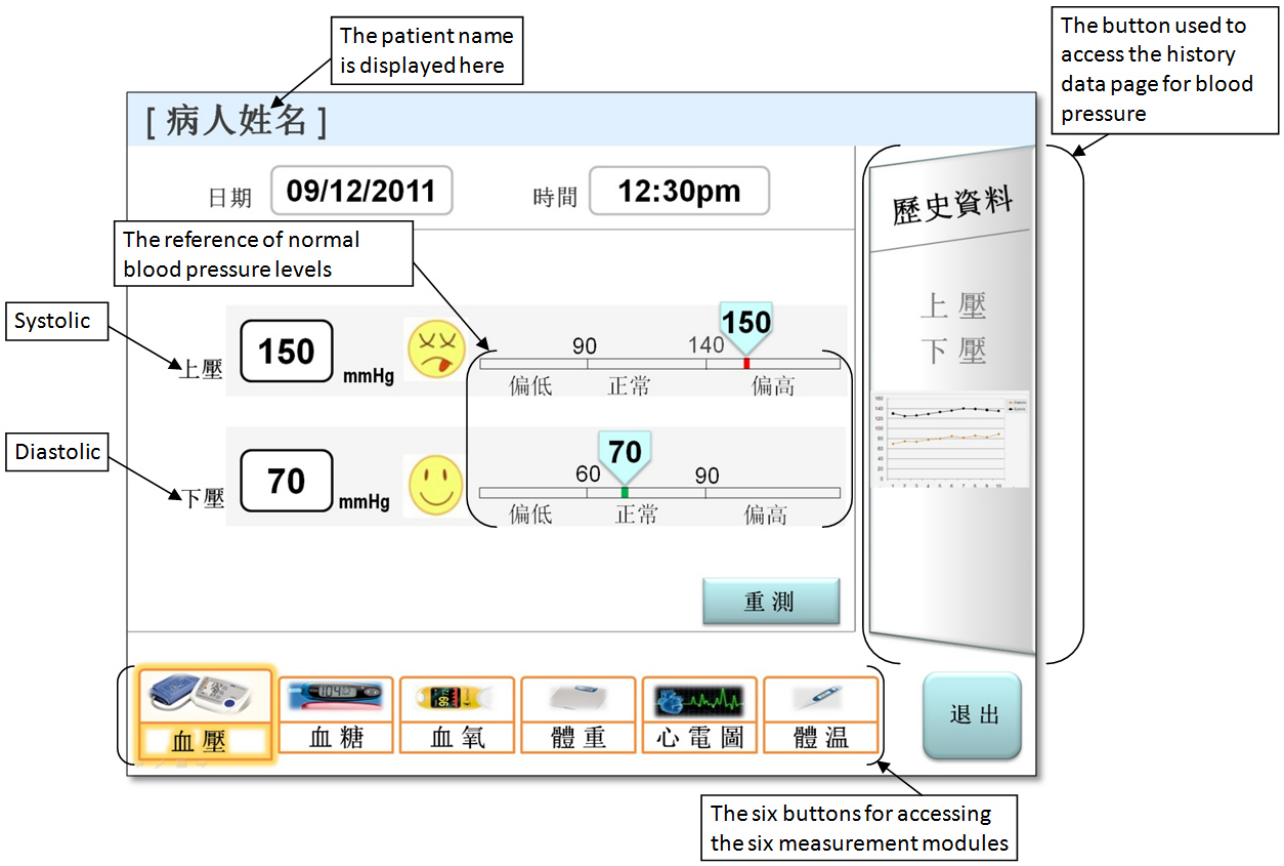
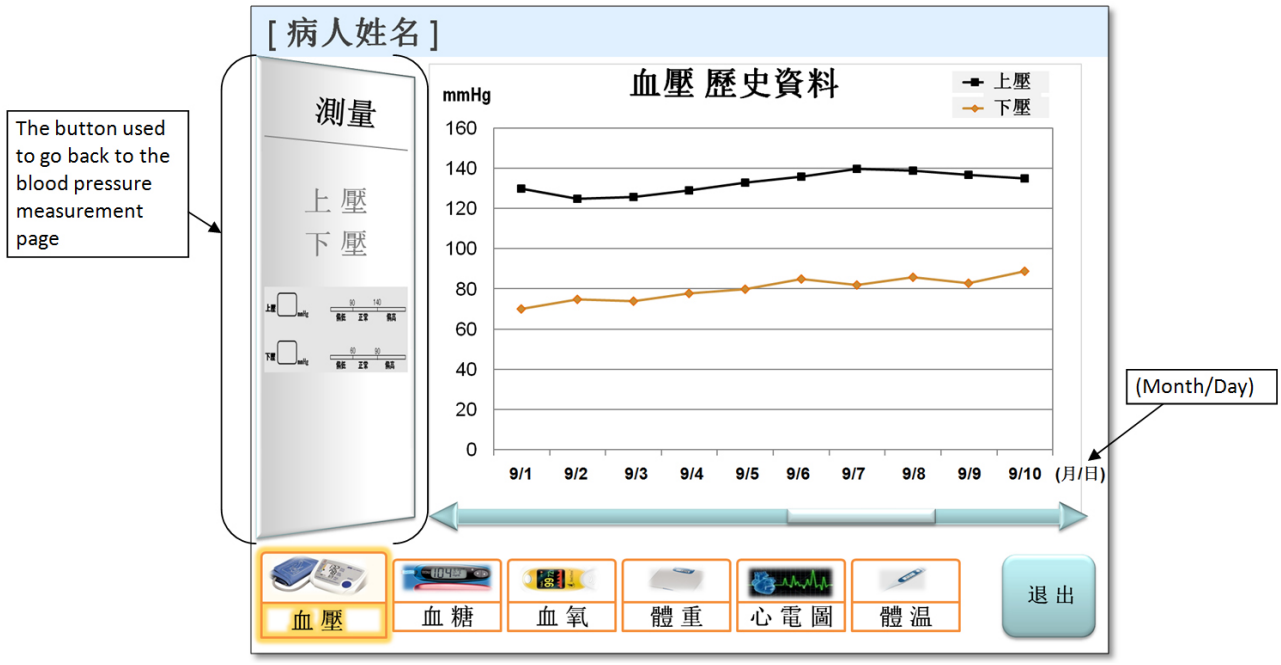


Figure 2. The blood pressure history data page presents the past blood pressure values on a two-dimensional line chart.



Heuristics Evaluation

Three important considerations were managed in our heuristics evaluation to ensure study quality: evaluators, heuristics, and evaluation process.

Evaluators

Our heuristics evaluation required the evaluators to be knowledgeable of usability and human factors engineering, be comfortable with health information system design and evaluation, be aware of the characteristics of older people (as

the system end users would be elderly patients), and be familiar with the scenarios and environment in which the system would be used. In this study, we employed one "double expert" who had a background in usability and a domain of interest, and two "single experts" with experience in usability and human factors design. All of the evaluators were familiar with the heuristic principles. Nielsen and Mack [42] recommend using 3-5 "single experts" or 2-3 "double experts" in heuristics evaluations. We believed the number of evaluators in this study and their expertise level to be sufficient for this evaluation.

Heuristics

We evaluated our system interfaces for their conformity to a set of 26 human factors design heuristics (see Table 1) that were identified based on Nielsen [4], Shneiderman and Plaisant [39], Czaja and Lee [19], and Demiris and colleagues [41]. Because the heuristics of Nielsen and those of Shneiderman and Plaisant were general human-computer interface design heuristics, our evaluation also included the principles reported by Czaja and Lee and by Demiris and colleagues who developed heuristics specifically for older adults and elderly patients. The heuristics evaluation was conducted on December 15, 2011.

Evaluation Process

Three human factors researchers independently evaluated the conformity of the interface design to the 26 heuristics. They determined the conformity by responding "yes" or "no" to each heuristic. A comment section was also provided to collect their specific comments on the design issue associated with each heuristic. The three evaluators then met to discuss all of the comments received, identify the design problems, and give recommendations for system modifications prior to end-user testing.

End-User Testing

The end-user testing was performed between January 16 and February 9, 2012, according to the three stages proposed by Nielsen [4], including preparation, testing, and follow up. Each test lasted approximately 30-40 minutes. The procedures implemented in these three stages are described below.

Preparation Stage

The preparation stage included participant selection, task design, and data collection.

Participants

The study participants were recruited from a non-profit medical organization in Hong Kong that provides medical services to the community in the Hong Kong East Cluster. The inclusion criteria for study participation included the following: (1) age 55 or older, (2) diagnosis of any chronic disease, (3) normal vision or corrected-to-normal vision, (4) no cognitive or physical impairment, and (5) the ability to read Traditional Chinese.

Task Design

The participants performed two practice tasks followed by 11 experimental tasks related to disease self-management (see Table 2). The tasks included a set of navigation tasks (tasks 1, 4, 5, 7, and 10) and a set of information search and simple cognitive tasks (tasks 2, 3, 6, 8, 9, and 11). In the navigation tasks, the participants were asked to access the measurement modules. To do this, they needed to search for and "press" the button associated with the module. In the information search and simple cognitive tasks, the participants were required to visually search for the measurement values (eg, blood glucose level) and to determine whether the values were normal based on the general "normal value range" presented on the interface.

Data Collection

Several performance measures were collected, including task incompletion rate, task completion time, frequency of error, and frequency of help. Task incompletion rate was defined as the percentage of participants who went through the task but were not able to complete it. Task completion time was the mean time it took to complete the task. The amount of time the participants had to complete the tasks was not limited, but they were instructed to try their best to perform the tasks. They were also asked to report to the research assistant (RA) if they were unable to complete the tasks. Frequency of error (n_{error}) was defined as the total number of errors made on the task by all of the participants who went through the task (errors included choosing a wrong button, unable to find and interpret the information correctly, etc). The participants were corrected and were asked to try again when they made an error. Frequency of help (n_{help}) was defined as the total number of times that all participants needed help on the task.

In addition, a questionnaire was administered in a face-to-face interview to examine the following variables: participant satisfaction with the system design (17 items), the perceived usefulness of the system (4 items), the perceived ease of use of the system (4 items), and the intention to use the system (1 item). The questionnaire was developed based on previous usability and technology acceptance studies [43,44]. Except for intention to use (which was a yes/no item with a follow-up question asking the participants to explain their responses), all other items were rated on 7-point Likert scales ranging from 1 = very bad to 7 = very good, 1 = strongly disagree to 7 = strongly agree, 1 = very unclear to 7 = very clear, 1 = very inappropriate to 7 = very appropriate, or 1 = very difficult to 7 = very easy. At the end of the interview, two open-ended questions were also asked to elicit the opinions of the participants about the interface design (eg, use of font size, color, and complexity) and about what they liked or did not like with the design.

Testing Stage

End-user testing was conducted in a community health service center by two trained RAs. Prior to the start of testing, one RA explained the study objective and research protocol to the participants. After the participants gave informed consent, the RA provided detailed information about the test procedures, described the purpose of the computer-based self-management system, and collected their basic demographical information. During the test, the participants were given two practice tasks to become familiar with the self-management system and the think-aloud method. Following the practice trials, the participants were asked to perform the experimental tasks. They were told to vocalize whatever they saw, did, and felt when performing the tasks. The participants did not go through the

information search and simple cognitive tasks if they failed to complete the associated preceding navigation tasks. In this study, all end-user testing was recorded on video. The RAs also took field notes about the participants' performance and comments. The RAs collected the questionnaire data and participant feedback on the difficulties they noticed when using the system after the completion of the end-user testing.

Follow-up Stage

In the follow-up stage, the study data were analyzed by two RAs using descriptive statistics and simple content analysis [45]. Data from the performance measures were extracted from the videos, and the means/frequencies were examined. Central tendency and distribution of the questionnaire item scores were determined. Audio interview data were transcribed and the content was analyzed. Practice task data were excluded from the data analysis.

Table 1. The 26 human factors design heuristics used in the heuristics evaluation.

Source	Heuristic
Nielsen [4]	1. Use simple and natural dialogue
	2. Speak the users' language
	3. Provide clearly marked exits
	4. Provide help and documentation
Shneiderman and Plaisant [39]	5. Strive for consistency (eg, screen information location and operating procedures)
	6. Enable frequent users to use shortcuts
	7. Offer informative feedback
	8. Design dialogues to yield closure
	9. Offer simple error handling
	10. Permit easy reversal of actions
	11. Support internal locus of control
	12. Reduce short-term memory load
Czaja and Lee [19]	13. Maximize the contrast between characters and screen background
	14. Avoid small targets and characters that are small (fonts < 12 point)
	15. Minimize irrelevant screen information
	16. Adhere to principles of perceptual organization (eg, grouping)
	17. Highlight important screen information
	18. Clearly label keys
	19. Avoid color discriminations among colors of the same hue or in the blue-green range
	20. Maximize size of icons
	21. Use icons that are easily discriminated and meaningful, and label icons if possible
	22. Minimize demands on spatial memory
Demiris and colleagues [41]	23. Use proper visual display (eg, concrete symbols that should look like the object they represent and be distinguishable from others; large buttons that increase the area that can be selected with the pointer)
	24. Avoid sound effects
	25. Eliminate distracting features
	26. Use a simple and clear page

Table 2. Self-management tasks used during end-user testing.

Task #	Task description
Practice	Access the SpO_2 measurement module
Practice	Indicate the SpO_2 value and determine whether it is normal
1	Access the blood pressure measurement module
2	Indicate the systolic pressure value and determine whether it is normal
3	Indicate the diastolic pressure value and determine whether it is normal
4	Access the blood glucose measurement module
5	Select the "before breakfast" test time for blood glucose measurement[a]
6	Indicate the blood glucose value and determine whether it is normal
7	Access the body weight measurement module
8	Indicate the weight value
9	Indicate the body mass index (BMI) and determine whether it is normal
10	Access the history data page for blood pressure
11	Indicate the diastolic pressure value on a specified date on the history data chart

[a] In this task, the participants had to search for and select (by "pressing") the "before breakfast" button for the measurement.

Results

Heuristics Evaluation

The evaluation results (Table 3) and comments of the three evaluators were discussed and compiled into four categories (Table 4). The evaluation identified some strengths in the system design, such as consistent information presentation and organization, low demand on user short-term and spatial memory load, clearly labeled keys, and consistent operating procedures within and across the system modules. Two types of usability problems were also identified. The first was general usability problems related to insufficient interface design, including unfamiliar terminology, confusing and inconsistent button design, lack of informative feedback for user actions, and a lack of online support and instruction. The second type was age-related usability problems that were more problematic for older adult patients due in part to small text and buttons, inappropriate use of serif font and gradient color, low contrast between information and background, and too much information on the interface. Based on these findings, changes were made to the system design for end-user testing.

End-User Testing

Participant Characteristics

A total of 57 eligible older adult patients participated. The first seven were pilot participants to try out the testing procedures through which the experimental design problems were identified and fixed prior to the main test. The other 50 participants completed the main test; only their data were used for analysis. Table 5 presents the characteristics of the participants.

Performance Measures

The performance data were analyzed with descriptive statistics. Table 6 shows the results.

Table 3. Heuristics evaluation results.[a]

Heuristic	Interface[b]									
	a	b	c	d	e	f	g	h	i	j
1	✓	✓	✓	•	✓	✓	✓	✓	✓	✓
2	✓	✓	✓	✓	✓	✓	✓	✓	•	✓
3	NA	✓	✓	✓	✓	✓	✓	✓	✓	✓
4	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
5	✓	•	•	•	•	•	•	•	•	•
6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
7	✓	•	✓	✓	•	✓	•	✓	•	✓
8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
9	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10	✓	✓	✓	•	✓	•	✓	•	✓	•
11	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12	✓	✓	•	✓	✓	✓	✓	✓	✓	✓
13	✓	•	✓	✓	•	✓	•	✓	•	✓
14	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗
15	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗
16	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
17	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
19	✓	•	✓	✓	•	✓	•	✓	•	✓
20	✓	•	•	•	•	•	•	•	•	•
21	•	•	✓	•	•	✓	•	✓	•	•
22	✓	✓	•	✓	✓	✓	✓	✓	✓	✓
23	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
24	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
25	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗
26	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗

[a] ✓: All three evaluators verified the conformity; •: only one or two of the evaluators verified the conformity, but the other evaluator(s) expressed nonconformity; ✗: none of the evaluators verified the conformity; NA: the heuristic was not applicable to the design of the interface.

[b] a: System home page with six measurement module buttons; b: blood pressure measurement page; c: history data page for blood pressure; d: blood glucose test time selection page; e: blood glucose measurement page; f: history data page for blood glucose; g: SpO_2 measurement page; h: history data page for SpO_2; i: body weight measurement page; j: history data page for body weight and BMI.

Table 4. Interface design strengths and usability problems identified in the heuristics evaluation.

Category	Strengths	General usability problems	Age-related usability problems
Readability	High contrast between most characters and background	Unfamiliar terminology	Small characters, texts, and buttons
		Confusing design of the navigation buttons and their icons	Low contrast between some numbers and background
			Inappropriate use of serif fonts and gradient colors
Information presentation	Consistent information presentation and organization	Unclear reference information and icons	Irrelevant screen information and too much information on one interface
	Adherence to principles of perceptual organization when grouping information	Inappropriate layout of some interface elements	Inappropriate use of green color to display information
	High conspicuity of important information		
Information retrieval and interpretation	Low demand on the user's spatial memory	Lack of informative feedback for users' actions	Lack of hints for older adults to find information
	Clearly labeled keys	Lack of online support and instruction on how to use the system	
	Consistent operating procedures with and across the system modules	No error message	
	No complex command language		
Navigation		Inconsistent button design	

Table 5. Study participant characteristics (N = 50).

Characteristics	n (%) or mean (SD)
Gender, n (%)	
Male	15 (30%)
Female	35 (70%)
Mean age (SD)	71.6 (9.7)
Previous technology experience, n (%)	
Experience using personal computers	17 (34%)
Experience using a touch screen computer	6 (12%)
Average weekly personal computer use, hours (SD)	4.1 (6.0)
Experience using any computer-based disease self-management system (n)	0
Chronic diseases diagnosed, n (%) [a]	
Hypertension	40 (80%)
Diabetes	22 (44%)
Heart disease	11 (22%)
Asthma	3 (6%)
Prostatitis	2 (4%)
Hypotension	2 (4%)

[a] Twenty-seven (54%) of the participants reported having two or more of the chronic diseases.

Table 6. Performance measures as assessed via 11 tasks.

Task	n	Task incompletion rate	Mean task completion time (sec)	Frequency of error n_{error} (n)[a]	Frequency of help n_{help} (n)[b]
Navigation tasks					
1	50	0%	12.6	4 (4)	22 (15)
4	50	0%	14.1	6 (6)	18 (11)
5	50	16%	23.0	39 (19)	48 (24)
7	50	2%	8.5	5 (5)	12 (7)
10	50	44%	58.4	93 (45)	60 (28)
Information search and simple cognitive tasks					
2	50	28%	6.7	18 (14)	18 (13)
3	50	34%	5.2	22 (16)	16 (6)
6	42	26%	7.2	20 (16)	13 (5)
8	49	22%	10.2	16 (12)	18 (8)
9	48	17%	12.2	14 (10)	26 (16)
11	28	50%	10.5	28 (17)	18 (12)

[a] n_{error} represents the number of times an error was made and n represents the number of people who made the error.

[b] n_{help} represents the number of times help was given and n represents the number of people who needed help.

Task Incompletion Rate

All participants completed all of the navigation tasks due to the nature of our experimental design; however, not everyone completed all of the information search and simple cognitive tasks because they failed to complete the preceding navigation tasks. For instance, only 42 participants completed task 6 because 8 participants failed to complete task 5. In the navigation tasks, tasks 1 and 4 yielded a task incompletion rate of 0%. A low incompletion rate (2%, 1/50) was yielded in task 7. However, task 10 had an incompletion rate of 44% (22/50). Task incompletion rates were moderate to high for the information search and simple cognitive tasks, ranging from 17% (8/48) to 50% (14/28), respectively. For example, half of the 28 participants were unable to complete task 11 (50% incompletion rate).

Task Completion Time

Among all of the navigation tasks, tasks 1, 4, and 7, which required the participants to access the measurement modules, yielded the shortest task completion times. The “access the history data page” task and “select the breakfast test time” task appeared to be difficult to perform, with fairly long task completion times. Among the 11 experimental tasks, tasks 2, 3, and 6, which required the participants to indicate a vital sign value and determine whether it was normal, had the shortest completion times. Task 9 (indicate the BMI and determine its normality), task 11 (read the history data chart and find the diastolic pressure value), and task 8 (indicate the weight value) yielded longer completion times.

Frequency of Error

Both navigation errors (eg, choosing wrong navigation buttons, incorrectly recognizing icons and symbols as buttons, and failing to follow the navigation paths) and information processing errors (eg, failing to locate and explain information; being unable to retrieve the measurement values, such as the blood glucose value; and being unable to obtain and comprehend the reference values of normal blood pressure levels) were observed. Overall, 93 errors (highest occurrence among all tasks) were made by 45/50 participants in the “access the history data page” task. The task that required the participants to select (by “pressing”) the “before breakfast” test time for measuring their blood glucose levels yielded the second highest number of errors (39 errors made by 19/50 participants). The information search and simple cognitive tasks yielded a moderate frequency of errors.

Frequency of Help

Similar to the frequency of error finding, tasks 5 and 10 yielded the highest frequency of help, indicating that the tasks were difficult based on our current design. For instance, 28 participants (56%) needed help a total of 60 times when doing the “access the history data page” task.

Satisfaction, Perceived Usefulness, and Perceived Ease of Use

Table 7 presents the central tendency and distribution of the questionnaire responses. The mean scores for satisfaction, perceived usefulness, and perceived ease of use were at least 4.9 (SD 1.4), 6.0 (SD 1.2), and 6.0 (SD 1.2), respectively. All of these were above the midpoint of the scale, indicating that the participant exhibited a positive impression of the system design. Of the 17 satisfaction items, 14 had a mean score of 6.0 or higher. The mean ratings of two satisfaction items (Sat2: the information on the interfaces are overloaded, and Sat9: finding information on this system requires a lot of mental effort) were relatively low, showing that the amount of information on the interface might be excessive and that finding this information required a large amount of mental effort.

Table 7. Descriptive statistics for satisfaction, perceived usefulness, and ease of use items (1 = negative to 7 = positive).

Item	Rating distribution, n (%)							Mean	SD
	1	2	3	4	5	6	7		
Satisfaction									
Sat1: System appearance	0 (0%)	1 (2%)	1 (2%)	4 (8%)	5 (10%)	23 (46%)	16 (32%)	5.9	1.1
Sat2: Amount of information	0 (0%)	3 (6%)	3 (6%)	18 (36%)	10 (20%)	7 (14%)	9 (18%)	4.9	1.4
Sat3: Graphic quality	0 (0%)	2 (4%)	0 (0%)	1 (2%)	3 (6%)	19 (38%)	25 (50%)	6.2	1.1
Sat4: Character size	0 (0%)	0 (0%)	1 (2%)	0 (0%)	5 (10%)	19 (38%)	25 (50%)	6.3	0.8
Sat5: Ease of reading the information	1 (2%)	0 (0%)	2 (4%)	2 (4%)	4 (8%)	18 (36%)	23 (46%)	6.1	1.3
Sat6: Text clarity/understanding	0 (0%)	0 (0%)	2 (4%)	1 (2%)	1 (2%)	13 (26%)	33 (66%)	6.5	1.0
Sat7: Congruence between information and expectations	0 (0%)	0 (0%)	1 (2%)	2 (4%)	2 (4%)	21 (42%)	24 (48%)	6.3	0.9
Sat8: Ease of finding information	0 (0%)	1 (2%)	0 (0%)	3 (6%)	3 (6%)	14 (28%)	29 (58%)	6.4	1.0
Sat9: Mental efforts in finding information	1 (2%)	0 (0%)	4 (8%)	4 (8%)	19 (38%)	11 (22%)	11 (22%)	5.3	1.3
Sat10: Helpful for finding health information	0 (0%)	1 (2%)	0 (0%)	1 (2%)	4 (8%)	12 (24%)	32 (64%)	6.4	1.0
Sat11: Helpful for understanding health problems	1 (2%)	2 (4%)	2 (4%)	3 (6%)	5 (10%)	12 (24%)	25 (50%)	6.0	1.5
Sat12: Improvement in health knowledge	0 (0%)	1 (2%)	1 (2%)	1 (2%)	3 (6%)	12 (24%)	32 (64%)	6.4	1.1
Sat13: Improvement in knowledge of chronic illness and their treatment	1 (2%)	0 (0%)	2 (4%)	1 (2%)	5 (10%)	9 (18%)	32 (64%)	6.3	1.3
Sat14: Easier and more efficient at self-management	0 (0%)	0 (0%)	2 (4%)	3 (6%)	3 (6%)	12 (24%)	30 (60%)	6.3	1.1
Sat15: Encouragement to taking better care	0 (0%)	1 (2%)	1 (2%)	4 (8%)	3 (6%)	14 (28%)	27 (54%)	6.2	1.2
Sat16: Helpful for performing better self-care	0 (0%)	1 (2%)	1 (2%)	1 (2%)	9 (18%)	13 (26%)	25 (50%)	6.2	1.1
Sat17: Saving time in self-management	0 (0%)	1 (2%)	2 (4%)	1 (2%)	7 (14%)	9 (18%)	30 (60%)	6.3	1.1
Perceived usefulness									
U1: Improvement of ability to self-management	0 (0%)	1 (2%)	0 (0%)	3 (6%)	9 (18%)	15 (30%)	22 (44%)	6.1	0.9
U2: Time saving in self-management	0 (0%)	1 (2%)	1 (2%)	6 (12%)	8 (16%)	10 (20%)	24 (48%)	6.0	1.2
U3: Effectiveness of self-management	0 (0%)	1 (2%)	3 (6%)	3 (6%)	4 (8%)	16 (32%)	23 (46%)	6.1	1.2
U4: Usefulness for self-management	0 (0%)	0 (0%)	0 (0%)	3 (6%)	7 (14%)	15 (30%)	25 (50%)	6.3	0.9
Perceived ease of use									
EOU1: Ease of learning the system	0 (0%)	0 (0%)	0 (0%)	2 (4%)	4 (8%)	19 (38%)	25 (50%)	6.3	0.8
EOU2: Ease of getting the system to do tasks	0 (0%)	1 (2%)	2 (4%)	1 (2%)	9 (18%)	17 (34%)	20 (40%)	6.0	1.2
EOU3: Ease of being skillful at using the system	0 (0%)	0 (0%)	1 (2%)	4 (8%)	5 (10%)	20 (40%)	20 (40%)	6.1	1.0
EOU4: Ease of using the system	0 (0%)	0 (0%)	1 (2%)	1 (2%)	6 (12%)	22 (44%)	20 (40%)	6.2	0.9

Intention to Use the System

Thirty-one (74%) participants expressed their intention to use the actual system for chronic disease self-management in the future, if the system was available. The reasons listed for wanting to use the system were that the system could facilitate their self-management of chronic diseases, such as providing them with specific and updated health information; automatically recording the health information for easy retrieval later saving time on their self-management; and improving communication with their health care providers. For those who said that they would not use the system, cost, unfamiliarity with the

technology, and limited space at home for the system were the major reasons cited for non-use.

Comments from Open-Ended Questions

All participants expressed a fondness for the system. They commented that the overall system interface was effective and appealing, the system was simple to use, the information on the interfaces was clearly presented, and using the system for self-management would allow them to obtain useful health information and improve their health conditions. However, comments related to usability problems were also mentioned. They were grouped into four categories and are presented in Table 8. Although some of the problems were similar to those identified in the heuristics evaluation (eg, unfamiliar terminology, small characters and texts, and inconsistent button design), the comments offered more details about the design that enabled us to develop specific directions for system redesign.

Table 8. Usability problems identified from the open-ended questions.

Category	Usability problem (n)[a]
Readability	Characters too small and words too busy (3)
	Low-quality graphics (10)
	Too small icons and words that were placed over the buttons (3)
	Low contrast of the color indicators (4)
	Too small decimal point symbol of the numbers (4)
	Inappropriate use of color in color indicators (7)
Information presentation	Inappropriate use of button icons (4)
	Complex design of the history data page interface (3)
	Unclear abbreviations and terminologies, such as "SpO_2" (16), the unit "kg" (1), and "BMI" (1)
	Unnecessary icons on navigation buttons (6)
	Obscure reference information (5)
Information retrieval and interpretation	Ambiguous emoticons, which were used to facilitate participants' information comprehension (14)
	Ambiguous information on "normal value range" presentation (14)
	Poor pairing design between the measurement value and its measurement date in the history data chart (9)
Navigation	Difficulty in choosing test time for blood glucose (11)
	Difficulty in accessing the history data page of blood pressure (27)
	Ambiguous design of the history page button because of its inconsistency with other buttons (10)
	Complex navigation between different measurement modules (2)

[a] n = number of participants who expressed the problem.

Discussion

This study assessed the interface design of a computer-based chronic disease self-management system using a set of design heuristics and evaluated the performance and perceptions of users about the system. Using the paper prototype, our evaluations quickly and effectively identified the system's strengths and usability weaknesses.

System Interface Design

Overall, our findings indicated that the participants were basically able to perform the study tasks using the current design. However, we also identified a number of design problems and areas that could be improved to further enhance usability. Moreover, based on our findings, we drew a number of long-reaching and significant implications on usability design guidelines for designing health IT systems for the elderly.

First, all four performance indicators showed that the "access the history data page" task (task 10) was difficult to perform. This was likely due to a design inconsistency where the appearance and position of the history page button was completely different from that of the six main measurement module buttons, as indicated by the findings of the heuristics evaluation and end-user test (ie, ambiguous design of the history page button). Because of this difference, when the participants performed the task, many of them attempted to find the button in the area where the six module buttons were grouped; therefore, the participants did not notice that the button was actually located in a different area of the interface. This inconsistency led to confusion and resulted in additional search efforts that would not be necessary if the location was changed. This finding confirms the design principle that the appearance, position, and configuration should be consistent across objects/displays (eg, buttons, icons) that serve the same basic functions (eg, going to a new page/module).

Second, the blood glucose test time selection task (task 5) was also challenging because it had a similar inconsistent design problem. Furthermore, in the blood glucose module menu, there

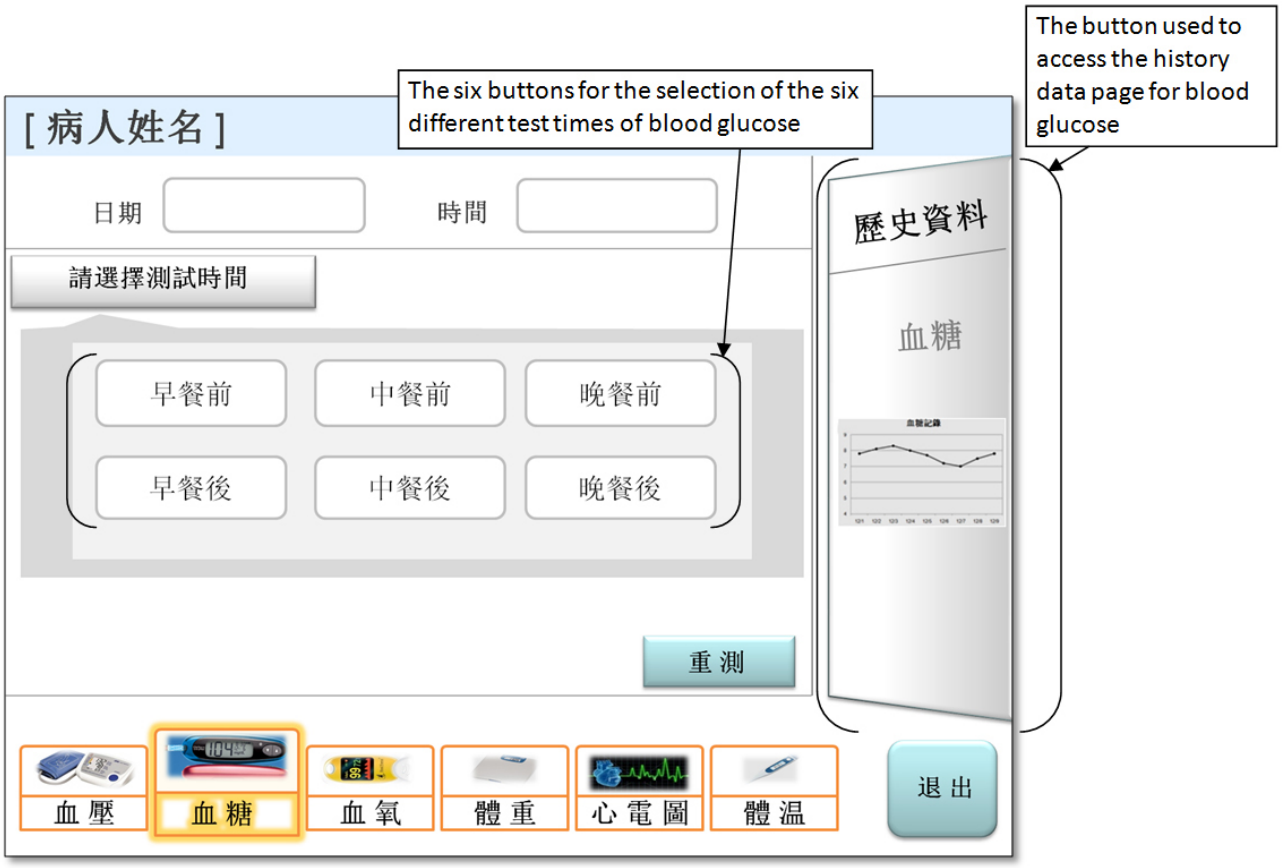
were a total of six alternative test times available for selection because the timing of the test could be before or after breakfast, lunch, or dinner (see Figure 3). Based on the participants' comments about the end-user test and our observation, it appeared that the menu offered too many choices that added decision complexity (see the Hick-Hyman Law [46,47]). Additionally, older adults may experience declines in cognitive abilities and eyesight that can make it more difficult to process complex information and locate information on complex interfaces [19]. Our sophisticated menu, with its six options, likely required more visual search and cognitive effort for information processing and may have contributed to the lower task performance of the elderly patients. From this observation, we suggest that the number of choices in a menu/interface be kept to an essential minimum. Therefore, we modified our design such that the system would automatically record the test time.

Third, although the history data chart followed a simple two-dimensional line chart design in which the measurement dates were displayed along the x-axis and the measurement values were plotted along the y-axis, most elderly participants could not easily comprehend the chart and retrieve the values, as indicated by the performance data and the participants' comments (ie, poor pairing design between the measurement value and its measurement date in the history data chart). This type of graphical representation can be especially difficult for older adults to read and comprehend. This finding suggests that when a graphical representation of measurement data is employed, it should be designed to help improve the older adults' ability to pair the measurement dates with the corresponding measurement values.

Fourth, readability was another design weakness identified. The size of the fonts (all the Chinese characters) were set at 18 points in the original design. Although the literature recommended that font sizes be at least 14 points (eg, Demiris and colleauges [41]), the findings of the end-user test showed that when Chinese characters were used, an 18-point font size was too small for the older adults to read due to the crowded strokes in the characters. Moreover, the sizes of the icons and symbols were too small. These findings suggest that the fonts, icons, and symbols should be larger for the elderly population. While the mean score of the satisfaction item that examined the graphic quality (Sat3: overall quality of graphics) was high, the participants' comments about the end-user test indicated that the picture quality of the icons and symbols was inadequate and that affected the overall readability. Therefore, high image resolution should be used in icons and symbols.

Fifth, regarding the presentation of information, a number of participants expressed their confusion about the pictures that were used to describe the functions of the buttons (eg, a picture of a scale was used to represent weight measurement). The selection and use of these icons should be revisited and meaningful pictures should be used to enhance the conceptual compatibility. Additionally, both the heuristics evaluation and end users' comments indicated that the abbreviations and some of the medical terminologies used in the interfaces (eg, SpO_2 and BMI) were unclear and too technical. The older adults in particular may not have the knowledge to understand the meanings of these terms. Therefore, they should be replaced with plain, non-technical terms that are less ambiguous to users.

Figure 3. The blood glucose module menu includes the six buttons for the selection of the six test times of blood glucose.



Usability Test Methodology and Design

A number of research methodology and design issues are worth discussing because these provide important implications for health information technology usability research. First, although using computer-based interactive system prototypes in the usability test can allow researchers to measure realistic user interactions, evidence shows that paper prototypes are as effective as computer-based prototypes in uncovering usability problems and understanding the users' subjective evaluation of a system [36,48,49]. Moreover, paper prototypes are less costly and can be created quickly.

Second, many of the previous studies adopted a single usability testing method. Our findings revealed a number of usability issues, not detected in the heuristics evaluation, discovered by the end-user testing. Furthermore, our heuristics evaluation only projected high-level structural usability problems (eg, font size and information grouping problems), whereas the end-user testing allowed us to discover a large number of usability weaknesses at detailed levels. Our study showed that using multiple evaluation approaches could help identify more potential problems and should be a more reliable practice for conducting usability studies (also noted in the literature; see [30,33]).

Third, one of the main criticisms of previous studies on health IT usability has been the lack of a theoretical basis for the development of the study methodology [50]. Our study method and procedures were carefully set up based on systematic usability study guidelines and models as well as empirical research, such as Nielsen and Mack [42] and Nielsen [4]. These guidelines provided valid directions for our experimental design and prevented erroneous testing protocols and data collection.

Fourth, effective disease self-management systems have the potential to improve care quality and safety [51,52]. However, one cannot meaningfully examine and then be certain of the true value of a newly developed health information system (such as the one in this current study) without having the usability and design problems discovered and eliminated beforehand. For instance, a system with an unpleasant and ineffective interface design found to have no impact on health outcomes could actually be beneficial if the design weaknesses had been overcome prior to the examination. Our study suggests that the usability test is one of the steps that should be performed during the system development process to avoid drawing mistaken conclusions about system effectiveness.

Strengths and Limitations

Our study had several strengths: (1) careful and systematic procedures were adopted in the heuristics evaluation and end-user testing; (2) context-specific consideration was exercised to generate heuristics for the heuristics evaluation and to develop performance measures in the end-user testing; and (3) compared to many other usability studies, our study involved a relatively large sample size, which may have helped identify more usability problems and design weaknesses of our system. However, a few limitations should be noted. First, no alternative system interfaces were assessed; therefore, no comparable results were available on a better interface design approach in our study. This may limit our findings and ideas on system

interface improvement. Second, although it was not the focus of this current study, it may be worth considering the effects of user characteristics (eg, age, severity of the chronic conditions, and computer experience) on measurement outcomes. Third, it may be valuable to verify the effectiveness of our design recommendations by conducting iterative usability evaluations. However, we are planning to conduct another round of usability studies using a computerized prototype with the design recommendations incorporated.

Conclusions

An inadequately designed health information system increases the likelihood of the users committing user errors and having difficulties using the system. These issues can be mitigated by identifying a system's usability problems using heuristics evaluations and end-user tests, and the results of these evaluations can be used for design refinement. Importantly, special attention should be given to the selection of design heuristics for evaluating systems for elderly patients because the general human factors design guidelines may be insufficient for addressing the unique characteristics and capabilities of elderly patients. Furthermore, the design problems discovered in this study allow for the implementation of new design guidelines that are of particular importance for the elderly and can be generalized to other health information systems that are designed for older adult patients.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
IT: information technology
RA: research assistant
SpO2: oxygen saturation

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Original Paper

Integrating Psychological Theory Into the Design of an Online Intervention for Sexual Health: The Sexunzipped Website

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Abstract

Background: The Internet can provide a confidential and convenient medium for sexual health promotion for young people.

Objective: This paper describes the development of an interactive, theory-based website (Sexunzipped) aimed at increasing safe sexual behavior of young people, as well as an outline of the evaluation protocol.

Methods: The website focuses on safer sex, relationships, and sexual pleasure. An overview of the site is provided, including a description of the theoretical constructs which form the basis of the site development. An integrated behavioral model was chosen as the guiding theory for the Sexunzipped intervention. A randomized trial design will be used to evaluate the site quantitatively.

Results: The content of the site is described in detail with examples of the main content types: information pages, quizzes, and decision-making activities. We describe the protocol for quantitative evaluation of the website using a randomized trial design and discuss the principal challenges involved in developing the site, including the challenge of balancing the requirements of theory with young people's views on website content and design.

Conclusions: Considerations for future interventions are discussed. Developing an online behavior-change intervention is costly and time consuming. Given the large public health potential, the cost involved in developing online interventions, and the need for attractive design, future interventions may benefit from collaborating with established sites that already have a user base, a brand, and a strong Internet presence. It is vital to involve users in decisions about intervention content, design, and features, paying attention to aspects that will attract and retain users' interest. A central challenge in developing effective Internet-based interventions for young people is to find effective ways to operationalize theory in ways that address the views and perspectives of young people.

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KEYWORDS

Internet; sex education; adolescents; young adults; health behavior; psychological theory

Introduction

The impact of sex- and relationship-related problems, such as sexually transmitted infections (STIs), unwanted pregnancy, sexual dysfunction, and gender-based violence, has been well documented globally [1]. In the United Kingdom, despite an overall decline in diagnoses of some STIs in recent years, there has been a steady increase in STIs in young people since 2001 [2]. There is evidence that sex education in UK schools may not provide young people with adequate information on sexual

health and contraception [3], suggesting the need for more effective and accessible sexual health interventions for young people.

The Internet provides an alternative medium for sexual health promotion that may be particularly attractive for young people because it offers a confidential, convenient, and anonymous medium for accessing health information, some of which may be too difficult or embarrassing to discuss with health providers [4-6]. This may be particularly important if access to sexual health services is difficult because of fear of being observed by community members or fear of health care providers' negative attitudes [7,8]. Most young people (in "developed" countries) have access to the Internet and are confident users of technology, and a high proportion seek health information online [4,9]; therefore, Internet interventions are potentially appropriate for health promotion for young people.

A systematic review of interactive computer-based interventions for sexual health promotion shows promise for these interventions [10]. Therefore, we produced a website that incorporated health behavior theory and the views of young people with the objective of giving young people the tools to improve their sexual well-being. We faced the challenge of developing a site that was both consistent with theory and appealing to young people, working within budgetary and technical constraints, to produce an Internet intervention for sexual health for young people between the ages of 16 to 20 years in the United Kingdom. The resulting Sexunzipped website (www.sexunzipped.co.uk) was evaluated in a randomized controlled trial that compared the Sexunzipped interactive, theory-based website to a static, information-only control website (trial registration number ISRCTN 55651027). This paper describes the content, structure, and theoretical rationale for the Sexunzipped website, followed by a description of the protocol for a randomized controlled trial to evaluate the website. Experiences of developing the site are discussed with reference to the principal challenges and implications for future online interventions.

Theoretical Rationale for the Sexunzipped Website Design

The Sexunzipped website was developed over an 18-month period using an iterative process. This included a review of the relevant literature to define the theoretical basis for the intervention, seeking the views of young people through extensive focus group research, conceptualizing the intervention with a Web development company, and developing the content for the site. We report the outcome of our consultation with young people in detail elsewhere (young people's views on the content, design, and interactive features of the Sexunzipped website) [11].

A central principle of the Sexunzipped intervention was the adoption of a holistic approach to sex and relationships. This focused on a broad range of topics, including sexual pleasure and relationships, rather than just safer sex behavior. The language used on the site aimed to be gender and sexuality neutral to allow engagement with the website content regardless of gender, sexuality, or sexual preference. Our preliminary focus group work suggested that young people value honest information about sexual pleasure and sexual practices [11]. Previous research highlights the multiple influences on sexual health behavior, including individual factors (eg, motivation and affect), interpersonal factors (eg, sexual scripts and communication), systemic factors (eg, peer norms and familial factors) [12,13], and the suggestion that a focus on sexual pleasure may facilitate safer sexual behavior [14]. The website emphasized equality and sexual rights, informed by the connection between power imbalances between the genders and sexual health risk [15]. In developing the intervention, one of a number of definitions proposed by the World Health Organization [1] was adopted in which sexual health is viewed as:

> *...a state of physical, emotional, mental, and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled.*

Health behavior research has shown that theory-based interventions can lead to larger effects on behavior than interventions without a theoretical basis [16], with this effect also reported for Internet interventions [17]. A number of theories and models of behavior are relevant to sexual health interventions, but identifying a unitary model for application in an intervention can be difficult given the similarities between them [18]. Because of the breadth of the intervention content, an integrated behavioral model was chosen as the guiding theory for the Sexunzipped intervention [19]. The integrated behavioral model integrates concepts from the theory of reasoned action (TRA) and the theory of planned behavior (TPB), as well as concepts from other health behavior theories [19]. The integrated behavioral model suggests that behavior is influenced primarily by intention, which is in turn influenced by attitude, perceived norms, and sense of personal agency. Salient beliefs influence each of these factors, for example, beliefs about whether an action will be of benefit to the individual and beliefs about the opinion of others. The integrated behavioral model further posits that environmental constraints, behavior salience, habits, knowledge, and skills have further direct influences on behavior. Although the core aspects of the TRA and TPB have been supported by extensive research, eg, [20], some authors have suggested that these theories can be enhanced by the inclusion of anticipated affect within behavioral formulations [21,22]. Anticipated affect "refers to the prospect of feeling positive or negative emotions (eg, exhilaration, regret) after performing or not performing a behavior" [21]. The core components of the integrated behavioral model and the concept of anticipated affect were central to the development of content for the Sexunzipped website, for example, including information and activities that challenged beliefs and encouraged reflection on anticipated affect.

Integrated behavioral model principles underpinned the website content that addressed safer sex behavior (condom and

contraception use and STI risk reduction). In line with the findings from our focus group work, the site covered topics such as relationship quality, sexual violence and control, and sexual pleasure [11]. These topics were included to provide information and encourage self-reflection (to support informed choices), but did not aim to change specific behaviors.

Table 1 lists the primary safer sex behaviors targeted by the website along with the determinants or beliefs salient for behavior change and ways in which these factors were addressed on Sexunzipped.

Table 1. Primary safer sex behaviors addressed by the intervention (Sexunzipped website).

Behavioral outcome	Determinants or belief related to behavior	Techniques for behavior change
Regular use of condoms	Negative attitudes or beliefs related to condom use or perceived norms concerning use	Assess and challenge beliefs and perceived norms related to the use of condoms
		Provide information on increasing sexual pleasure when using condoms
		Review of past behaviors and consequences from not using a condom
	Limited self-efficacy in use of and communication about condoms	Assess and increase confidence in using and talking about condoms
		Provide instruction on the use of condoms and talking about condoms
		Identification of risk situations for failing to use a condom and ways to avoid these
		Provide information on reducing problems associated with condom use
		Provide information to reduce any loss of pleasure associated with condom use
	Low salience of behaviors related to condom use	Review of past behaviors and consequences from not using a condom
Regular use of contraception	Belief or attitude of low risk of pregnancy from unsafe sexual practices	Assess and challenge common myths and beliefs related to the risk of pregnancy
	Low salience of behaviors related to regular contraception use	Review of potential consequences and changes to life should pregnancy occur
Reduction in being pressured into unsafe sex	Limited communication abilities and skills to deal with pressure	Information and advice on assertive behavior in sexual situations
		Information and advice on communication
		Identification of high-risk situations and ways to avoid these
	Low self-efficacy in dealing with high pressure situations	Identification of situations where pressure has been exerted
		Provide advice on dealing with sexual pressure
	Beliefs or attitudes facilitative of the use of pressure or of giving into sexual pressure	Challenges to beliefs suggesting the use of pressure is acceptable and the norm
STI protection and testing	Belief or attitude that the individual is not at risk from STIs	Assess risk of STI from behavior and challenge belief that risk is low
		Challenge beliefs and common myths related to contraction of STIs and testing
	Low salience of STI protective behaviors	Information on STIs and STI transmission to increase salience of STI protective behaviors
	Limited self-efficacy in ability to reduce STI risk	Identification of possible risky sexual practices and situations, and ways to reduce these
		Provide information on testing services

In terms of the site content and design, the initial focus group research and literature review shaped the overall scope of the content and helped to identify salient beliefs and behaviors to target; the integrated behavioral model provided the framework for identifying for relevant beliefs and factors related to safer sex behavior. The development of the content, particularly the interactive activities, drew heavily from cognitive behavioral therapy [23] and motivational interviewing [24], for example, exploring links between thoughts, feelings, and actions, and drawing on techniques such as identification and rating of thoughts and feelings, consideration of the importance or pros and cons of a particular behavior, and reviewing past experiences or future consequences.

Such behavior-change techniques were employed to differing degrees throughout the site to prompt safer sex behavior change [25,26]. The techniques most commonly utilized were "provide information on consequences of the behavior in general," "provide information on consequences of behavior for the individual," "prompt anticipated regret," "barrier identification," "provide instruction on how to perform the behavior," "prompt practice," and "general communication skills training" [26].

Overview of the Sexunzipped Content

The site was organized into 3 distinct but related sections each containing a number of topics: relationships, safer sex, and sexual pleasure. The aims and rationale of each section are presented in Table 2. Content was presented in 3 formats: (1) text-based information, (2) interactive quizzes, and (3) interactive decision-making activities.

Table 2. Description of Sexunzipped content sections and aims.

Topic		Aim
Relationships		
	Relationships—"sorting it out"	To provide information on sex and relationships, encourage equal and respectful relationships, and to encourage reflection on the participant's own relationships and relationship needs
	Dealing with pressure	To challenge beliefs related to behaviors which constitute being pressurized into sexual activity, to encourage reflection on participant's experiences of being pressured or pressurizing and to enhance self-efficacy and assertiveness in dealing with pressure in sexual situations
	Sexual violence and control	To provide information on situations which constitute sexual violence or abusive behavior and to assist individuals in identifying and dealing with these situations; similar to the "dealing with pressure" section, but with a greater focus on more abusive behavior
	Taking control, avoiding regrets	To provide information and skills for individuals to reflect on and identify situations which may lead to regretted sexual behavior or increased risk of pregnancy or STIs
Safer sex		
	Sexually transmitted infections	To provide information on STIs; to challenge some common beliefs and attitudes associated with increased risk of STIs and to assist individual in considering their own risk for contracting an STI
	Contraception and pregnancy	To provide information on contraception and to challenge some common beliefs and myths related to contraception and pregnancy; to assist individuals in considering the effect of a pregnancy on their lives
	Condoms	To challenge beliefs and attitudes associated with poor condom use; to increase self-efficacy in using and negotiating condoms and to identify potentially risky situations
Sexual pleasure		
	Sexual practices	To provide information on a range of different sexual practices and to enhance ability to discuss sex
	My body	To challenge a number of negative beliefs and attitudes associated with poor self-image; to normalize differences in sexual preferences and sexual behavior; to provide skills for addressing sex and self-image problems
	Talking about pleasure	To provide information and advice on talking about sex; to challenge a number of common beliefs that reduce ability to communicate about sex and pleasure

Each of the 3 website sections (relationships, safer sex, and sexual pleasure) consisted of interactive activities and detailed information (see Table 3). The information sections comprised factual information, as well as arguments or information to challenge beliefs related to safer sex behaviors. At the end of each activity or information section, users were presented with links to other relevant topics within Sexunzipped and/or links to organizations providing specific services, such as treatment of STIs or help with domestic abuse. Given the breadth of the site, the navigation was designed so that users would self-direct to the sections of interest and salience. Quotations from young people were employed throughout the site in response to focus group findings that the site should represent the views of a range of young people [11].

Table 3. Description of activities and information pages in content sections of the Sexunzipped website.

Topic	Activity type	Activity content
Relationships		
Relationships—sorting it out	Quizzes	Assessing the quality of a relationship
	Decision-making activities	Activities to help the user to consider what they want from a current or future relationship
	Main topics covered in information pages	Improving a relationship; negotiating sex in a relationship; ending a relationship; identifying relationship needs; timing of first sex in a new relationship
Dealing with pressure	Quizzes	Experiencing sexual pressure; being assertive in sexual situations; dealing with pressure from a partner to have sex
	Decision-making activity	Identifying risk situations and the consequences of being pressured into sexual behavior
	Main topics covered in information pages	Consent; pressure in a relationship; peer pressure; strategies for dealing with sexual pressure; sexual double standards
Sexual violence and control	Quizzes	Assessing the degree of controlling behavior in a relationship; improve knowledge about violence and control in relationships
	Decision-making activity	None
	Main topics covered in information pages	Signs of an abusive relationship; rape and sexual assault; personal safety in sexual situations; intimate partner violence and control; links to specialist organizations
Taking control, avoiding regrets	Quizzes	None
	Decision-making activities	Helping the user to think through the costs and benefits of a currently abusive of controlling relationship; previous regretted sexual encounters and how to avoid them in the future; potentially problematic motivations for engaging in sexual relationships (eg, to gain friendship or acceptance into a social group)
	Main topics covered in information pages	Use of sex as a coping strategy; sex and self-esteem
Safer sex		
Sexually transmitted infections	Quizzes	Assessing risk of contracting an STI; improving knowledge of STI transmission
	Decision-making activities	Assessing advantages, disadvantages and consequences of risky sex; prompting consideration of strategies for avoiding high-risk situations
	Main topics covered in information pages	STI transmission; STI symptoms; STI risk behaviors; STI health checks; finding an STI clinic
Contraception and pregnancy	Quizzes	Improve knowledge about contraception and pregnancy; options following an unwanted pregnancy
	Decision-making activities	The effects of an unwanted pregnancy; consideration of the impact of parenthood
	Main topics covered in information pages	Different types of contraception available; seeking advice and support with a pregnancy
Condoms	Quizzes	Barriers to condom use; competency in using condoms; improving communication about condoms with new partners; improving confidence in using condoms
	Decision-making activities	Reflection on previous risk behaviors and situations and formulation of plans to avoid such situations
	Main topics covered in information pages	Information on condoms; communication about condoms; addressing sexual problems associated with condom use; making condoms sexy
Sexual pleasure		

Topic	Activity type	Activity content
Sexual practices	Quizzes	Improve knowledge on different sexual activities; address common misconceptions about sex; increase understanding of sexual pleasure
	Decision-making activities	None
	Main topics covered in information pages	Information on a wide range of different sexual activities; ideas for enhancing sexual pleasure; other sex-related issues, such as pornography
My body	Quizzes	Assessing and improving sexual self-confidence and body confidence; providing normative information on sexual performance and bodily concerns
	Decision-making activities	None
	Main topics covered in information pages	Information on sexual pleasure; understanding one's own body and sexual responses; sexual problems; sexuality; sexual self-confidence
Talking about pleasure	Quizzes	Assessing current confidence in communicating about sex; challenging attitudes related to poor communication
	Decision-making activities	None
	Main topics covered in information pages	Communication about sexual pleasure

Two interactive activity templates were developed to allow for the repetition of interactive formats across the site. The first was an interactive quiz, whereby the user received feedback based on responses to questions. The second was a decision-making activity where responses were recorded and presented back to the user with a series of prompts to encourage reflection on behavior, emotions, and consequences, or to aid with decision making. A template for text-based information pages was also developed. Examples of these activities are presented later in this paper.

In the "Relationships" section, there were a total of 19 activities and 15 information pages. The content was informed by previous research identifying the beneficial effect of communication and assertiveness skills training in reducing risky sexual behavior [27,28]. Recent research on the extent of intimate partner violence among young people in the United Kingdom [29] suggested the need to address violence and coercion.

The "Safer sex" section was comprised of 15 activities and 45 information pages. Content in this section contained primarily information about STIs and contraceptive methods and activities to encourage safer sex behavior, such as better communication with partners, condom use for penetrative sex, and STI testing with new partners. The content was based on a number of empirical findings. For example, previous research has established the importance of including clear messages about risk [30] and methods to review past risk experiences and develop risk reduction plans [12]. A meta-analysis of different approaches to human immunodeficiency virus (HIV) prevention suggested that interventions for young people should provide discussion of normative behavior and attitudes, as well as condom provision and skills training [31]. Several reviews have identified the importance of including content related to increasing communication about safer sex [30,32,33], which formed a central part of the website.

The "Sexual pleasure" section contained 13 activities and 44 information pages. Content in this section focused mainly on descriptions of different sexual practices, enhancing sexual pleasure, and communication about sex and sexual pleasure. This was primarily informed by our focus group research that suggested young people wanted information on sexual practices and sexual pleasure [11]. Some commentators have suggested that a stronger focus on sexual pleasure may increase safer sex behavior and use of condoms [34,35]. Although empirical research on this is limited, there is some evidence suggesting that eroticizing safer sex messages may facilitate safer sexual behavior [14] and that condom discomfort or loss of sensation may reduce use of condoms [36,37]. The site made links between sexual pleasure and safer sex, for example, suggestions on how to deal with the reduced sensation and interruption of sex associated with condom use.

Sexunzipped Features

Information Pages

The website Information pages were written to convey information concisely, covering factual information, advice, and guidance. Quotations from young people were also used to illustrate the real-life experiences of other young people. The site provided information to increase knowledge of a wide range of issues including sexual risk, safer sex behavior, communication, and sexual pleasure. The information pages drew on specific behavior-change techniques to challenge myths, social norms, and negative beliefs related to sexual behavior, such as barriers to condom use, communication about condoms, and sexual pressure. Some pages also provided guidance or instruction on safer sex-related behaviors, such as instructions for putting on a condom.

Figure 1 shows a sample information page. This section acknowledged the embarrassment that can be involved in talking about sex and provided tips, such as talking in a relaxed way, asking a partner what they enjoy, and paying attention to body

language. There were further paragraphs explaining the importance of knowing one's own body, communication in different situations, and ways to approach the subject in a positive and fun manner (Figure 1).

Figure 1. Example information page.

Interactive Quizzes

The quizzes on Sexunzipped presented a number of questions with feedback provided depending on selected answers. Two types of quizzes were used. The first provided feedback based on the answer to an individual question; the second provided feedback based on a score derived from answers to multiple questions. Quizzes gave different types of feedback, including providing correct answers, providing comments to provoke thinking or an alternative perspective, "expert" feedback from the Sexunzipped team, and/or feedback from other young people. The expert feedback was factual or would highlight an important belief or attitude. Young person feedback consisted of either an anecdote or other form of comment. Feedback activities were used to provide information on social norms or to encourage beliefs and attitudes associated with improved safer sex behavior. A number of the feedback activities provided information which directly challenged common myths related to issues such as contraception and pregnancy (eg, "Pregnancy myth busting"), condoms (eg, "Condoms—it's not my problem"), and STIs (eg, "STI myth busting"). Some quizzes prompted self-reflection on a range of relationship and sexual health related issues, for example, relationship satisfaction (eg, "How good is my relationship?"), condom negotiation skills (eg, "Hang on, I've got a condom right here"), and confidence in using condoms (eg, "Condoms, how do I roll?").

Figure 2 shows an example question from the "sex myths" quiz. It was comprised of 5 statements related to sexual practices with users selecting whether the statement was true or false. The feedback provided the correct answer and/or further information

on the statement. For example the statement “sexually active young couples have sex at least twice a week” included the feedback that most sexually active young people aged 16 to 20 years have sex once a month or less [38] (Figure 3).

Figure 4 shows an example question from a score series interactive quiz. It was comprised of 10 questions related to positive and negative behaviors in a relationship. Each answer had an assigned score, weighted depending on the behavior, attitude, or belief assessed. For example, the use of violence in a relationship had a high negative score, whereas difficulties with communication had a lower negative score, with feedback depending upon participants’ total scores for all 10 questions (Figure 5).

Figure 2. Interactive quiz - example question.

Figure 3. Interactive quiz - example feedback.

Figure 4. Interactive quiz - example question from a score series.

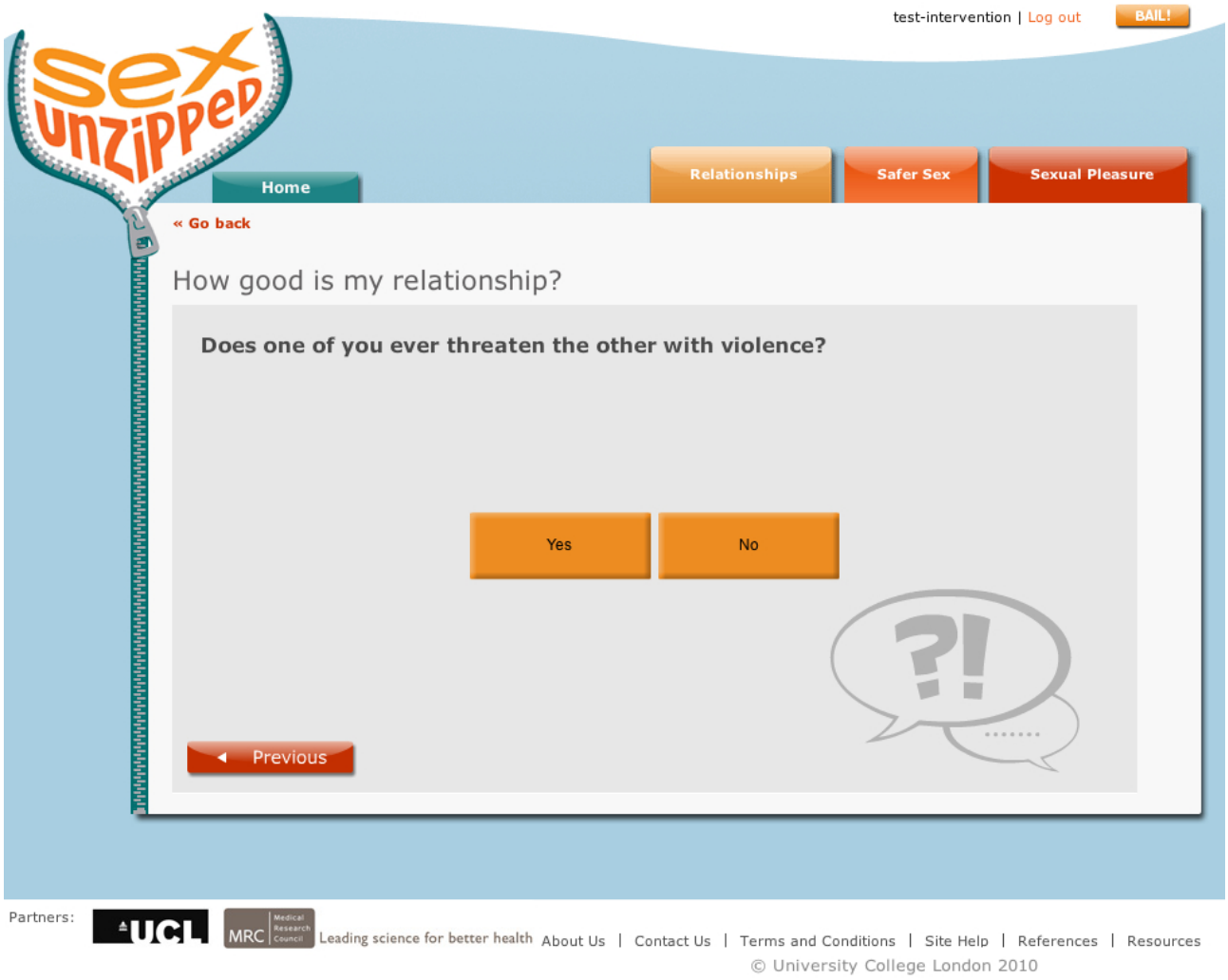
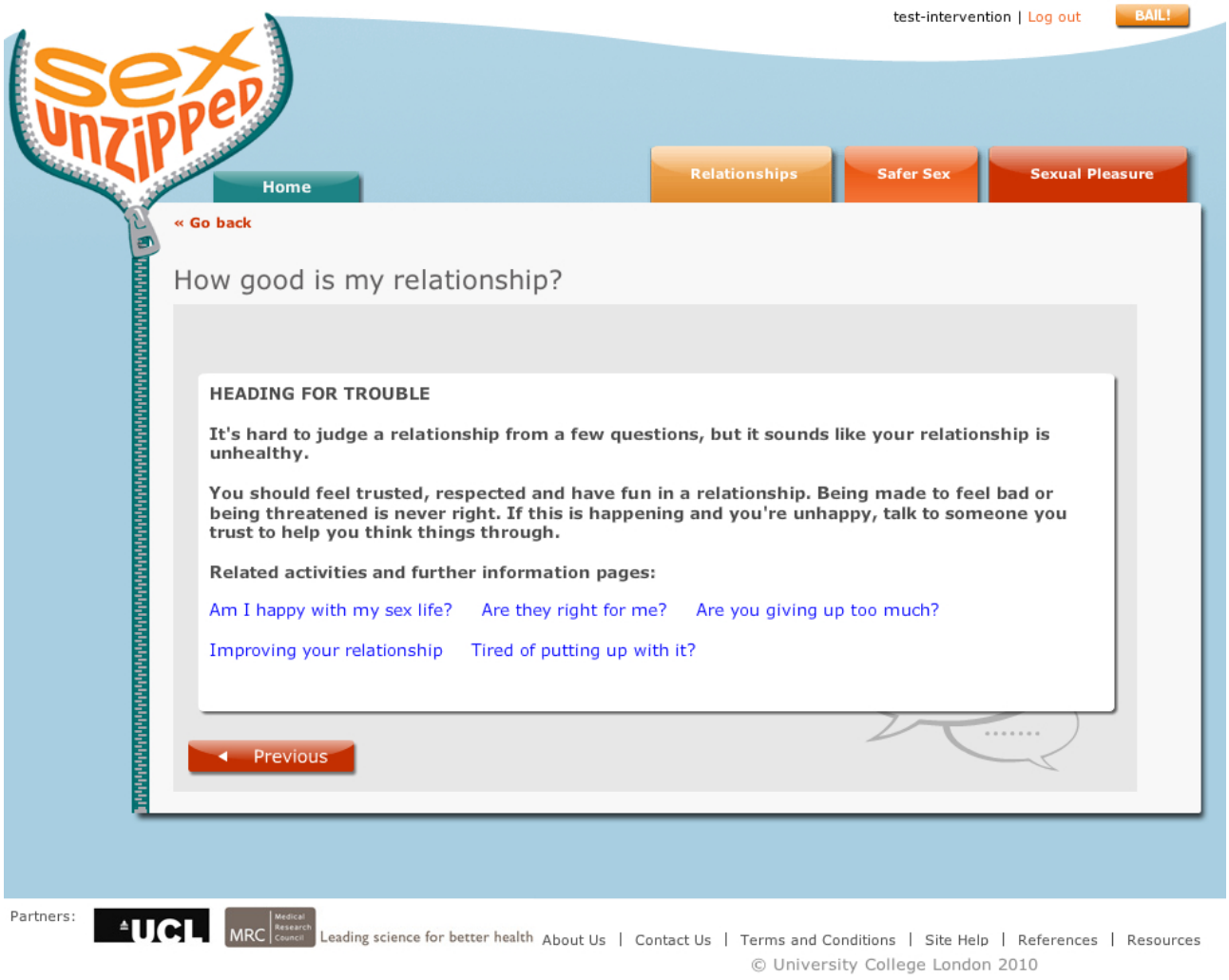


Figure 5. Interactive quiz - example of feedback from a score series.



Interactive Decision-Making Activities

The decision-making activities were designed to provoke self-reflection about behaviors related to sex and sexual health. Activities focused on problematic situations or dilemmas where users were asked to consider options, selecting either predefined suggestions or defining their own. Users' answers to these questions were fed back to them in the form of a table followed by several further questions to initiate thoughts about the behavior or anticipated affect from performing or not performing the behavior. Some self-reflection activities addressed relationship quality, but they were used primarily to prompt consideration of safer sex behaviors.

Figure 6 shows an example question from a decision-making activity. The user was asked to choose a situation where they felt at risk of being pressured into a sexual activity they did not want, such as sex without a condom. Further questions assessed the importance of avoiding the activity, the consequences if they engaged in the activity, and strategies to prevent such activities. The answers were fed back to the user with additional questions to prompt reflection, such as considering confidence and further avoidance strategies (Figures 7 and 8).

Figure 6. Decision-making activity - example question.

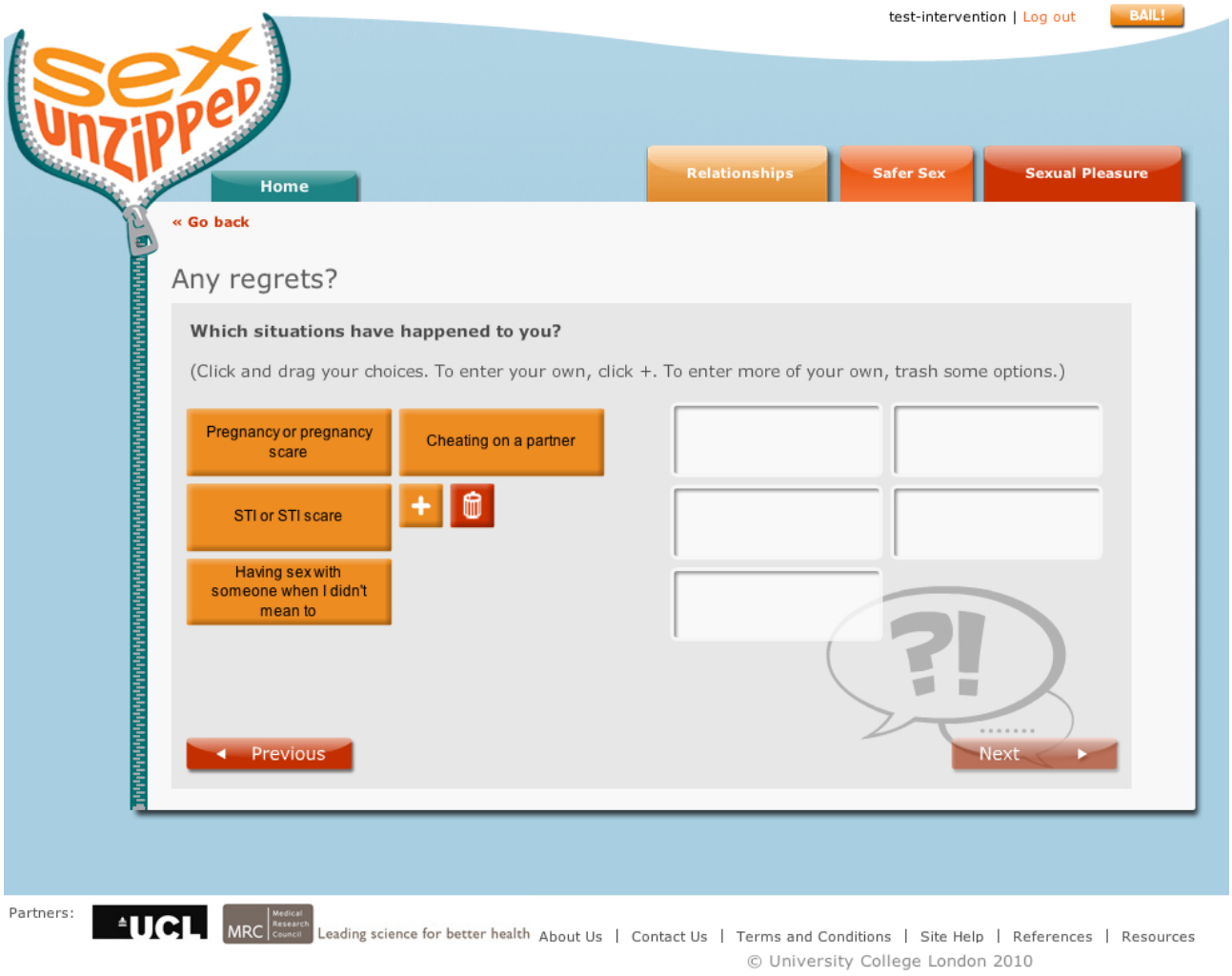


Figure 7. Decision-making activity - example feedback.

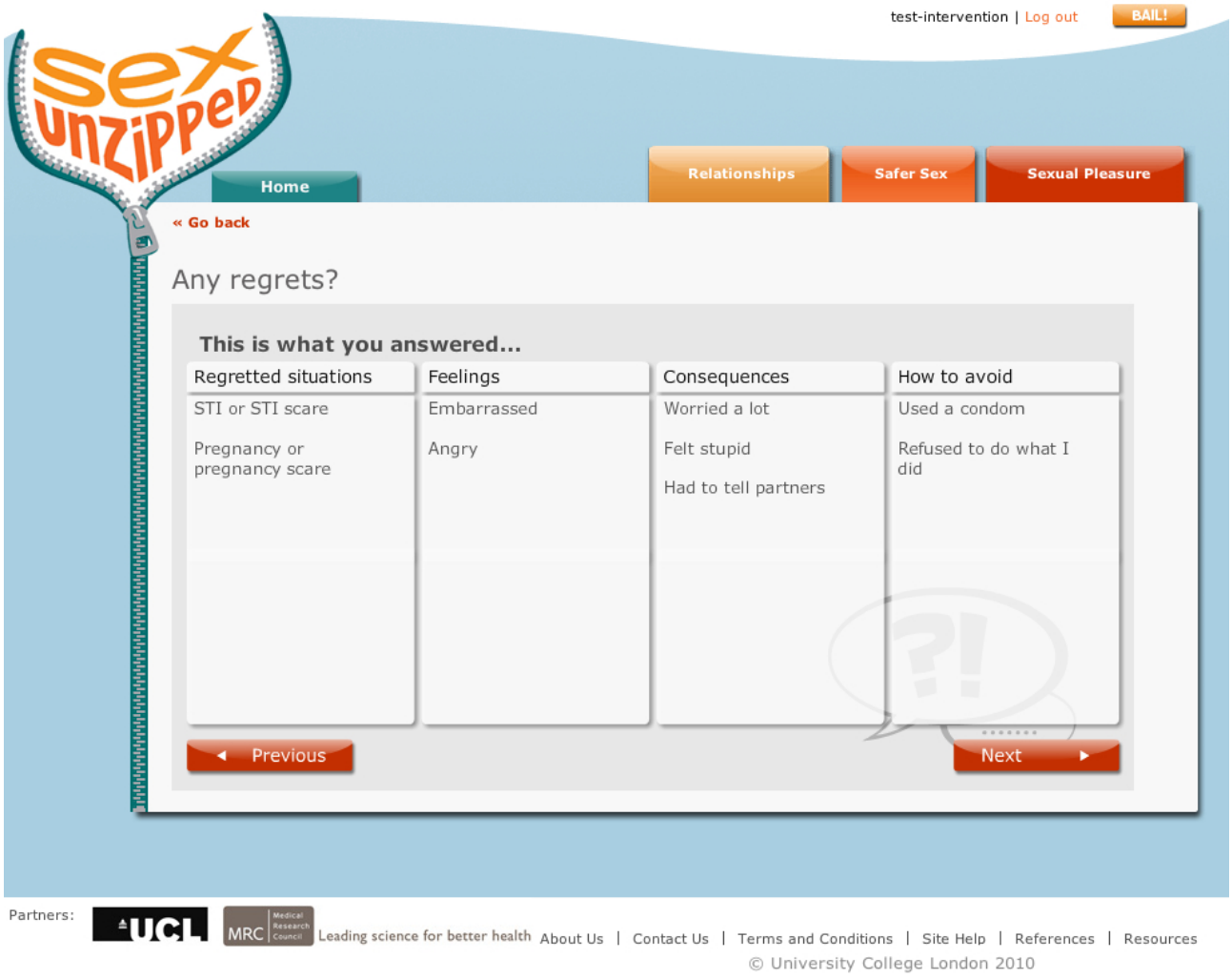


Figure 8. Decision-making activity - example follow up prompt.

Evaluation Design

The Sexunzipped website was evaluated in an online, randomized controlled trial (RCT) that compared Sexunzipped to an information-only control website. The protocol for this study is presented subsequently.

Study Design

We conducted an online RCT designed to test the hypothesis that the Sexunzipped theory-based, interactive, online intervention would be more effective in promoting sexual health in young people than an information-only website. A total of 2006 young people aged 16 to 20 years were enrolled in the trial between November 2010 and March 2011. Participants completed a baseline demographic and sexual health questionnaire online and were automatically randomized by computer to the intervention website or the control website. We measured sexual health outcomes at 3 months by repeating the online sexual health questionnaire and by asking half of the participants to return (by mail) a urine sample for genital chlamydia testing. Ethical permission for the study was granted by the University College London Ethical Committee (ref: 1023/002).

Retention in online trials can be difficult [39]: this study was a pilot (feasibility) trial with a number of substudies to test the best ways to maximize retention at follow-up. The full results of the website evaluation and trial design substudies are reported separately.

Recruitment

We invited young people aged 16 to 20 years to participate in the study by placing advertisements on sexual health websites and on the social networking site, Facebook. Also, advertisements were placed on UK school and college notice boards and flyers were distributed outside 3 sexual health clinics and 1 sixth-form college (comparable to senior high school in North America) in London, United Kingdom. We also emailed study participants to ask them to invite friends to participate.

Online Enrollment and Consent

Young people enrolled through the Sexunzipped website, which offered a £10 (US $16) incentive for participation. Two eligibility screening questions allowed only those who said they were currently resident in the United Kingdom and aged between 16 and 20 years to register. Eligible participants were presented with study information and a consent form online. They then created a username and password, and were directed to the online questionnaire that solicited demographic information and baseline sexual health outcomes.

Methods of Randomization

Participants (n = 2006) were individually randomized in a factorial design to either the intervention or control website, and to receive a urine sample collection cup for chlamydia testing at follow-up (or no sample collection cup). In a substudy to increase retention, 902 participants were randomized after recruitment, but before follow-up, to a £10 (US $16) or £20 (US $32) incentive for complete follow-up data. The first 2 randomizations were performed using an automated computer algorithm, and the third was performed offsite by random permutation of the participant identifiers, implemented by the trial manager. Neither participants nor researchers were aware of allocations in advance.

Outcome Measurement

Demographic information, including date of birth, gender, ethnicity, employment, email address, and postal address, were collected online at baseline. We also measured mediators of sexual behavior change (including sexual health knowledge, sexual communication self-efficacy, and intention) as well as sexual behavior (condom and contraception use, use of services, partner numbers), and self-reported sexually transmitted infections and pregnancy. We collected information on sexual problems, partner abuse, regretted sex, sexual pleasure, and relationship and sexual satisfaction. Key outcomes were the composite outcomes (1) correct condom use for vaginal sex and (2) correct condom use for anal sex.

Identity Verification

We requested date of birth at baseline and also at 3-month follow-up and excluded those participants who reported differing dates of birth. We also excluded participants with suspicious registrations, for example, repeat registrations using the same postal address or very similar names or email addresses.

Intervention and Control Websites

The intervention was the Sexunzipped website as described previously. The comparator information-only control website shared the same logo and colors as the Sexunzipped intervention site, but featured no interactive activities. The comparator website gave information on topics such as sexually transmitted infections, contraception, and sexual practices without encouraging self-reflection, decision making, or the development of communication skills. Participants were given unlimited access to their allocated website during the course of the study.

Outcome Data Collection

Participants were sent an email 13 weeks after registration with a Web link to the outcome questionnaire, which was identical to the sexual health questionnaire completed at baseline. Non-responders were sent up to 7 further reminders, initially by email and then by postal mail. Participants randomized to receive a urine sample collection cup by mail at 3 months were sent a postal kit for genital chlamydia testing and a prepaid return envelope; non-responders received 1 repeat postal kit. Urine samples were tested for *Chlamydia trachomatis* DNA by polymerase chain reaction. Results were sent to the participant by text, by phone, or by mail according to participant preferences.

Data Analysis

Three predictors of retention were examined for association with retention: (1) allocation to intervention website, (2) request for urine sample, and (3) level of incentive. We analyzed sexual health outcomes at 3 months in 2 ways: using available cases according to intention to treat and then restricted to participants who accessed the intervention or control websites during the study. Change in outcomes from baseline to 3 months were analyzed using logistic regression for binary outcomes, ordinal logistic regression for ordinal outcomes, and linear regression for continuous outcomes, reporting adjusted odds ratios, odds ratios, and mean differences, respectively. All effect measures were presented with 95% confidence intervals with *P* values based on 2-sided tests at a 5% significance level.

Discussion

This paper describes the development of the Sexunzipped website, a theory-based, interactive, online sexual health intervention for young people in the United Kingdom that addresses safer sex as well as sexual practice, relationships, and sexual pleasure. The site comprises both information and interactive elements aimed at giving young people the tools to make informed decisions about their sexual well-being by targeting communication skills and safer sex behaviors.

Sexual behavior and sexual health are complex issues, with multiple factors shaping sexual behavior [40]. For behaviors such as smoking and excessive alcohol use, the risk is clearly defined and interventions can be more focused on reducing this risk. With sexual health, young people may not identify themselves at risk of a particular problem and may not be seeking to change a particular behavior. Therefore, it was necessary to not only target specific behaviors, such as condom use, but also to prompt awareness of sexual risk.

There were some interactive features that were requested by young people [11] or suggested by the integrated behavioral model [19] that were omitted for a number of reasons. The integrated behavioral model suggests that perceived norms are an important factor influencing behavior [19]. Video clips of young people discussing sex-related topics were considered as an approach and this idea was piloted with focus group participants. This approach was not pursued because cultural signifiers, such as clothing and language, are specific to particular youth subcultures and will quickly become outdated. Similarly, discussion boards and social networking capabilities were considered to address normative beliefs because these could have provided opportunities for peer learning and act as a motivator for engagement in the site. We did not include these functions because they would require resource-intensive moderation, and because of concerns of potential abuse or bullying.

The integrated behavioral model suggests that behavior is influenced by intention, which is influenced by beliefs, attitudes, perceived norms, and personal agency [19]. Educational theory suggests that cognitive and affective engagement with material is needed to facilitate learning [41]. To this end, a diary or personal data area was considered because this would have

provided scope for behavior-change techniques, such as for goal setting, reviewing of behavior, and affective reactions to behaviors and greater consideration of behavioral intention and attitudes. However, the focus group research strongly indicated that young people were not interested in this feature, resisting activities which might take too much time or which seemed too much like "school work." To increase personal agency and self-efficacy as posited by the integrated behavioral model [19], we considered developing storylines or dilemma scenarios in which the user would make choices leading to different sexual health consequences. This would have allowed for the development of self-efficacy through the rehearsal of common risk situations, such as pressure to not use a condom. However, these were not developed further because young people indicated that they would not find these realistic or believable.

The online medium presents some unique challenges. Capturing the complexities of discussion and debate that may occur in face-to-face interaction is particularly complex online. It requires specifying in advance the beliefs and attitudes that are important mediators of sexual behavior in a particular population and defining automated responses to address these factors.

Implications for Future Interventions

Developing an online behavior-change intervention is costly and time consuming. It requires the bringing together of different sets of skills and knowledge, primarily expertise in sexual behavior change, user involvement, and website design and technology. It is necessary to partner with technical and design experts from an early stage in order for behavior change experts to understand the technical implications and costs of different online formats and for technical and design experts to understand the processes that facilitate behavior change. A good understanding of the requirements of the target group is also required, including how they use the Internet. This may be particularly important for interventions for young people given their rapid adoption of new technology [4]. Furthermore, the process of translating behavior-change techniques and theories into an interactive format requires careful specification of the intervention aims and objectives [42]. Given the large public health potential, the cost involved in developing online interventions, and the need for attractive design, future interventions may benefit from collaborating with established sites that already have a user base, a brand, and a strong Internet presence.

The Internet is a fast-changing medium, with increasing competition for the attention of young people, and design and technology quickly becoming obsolete. This presents a number of challenges for designers of interventions. Unlike face-to-face interventions, or facilitated computer-based interventions where users may be a captive audience to some extent, Internet interventions require the development of an online presence that will attract users. It is vital to involve users in decisions about intervention content, design, and features, paying attention to aspects that will attract and retain users' interest. Given the finding that theory-based online interventions lead to better outcomes than interventions that are not theory-based [17], a central challenge in developing effective Internet-based interventions for young people is to find effective ways to operationalize theory in ways that address the views and perspectives of young people.

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Conflicts of Interest

None declared.

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Abbreviations

HIV: human immunodeficiency virus
RCT: randomized controlled trial
STI: sexually transmitted infection
TPB: theory of planned behavior
TRA: theory of reasoned action

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Original Paper

Web-Based Intervention for Postpartum Depression: Formative Research and Design of the MomMoodBooster Program

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Abstract

Background: Postpartum depression is a significant public health problem affecting approximately 13% of women. There is strong evidence supporting Cognitive Behavioral Therapy (CBT) for successful psychosocial treatment. This treatment model combines cognitive and behavioral strategies to address pessimism, attributions for failure, low self-esteem, low engagement in pleasant activities, social withdrawal, anxiety, and low social support. Encouraging results have been reported for using Web-based CBT interventions for mental health domains, including the treatment of panic disorder, post-traumatic stress disorder, and complicated grief and depression. To date, however, Web-based interventions have not been used and evaluated specifically for the treatment of postpartum depression.

Objective: We describe the formative work that contributed to the development of our Web-based intervention for helping to ameliorate symptoms of postpartum depression, and the design and key components of the program.

Methods: A total of 17 focus group participants and 22 usability testers, who shared key characteristics with the participants of our planned feasibility study, took part. The proposed structure and ingredients of the program and mock-ups of selected webpages were presented to focus group participants. At various points, participants were asked a series of thought questions designed to elicit opinions and set the occasion for group discussion. At the end of the session, participants were asked to describe their overall reaction to the proposed features of the program emphasizing candid opinions about what they did not like and features they thought were missing and should be added. Usability testers were asked to interact with a series of seven different Web-based interactions planned for the program while receiving minimal direction. Each tester was asked to describe her thoughts using a *think-aloud* technique. They were then asked to consider all that they had learned about the program and complete the System Usability Scale that we adapted slightly to be appropriate for evaluating the proposed website. Transcripts from the focus groups and usability tests were reviewed by research team members for overarching themes with particular emphasis on suggested changes. A list emerged, and iterative and incremental adjustments were made as a result.

Results: The qualitative and quantitative data gathered in the focus groups and usability sessions reported here suggest that the new mothers involved had largely positive reactions to the major features of the program and that those program features performed well in terms of usability.

Conclusions: An overview of the eventual design, architecture, and key program ingredients of the *MomMoodBooster* program is provided including innovative features supplementing 6 core CBT sessions, which include a partner's website, a library, and individual feedback by a personal coach.

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KEYWORDS

postpartum depression; Web-based intervention; formative research

Introduction

Postpartum depression (PPD) is a significant public health problem affecting many women with incidence estimates ranging from 5% to more than 13% of new mothers [1-3]. PPD causes significant suffering in women and their families and has an adverse impact on infant development [4-6].

Stuart, O'Hara, and Gorman [7] have classified two types of psychosocial interventions for postpartum mood disorders: (1) preventive programs introduced during pregnancy or early during the puerperium, and (2) interventions designed to help ameliorate the depressive symptoms experienced by women who have already developed postpartum depression (PPD). For a meta-analysis of psychosocial interventions for PPD, see Dennis and Hodnett [8]. Cognitive Behavioral Therapy (CBT) has been found to be a successful psychosocial treatment approach for depression [9-14].

Lewinsohn's Coping With Depression (CWD) course [15,16] is a treatment model that combines cognitive and behavioral strategies to address pessimism, attributions for failure, low self-esteem, low engagement in pleasant activities, social withdrawal, anxiety, and low social support and has been adapted and evaluated in over 25 Randomized Controlled Trials (RCTs) in the treatment or prevention of depression [17]. Two meta-analyses [17,18] confirm the efficacy of the core CWD treatment approach and its adaptability for specific groups, reporting the average effect size (Cohen's d) as ranging from .28 to .65. CBT has been widely disseminated [17,19], extensively evaluated with different populations (adolescents, adults, the elderly), and delivered via a range of modalities (individual, group, bibliotherapy, television, the Internet). Research results indicate that CBT is particularly helpful for individuals with mild to moderate depression [20,21].

Milgrom, Martin, and Negri [22] adapted Lewinsohn's approach to create their Getting Ahead of Postnatal Depression program that included: (a) introducing behavioral activation (increasing pleasant activities) before presentation of cognitive strategies; (b) recommending relaxation "on the run" techniques; (c) reducing "homework"; (d) building support networks; and (e) incorporating partner sessions [22-25]. Milgrom's program included three partner sessions due to the impact of postpartum depression on the relationship and the finding that poor dyadic adjustment is a risk factor [26,27]. The program also emphasizes the infant, due to the impact of postpartum depression on the infant and mother-infant relationship [28,29]. Content for the Partner Support Program and some library articles drew on other PIRI programs "Towards Parenthood" [25] and the Community HUGS Specialized Playgroup [30].

Limited Utilization and Barriers to Treatment

It is becoming evident that even when postnatal depression is detected, use of clinic-based treatment for postnatal depression is poor, with only around 30-40% of women taking up treatment services [31-32]. Maternal beliefs and attitudes can form barriers that can significantly reduce the uptake of treatment for postpartum depression. One study [33] found that for many depressed new mothers, fear about acknowledging emotional distress (even to themselves) or admitting they may not be coping and the stigma associated with this leads them to "keep up appearances". The end result is that they decide not to seek help. Practical aspects of help-seeking with a young baby (eg, travel, cost, tiredness, child care, organization, and lack of motivation) while suffering from the symptoms of depression further increase the barriers to treatment uptake [33,34]. Delivering CBT treatment via the Internet may well reduce these barriers and make helpful treatment more readily available and attractive. Moreover, Internet treatments enable mothers to reduce feelings of stigma by being somewhat anonymous, as they do not have to attend a clinic in person. Internet treatments can thus significantly extend the reach of treatment to mothers who may benefit but would not otherwise attend regular clinic treatment.

Web-Based Approaches for Depression

Although early attempts to use Web-delivered interventions to reduce depressive symptomatology yielded equivocal results [35,36], subsequent studies have reported more promising findings [20,37-42]. It is important to note that encouraging results have also been reported for using Web-based CBT interventions for other mental health disorders including the treatment of panic disorder [43,44], post-traumatic stress disorder [45,46], and complicated grief [47]. To date, Web-based interventions have not been used and evaluated for the treatment of postpartum depression.

Web-based interventions offer unique advantages that should increase engagement and improve impact [48,49]:

- Web-based treatment programs can reach a larger percentage of women in need than clinic-based programs. This public health impact is especially important for women in rural settings with limited transportation, childcare resources, and access to mental health professionals [50,51].
- Program content can be tailored to participant characteristics and interests. While there are not yet clear data as to which factors may have the greatest impact on outcomes, there is broad consensus that tailoring of materials to individual participant characteristics enhances program credibility [52] and is likely to increase program efficacy [53,54].
- The program can monitor which intervention materials each user has accessed in order to encourage participant engagement by presenting fresh, non-redundant content.
- Information from past sessions can be used more efficiently than in a face-to-face setting to reinforce gains made, to shape the subsequent program content, and to provide ongoing feedback [55,56].
- Users can set their own pace and can access information at any time. This "on demand" capability is of particular

importance with postpartum women, for whom flexible access to program content is a requirement given their childcare commitments and general lack of time.
- Web forums can provide helpful advice and support within an anonymous environment [35,54].
- There is low post-development cost to deliver the program to each participant.

Guided human support (ranging from a technician-level coach to a more highly skilled therapist) has been shown to increase adherence to online mental health treatments [57,58] and a number of Web-based mental health interventions have used telephones or other mediums to deliver this [20,37,59,60]. Mohr, Cuijpers, and Lehman [57] have developed a robust model ("supportive accountability") of the mechanisms by which adherence to technology-delivered interventions can be enhanced by human support. Alliance with a "trustworthy" coach is central to this model and a number of studies have now shown that a strong online working alliance can be achieved in guided Internet treatments for PTSD and depression [eg, 48,63]. However, while amount of contact time correlates positively with efficacy [61], there are nevertheless diminishing gains in increasing contact time above a certain threshold [62,63]. Similarly, there is growing evidence that less clinically skilled workers (ie, technicians versus clinicians) can provide sufficient low-intensity support to enhance the therapeutic effects of Internet CBT programs, even in clinically diagnosed samples [60]. The emerging picture is that very encouraging therapeutic effects can be achieved through structured Internet programs, supported by low intensity-guidance (typically <3 contact hours in a six-week program), which has further implications for cost-effectiveness, reach, and widespread dissemination [64].

Overview of Approach

The *MomMoodBooster* program (USA) and *MumMoodBooster* program (Australia) are Web-based interventions, supplemented with a series of calls with a personal coach, based on an adaptation of Milgrom's group CBT treatment for postpartum depression. The program was developed by a multinational team composed of researchers based in three organizations: Oregon Research Institute (ORI), Parent-Infant Research Institute (PIRI) in Melbourne, Australia, and the Iowa Depression and Clinical Research Center (IDCRC). This report delineates the formative research procedures used to develop the program content and provides an overview of the eventual design, architecture, and key program ingredients of the *MomMoodBooster* program.

Methods

As we have described elsewhere [65], the current research is an adaptation of Stage I in the Stage Model of Behavioral Therapies Research [66] and the multistage research model recommended by the USDHHS Science Panel on Interactive Communications and Health [67]. Stage I typically involves formative evaluation to assess the nature of the problem behavior in addition to the needs of the target population in order to inform intervention design and program content. Process evaluation is then used to assess and improve the administrative, organizational, and operational features of the intervention. The current report describes preliminary phases of Stage I research that involved intervention development and formative evaluation that represented a link between feasibility research and subsequent, more controlled research stages. The formative research procedures used to inform the development of the *MomMoodBooster* program involved focus groups and usability testing. We followed an iterative and incremental process in which early feedback was used to accomplish rapid changes [68]. Testing occurred first in Melbourne, Australia, and was followed by testing in Iowa City, Iowa. As a result, the feedback we received in Melbourne was used to further refine the content that was then tested in the subsequent sessions in Iowa.

Participants

Eligibility criteria for participants in focus group and usability testing were used in order to enroll mothers who shared key characteristics with the participants of our planned feasibility study. Specifically, mothers had to be English-speaking, less than 12 months post partum, at least 18 years of age, have home access to the Internet, and use personal email. They had to report a personal history of depressive episodes in the period following the birth of their baby as indicated by either the Edinburgh Postnatal Depression Scale (EPDS ≥ 12) or the Beck Depression Inventory (BDI-II ≥ 14). The EPDS is a widely used self-rated depression screening assessment that has been validated using various cut-offs [69,70]. Similarly, the BDI is a widely used assessment tool for depression in the postpartum period [71,72]. There were two separate cohorts of participants, corresponding to the design of the subsequent feasibility study that called for participants to be recruited from Iowa and Melbourne, Australia.

Focus groups and usability testing sessions were held in Melbourne, Australia, in late September 2010, followed approximately 2 weeks later by sessions held in Iowa. Eligibility criteria for focus group participants essentially mirrored the eligibility criteria of participants of the eventual feasibility trial of the *MomMoodBooster* intervention. The focus group protocol and related Informed Consent procedure were reviewed and approved by the Human Research Ethics Committee of Austin Health in Australia and the Institutional Review Boards of both ORI and the University of Iowa.

Recruitment

Recruitment for the Australian testing used promotion of the study to health professionals and services in the Parent-Infant Research Institute's (PIRI) existing referral networks, including over 100 Maternal and Child Health Centers (MCHCs) in northern and central metropolitan Melbourne. Women were also recruited from PIRI's clinic population. Women were screened for eligibility, completed the EPDS, and those meeting eligibility criteria were invited to participate.

Recruitment in Iowa involved sending letters to women listed in the State of Iowa birth registry as having given birth in the last 12 months and who lived within three counties within an hour's driving distance from the University of Iowa. Research staff then called these women. After consenting to participate, these new mothers were briefly screened for eligibility including completion of the EPDS over the phone. Those mothers who passed the second round of eligibility were then scheduled to participate in a specific focus group. The mothers signed the

consent and completed additional questionnaires prior to the start of the focus group. These participants signed the consent and completed additional questionnaires prior to the start of the focus group.

Focus Groups

The Australian focus group was conducted at PIRI in Melbourne and involved 8 women who had a mean age of 36.0 years (SD = 5.5 years). All women were Caucasian Australians from mixed ethnic backgrounds as is typical of the population. Childcare resources were available, and participants received $50 for their participation. Each session was audio recorded and transcribed.

The Iowa focus group was held in the Iowa Depression and Clinical Research Center (IDCRC) in Iowa City, IA, and involved 9 women who had a mean age of 29.4 years (SD = 6.29 years). Eight mothers identified themselves as Caucasian, and 1 mother identified herself as African American. Two ORI researchers (BD and JS) participated in all focus group sessions.

Usability Testing

The Australian usability testing sessions were conducted at PIRI in Melbourne, Australia, and the Iowa usability testing sessions were held at IDCRC in Iowa City, IA. These sessions typically involved women who had participated in focus groups and were scheduled to occur in the same location and at a time immediately following completion of focus group sessions. This approach ensured that usability testers would have a broad familiarity with the research project and preliminary design ideas about the Web-based intervention. All usability testers met eligibility criteria that mirrored what was planned for participants of the eventual feasibility trial. The mean age of the 14 usability testing participants at PIRI was 36.2 years (SD = 3.9 years), and the mean age of the 8 women at IDCRC was 29.3 years (SD = 6.6 years). Participants received $75 each for their participation.

Procedures

Focus Groups

Our focus group procedures were informed by our experience and by published guidelines [73]. Each session began with participant completion of the Informed Consent followed by a brief pre-assessment. The session lasted approximately 1.5 hours. Focus groups were facilitated by project researchers and observed by additional research team members.

The initial portion of the session provided an overview of the research team followed by a description of the proposed structure and ingredients of the *MomMoodBooster* program including a series of sequential sessions (eg, Getting Started, Managing Your Mood, Increasing your Pleasant Activities), a library of relevant articles, tracking tools, and tools for support. The presentation also highlighted the use of videos, the ability to personalize the webpages with picture files from home, the role of Personal Coach calls, and a possible weekly schedule for sessions that would be flexible to accommodate somewhat longer time periods so that each mother had the opportunity to spend some extra time on any session in order to learn—and use—the recommended strategies.

Mock-ups of selected webpages were presented including a welcome page, a webpage on negative thoughts that prompted discussion about the proposed left navigation features and the contents of the top menu, and a webpage from the tools menu that users would access in order to track daily mood and pleasant activities.

At various points, participants were asked a series of questions designed to elicit opinions and set the occasion for group discussion. For example, following the discussion of the Web forums, participants were asked how often they would post messages to a forum or would choose to read the posts made by other program participants. Following the discussion of the Partner Support program, participants were asked whether they would recommend the Partner Support program to their partner, whether their partner would visit the program, and whether the label "partner" was acceptable for the Partner Support website. Following presentation of the Personal Coach calls, participants were asked whether they thought such calls would be helpful, who should initiate the calls, the preferred characteristics and experience of Personal Coaches, ways calls might be scheduled in order to make them more practical, what to do when scheduled calls were missed, and the length of calls.

At the end of the session, participants were asked to describe their overall reaction to the proposed features of the program (the colors, fonts, imagery, and complexity of the webpages). Candid opinions were encouraged including what participants did not like as well as any features they thought were missing and should be added.

Usability Testing

Web-based interventions should embody established usability standards [74,75]. Once functional program components have been created, usability testers can be asked to provide feedback on program completeness and relevance as well as on the extent to which the program functions properly (eg, that buttons work when clicked, that navigation indicators change to properly reflect each participant's location in the program). Usability testing was scheduled to occur at interim points in the development process to allow incorporation of iterative feedback from usability testers.

A relatively small number of usability testers can provide extremely valuable data that would inform revisions to the program [76]. Each tester met individually with a research staff member who acted as a facilitator. At times, another staff member would be present in an observer role. Usability testers were asked to explore these interactions while receiving minimal direction from the facilitator. Each tester was asked to describe her thoughts using the *think-aloud* technique that was derived from cognitive science [77] and has proven effective in the study of human-computer interactions [78,79]. As noted by Hughes [80], the think-aloud technique provides "…direct, real-time observations of the user rather than self-reports such as surveys" (p. 493). Think-aloud methods assess cognition concurrently with its occurrence. Thus these procedures may be better able to describe the thoughts and attitudes of users [81]. The audio from each usability test session was digitally recorded and transcribed.

We report here upon a preliminary usability test phase in which participants met individually with a facilitator to interact with a series of eight different Web-based interactions planned for the *MomMoodBooster* program that had been selected because they were deemed to be important as well as especially challenging (from a usability perspective). These interactions included mood spirals animation, pleasant activity list, mood *plus* pleasant activity rating form, partner support program, practicing change form on extreme thoughts, daily pleasant activities (pie chart), mood ratings plus pleasant activities line chart, and mood rating form. The usability testing was limited to these key interactions excerpted from the program rather than the program in its entirety.

Measures

Focus Groups

We obtained qualitative data from notes created by research staff who observed the focus group session. Session transcripts were also reviewed by research team members for overarching themes with particular emphasis on suggested changes. All of the focus group transcripts were electronically imported into the qualitative analysis software Atlas.ti (version 6.0) [82]. All participant dialogue was transcribed anonymously. Atlas.ti allows for on-screen coding and aids in managing multiple codes including groups (families) of codes. Atlas.ti also contains an advanced search option (query tool) that facilitates the identification of multiple themes across large amounts of text as well as permitting the analysis of similar participant responses. An open-coding strategy was used based on: (a) the central concepts of the proposed *MomMoodBooster* program, (b) themes that had arisen during the focus groups (suggestions by participants), and (c) codes that emerged during textual analysis. Related codes were then grouped together to create categories and subcategories until all relevant themes had been identified.

Usability Testing

Participants were asked to consider all that they had learned about the *MomMoodBooster* program and complete the System Usability Scale (SUS) that we adapted slightly to be appropriate for evaluating the *MomMoodBooster* website (Table 1) [83,84]. Brooke [85] has reported that "…the principal value of the SUS is that it provides a single reference for participants' views of a product's usability" (p. 194). The value from a 5-point scale in the 10-item SUS scale describes the features of the website. We followed the recommendation by Brooke [85] and Sauro [86] to convert raw score ratings ranging from 1 to 5 based upon directionality of items.

Table 1. System Usability Scale item responses: Combined sample (N= 21).

		Negative		Positive		
		0	1	2	3	4
1	I think that I would like to use this website frequently.			14.3%	47.6%	38.1%
2	I found the website unnecessarily complex.[a]			4.8%	33.3%	61.9%
3	I thought the website was easy to use.			14.3%	28.6%	57.1%
4	I think that I would need the support of a technical person to be able to use this website.[a]				14.3%	85.7%
5	I found the various functions in this website well integrated.		4.8%	19.0%	42.9%	33.3%
6	I thought there was too much inconsistency in this website.[a]			14.3%	28.6%	57.1%
7	I would imagine that most people would learn to use this website very quickly.		4.8%	4.8%	38.1%	52.4%
8	I found the website very cumbersome to use.[a]			9.5%	28.6%	61.9%
9	I felt very confident using the website.	4.8%		4.8%	38.1%	52.4%
10	I need to learn a lot of things before I would get going with this website.[a]				33.3%	66.7%
	Proportion for all participants	0.5%	1.0%	8.6%	33.3%	56.6%

[a] Values of responses to these items were reversed when scored.

Results

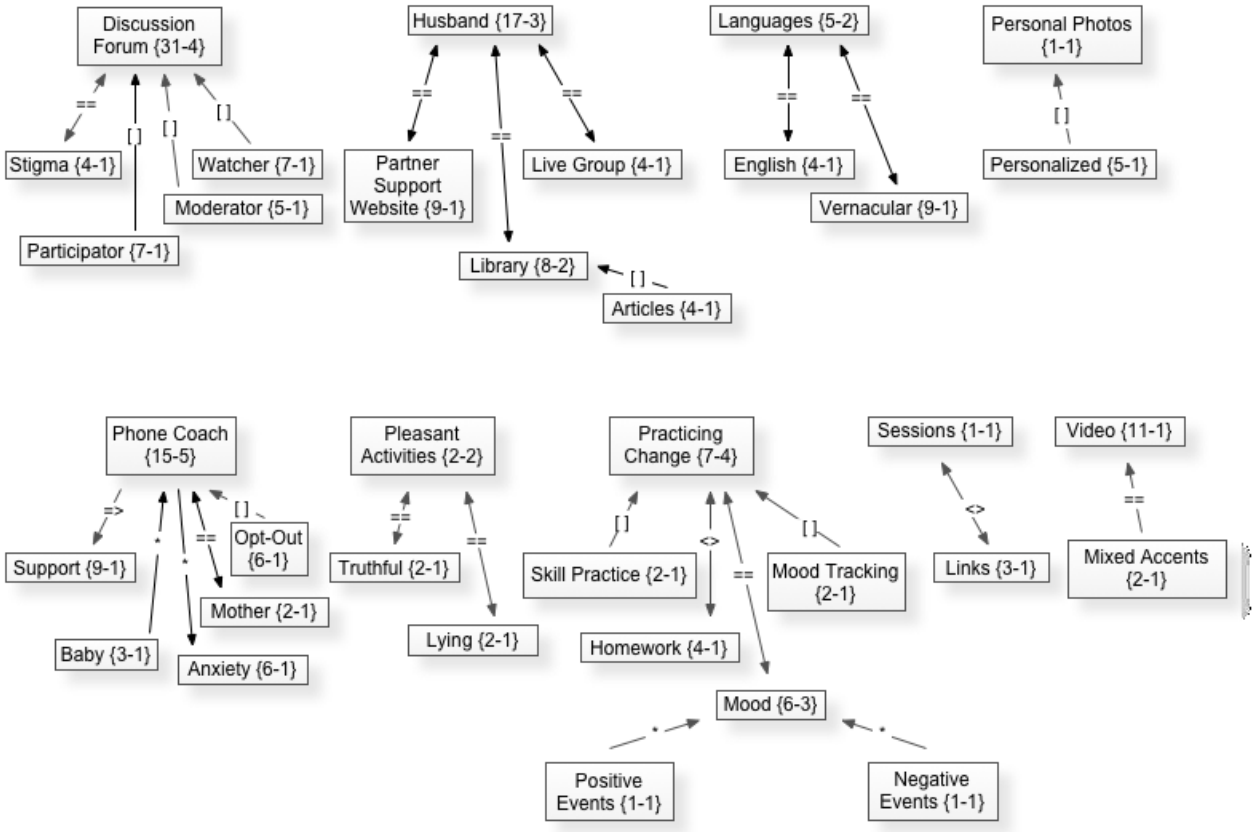
Focus Group

The network view option in Atlas.ti allowed us to analyze relationships between codes and themes in a visual format. In Atlas.ti, codes are independent of each other until you create a network and "link" the codes together. The links are tagged with unique symbols to delineate what kind of relationship the codes have, ie, affects (*), is a part of ([ ]), is associated with (==), contradicts (<>), etc. This particular network view (Figure 1) is structured around the theme "Engagement" and all of the codes associated to this particular concept.

From this network view diagram (Figure 1), it can be seen that nine themes were discussed relating to engagement. Some examples include participants voicing opinions and concerns related to their husbands' participation in the program, the expressed benefits and roadblocks they would have with the phone coach aspect of the program, and their suggestions related to the proposed discussion forum. The lines connecting codes in this network view are the relationship links discussed previously. The numbers that appear under (or beside) each

code have separate meanings. The first number denotes the number of quotations in the transcripts associated with that code, and the second number denotes how many codes are linked to that code in the network view option of Atlas.ti. For example, the topic of "Discussion Forum" arose in participants' discourse 31 times across all of the transcripts, and discussion forum is directly linked to 9 other codes, 3 of which are in this particular network view: stigma, participator, and watcher. The number of times a theme is mentioned in quotations taken from the transcripts provides a possible index of its importance.

Figure 1. Mock-up of Atlas.ti network view diagram of focus group participant comments showing theme of Engagement.



Participant Comments

Focus group participant comments in both Iowa and Melbourne were quite positive for the most part:

- "I think this is wonderful, because you can do it at home."
- "Very successful in making me feel confident to use it."
- "Consider tips for single parents."
- "The colors and font were very inviting."
- "The graphics and videos are great, and the anecdotes from other mothers would be brilliant."
- "It wouldn't take me long at all to get the hang of it."
- "I probably wouldn't click a video."
- "With this it would be so convenient because it would be right there in my house. I would definitely be a lot more likely to use that."
- "It's nice to know that you're not alone in the universe."
- Regarding phone coaching: "Having one more thing to do/remember would be difficult...The phone always rings when the baby is screaming."
- "I really think this is wonderful, because you can do it at home and you don't have to go somewhere and talk to somebody."

A list of the overarching themes and summarized participant statements are described in Table 2. In general, mothers indicated support for the web forum and partner support features of the website. The use of multicultural video vignettes was also endorsed by the focus group participants. Participant feedback was also informative with respect to encouraging skill practice (eg, do not refer to practice assignments as "homework") and the personal coach (eg, assign the same coach for each session; female coach; flexible scheduling).

Table 2. Summary of comments from focus group participants.

Theme	Comments
Web Forum	Definitely use
	More likely to read than post
	Like “Ask the Expert” as a reliable source
	Desire moderation/monitoring of posts
Partner Support Program	Most agreed they would invite partner
	Many believe partner would not use support program
	Motivate partner by emphasizing mother wellbeing
	Could facilitate communication between spouses
	The use of the term “partner” was acceptable to most
Videos	Mixture of US & Australia videos would be fine
	Comfort that other cultures experience PPD
	Make program more engaging
Practice Change Activity	Term more acceptable than homework
	Provides encouragement
	Need flexible schedule
	Keep simple
	Reminder would be helpful; on website or email
Personal Coach	Prefer same coach each call (all participants agree)
	Woman-Mom would be preferable as coach
	Coach should call participant
	Flexible scheduling
	Use email reminders
	Pick a set duration; anything under a half hour OK
	Could opt out without being dropped from program
	Strongly suggest call 2 times before discontinuing
Tools	Generally like the idea of daily tracking
General	Name and colors agreeable

Usability Testing

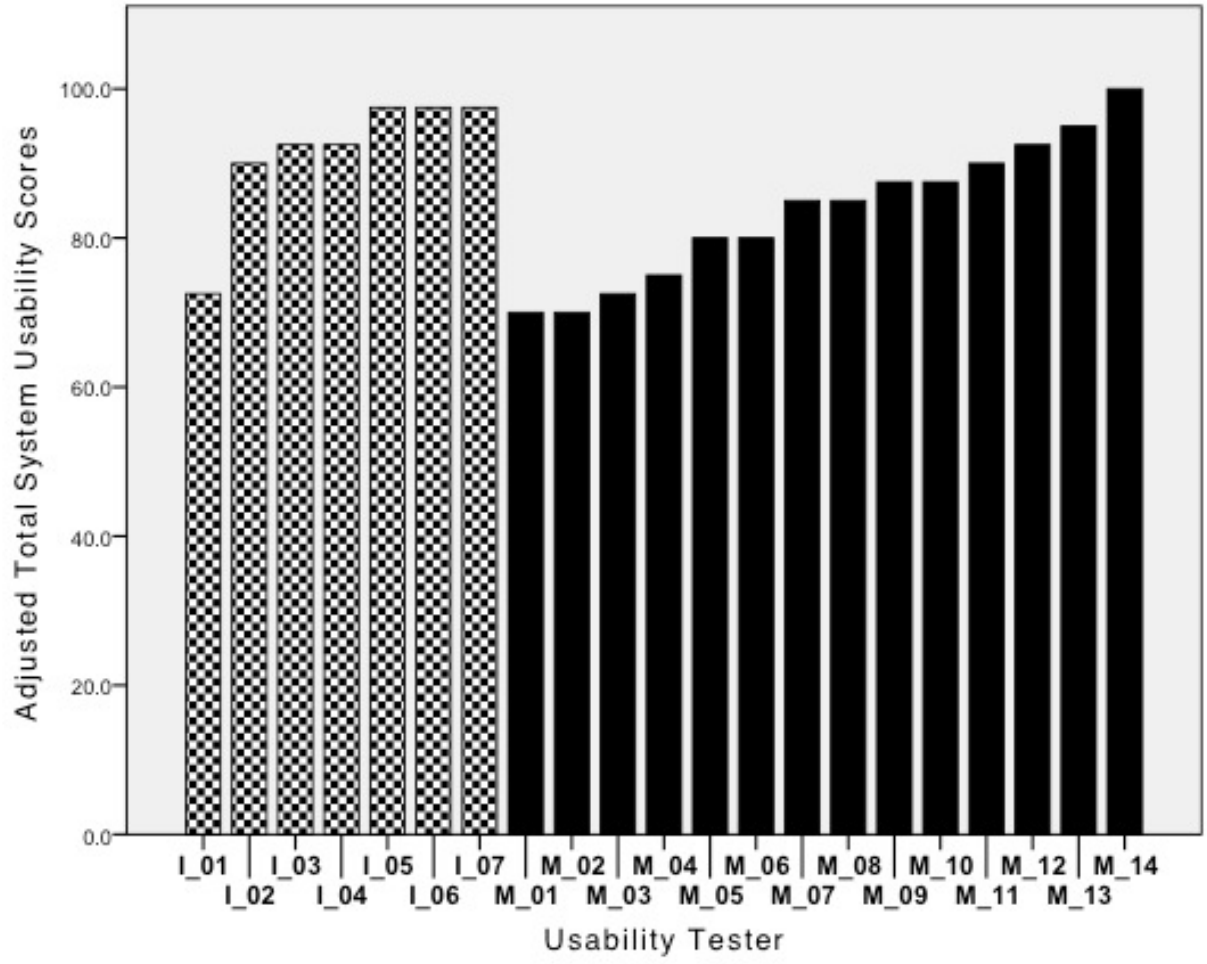
Quantitative Results

SUS ratings (0 = extremely negative; 4 = extremely positive) were obtained for 21 of 22 (95.5%) of the usability testers: the Melbourne sample (N = 14; mean = 3.36; SD = 0.38) and the Iowa sample (N = 7; mean= 3.66; SD = 0.36). The combined samples had a SUS score mean of 3.45 (SD = 0.39). It is helpful to examine the proportion of responses across participants by the assigned adjusted SUS ratings (see Table 1). Using this perspective, we note that 33.3% of testers assigned a score of 3, and 56.6% of respondents assigned a score of 4 that resulted in 90.9% of respondents having a positive reaction to the usability of the *MomMoodBooster* program.

Results for the SUS total scores that had a range of 0 to 100 were as follows: for the Melbourne sample (N = 14; mean = 83.57; SD = 9.39), for the Iowa sample (N = 7; mean = 91.43; SD = 8.88), and for the combined samples (N = 21; mean = 86.19; SD = 9.77). As shown in Figure 2, the individual SUS are quite uniform with scores greater than 80 being reported by 14 of the 21 participants (67%).

A SUS score of 73 has been described as good, a score of 85 as excellent, and a score of 100 as the best imaginable [86]. Using the scoring interpretation for the overall adjusted SUS score results obtained, it appears that each of the usability testers found the selected interactions from the *MomMoodBooster* program to be very usable.

Figure 2. Overall adjusted System Usability Scale scores (N= 21) (patterned fill= Iowa usability testers; solid fill= Melbourne usability testers).



Qualitative Results

As part of *thinking aloud*, usability testers at times shared evaluative comments about program features. Examples included the following:

- "I love that I can click on this and make it big, so I can see it and understand it. Ooh, the pie chart cracks open. I like this, this is really cool."
- "Red text draws attention; I don't need to know what I did not do. Get rid of red."
- "It's very good. It's [a] very easy program, it doesn't have a lot of—you know how sometimes you get on web pages and there's so much to see, and it seems like every time you go to the spot you need to go to, you always need to go back four pages. It doesn't seem to have any of that sort of stuff."
- "I do like the partner part…I think that coming to see the psychologist, I think my partner missed out, and he would have liked to have known—he was so scared of what was being said."
- "A lot of reading here. He would not read this much."
- "It was good, actually, because it sounds like it's a really useful tool for mothers."
- "Chunks of writing [are] too much; needs colors to stand out more."

Feedback in terms of tester comments and the observations of the research staff who facilitated the formative sessions led to myriad important refinements to the eventual design of the *MomMoodBooster* program. For example, we added language and tone gleaned from comments shared in focus group and usability testing sessions to enhance the relevance of our content and increase the credibility of our program. Portions of some of the stories shared in the focus group were used as the basis of stories presented in our online video vignettes. The eventual protocol we used for coordinating calls between personal coaches and program participants took into consideration the opinions mothers shared with us in focus group sessions regarding the fact that the Personal Coaches should initiate the calls, but mothers have an online method to share scheduling messages with their Coach.

Usability feedback about challenges with our initial online tracking tools led us to further simplify their interface and add more context-sensitive user instructions. Based on comments we received, the Practice Change (homework) activities in the program became key components that encouraged home practice of the recommended behavioral skills. Because participants emphasized the importance that their Practice Change activities along with their other progress in the program should be available to Personal Coaches to enhance the relevance of their shared calls, a sophisticated administration website was created

that provided Personal Coaches with a digital dashboard showing details of participant progress in using the *MomMoodBooster* program.

MomMoodBooster Program Design

The resultant *MomMoodBooster* program combines a tailored, interactive Web-based postpartum depression intervention for individual mothers who also receive a series of Personal Coach calls. The overall program also includes two additional websites: a Partner Support website and an Administrative website that includes a dashboard for Personal Coaches (Figure 3). A schematic depiction of the final content design of the *MomMoodBooster* program is shown in Figure 4. The program guides participants through a series of six sequential sessions: (1) Getting Started, (2) Managing Mood, (3) Increasing Pleasant Activities, (4) Managing Negative Thoughts (example webpage shown in Figure 5), (5) Increasing Positive Thoughts, and (6) Planning for the Future. The program follows a schedule that makes available each successive session across a 6-week period. Each session opens with an auto-play video introduction of session goals and content provided by the program host. Webpages in each Session use text, interactions, animations, and video to present program content.

The secure program encourages participants to personalize their program content by typing in their personal lists, setting personal goals, and performing *practice change* activities in their everyday routines. Mothers can print out a personal workbook that summarizes their personalized content while also providing a brief written record of the content they covered. *MomMoodBooster* program users can further personalize their program by uploading their own photos so that they are displayed on program webpages that they view. The program includes self-monitoring tools that enable the daily tracking and online charting of both mood and pleasant activities (Figure 6) and other online resources. It also includes ad hoc (anytime) access to a library of relevant articles on communication skills, getting support, managing stress, managing time, solving problems, sleep and caring for baby, baby's needs, and your partner.

Since social isolation and stigma are often experienced by depressed mothers with newborn babies, the *MomMoodBooster* program provides access to a private peer-based Web forum in which mothers can post a message as well as read and interact with the messages of other participants.

The *MomMoodBooster* program includes a weekly phone call from an assigned Personal Coach. This role is designed to be largely non-therapeutic as it is intended only to provide support, encourage program engagement, and clarify how best to use the online program. Personal Coaches can access a special digital dashboard that describes the extent that an assigned participant has interacted with the program (Figure 3). During bi-weekly coach calls study participants are asked to complete the PHQ-9 assessment, which is used as a safety check of each participant's status [87]. Deterioration in PHQ-9 scores of ≥ 20% of baseline is used to trigger a participant safety procedure that was well-established in both research sites (Melbourne and Iowa).

Finally, because partners/fathers also have an important role to support mothers in working with the program, the program provides an email feature to enable mothers to invite their partners to visit a separate Web-based partner support program that describes postpartum depression, the *MomMoodBooster* program, and ways they can be supportive.

Figure 3. Dashboard for Personal Coach Webpage in MomMoodBooster Administrative Website (checkmarks indicate that participant has used certain interactions or viewed specific webpages).

Figure 4. Structure of MomMoodBooster program.

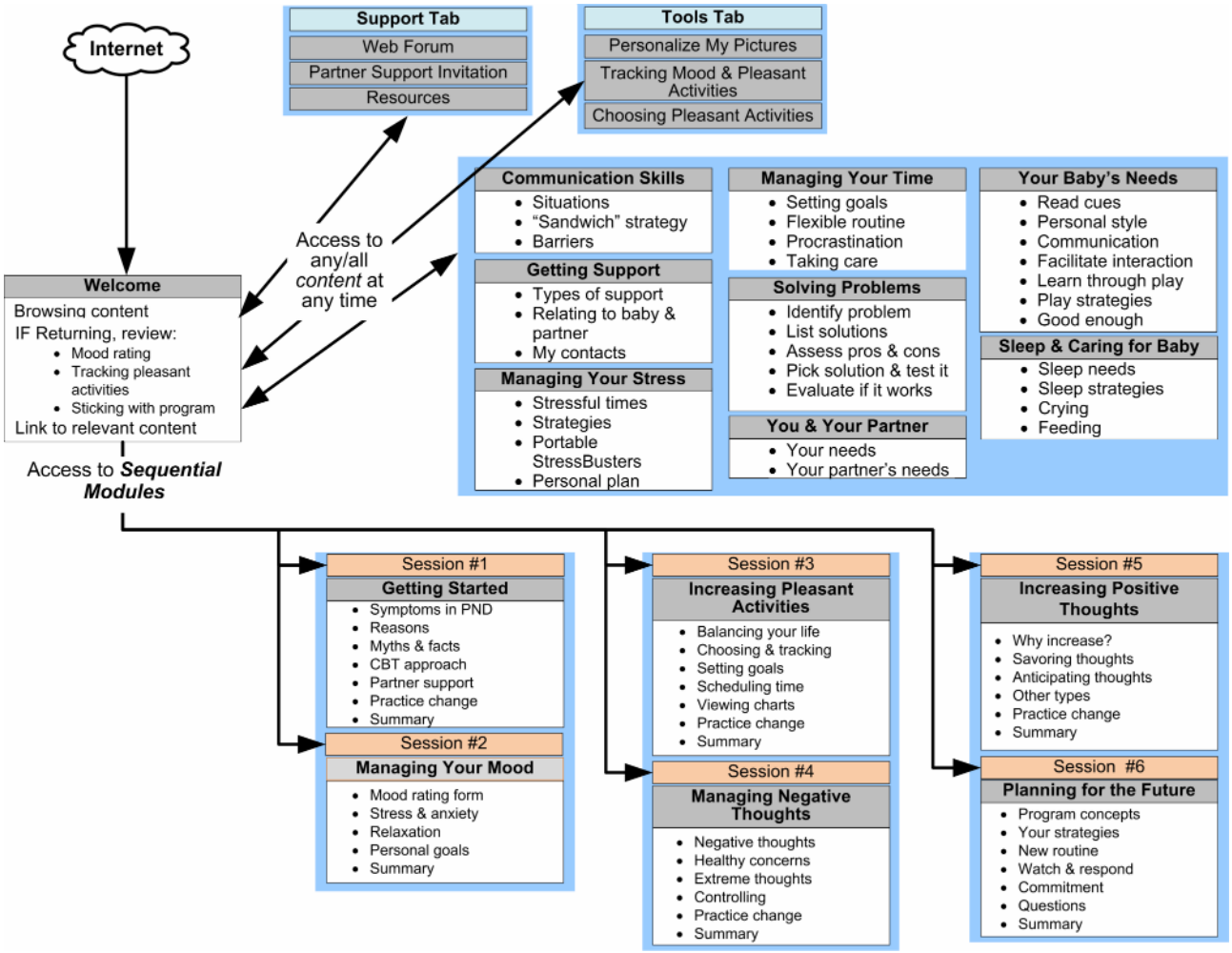
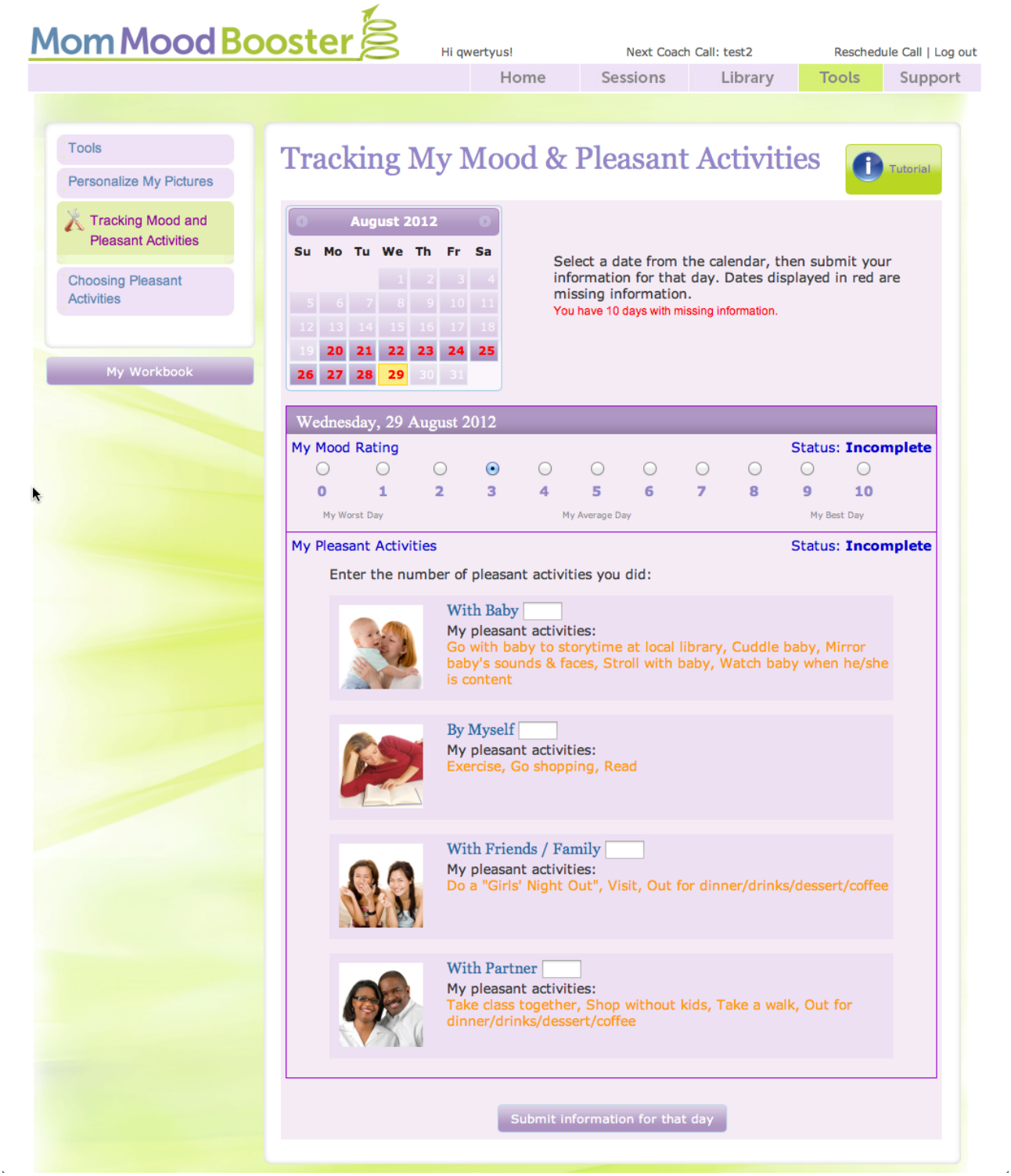


Figure 5. Webpage from MomMoodBooster Session 3 (Displays content participant has entered for personal list of Catastrophisizing Thoughts).

Figure 6. MomMoodBooster Tracking Tools used daily to track Mood Ratings and number of personally-selected Pleasant Activities accomplished.



Discussion

Postpartum depression represents an important public health problem especially because many new mothers are unable or reluctant to seek help. Poor treatment uptake results in many mothers not accessing services or receiving support to ameliorate their depression. This can have substantial consequences for themselves, their partners, and their infants. Web-based depression interventions represent a rapidly emerging approach for extending the reach of efficacious treatments [64,88]. The *MomMoodBooster* program is a highly innovative Web-based intervention specifically designed to ameliorate postpartum depression. In this report, we have described: (1) the formative work that contributed to the development of our Web-based intervention for helping to relieve symptoms of postpartum depression, and (2) the design and key components of the program.

The qualitative and quantitative data gathered in the focus groups and usability sessions reported here suggest that the new mothers involved had largely positive reactions to the major

features of the *MomMoodBooster* program and that those program features performed well in terms of usability. Specifically, the formative results supported our use of sequential sessions, involvement of the Personal Coach having certain characteristics, the availability of a separate support website for the partner, etc. In addition, we found that using the ATLAS.ti qualitative analysis tool helped to identify useful themes from our focus group session transcripts.

Limitations of the current formative research are largely related to the fact that our focus group and usability testing samples were not representative of all mothers nor did all participants provide us with a complete data set. Although participants in the formative research satisfied eligibility criteria similar to those we intended to use for participants in our planned feasibility study, this group of women is best considered a convenience sample that may not generalize to all postpartum mothers. For example, the Australian sample was somewhat older (focus group: M = 36 years, SD = 5.5) than the median age of mothers in Australia (2010 births; 30.7 years) but more consistent with Australian women ages 30-34 years who have the highest fertility rate of all age groups in that country [89]. The Australian sample was also older than the American participants, which is consistent with 2010 birth data for both countries (in Australia, 51% of mothers giving birth were 30-39 years old [89], whereas in the US that age range accounted for only 36% of mothers giving birth [90]). We did not collect data on participant education or income, which prevents any discussion of representativeness of our sample.

It is also important to acknowledge that the usability test results described in this report were obtained in a preliminary usability phase. Our usability testing efforts did not end at this initial step in the process. Instead, usability feedback continued to occur in an iterative and incremental manner as the *MomMoodBooster* program continued to be developed [68]. In addition, participants who provided SUS ratings at this initial phase had only relatively brief interactions with preliminary designs of key program tools and interactions. We anticipate that positive SUS results will also be obtained from feasibility study participants who use the completed, fully integrated *MomMoodBooster* program.

In terms of lessons learned, we concluded that there were many more similarities than differences between our Australian and American samples of postpartum mothers. There were differences in language in terms of spelling and in terms of common usage. We concluded that these differences were critically important features that need to be localized in the final Web-based program. But some differences in language and accent did not preclude the use of Australian videos and audios with an American audience and vice versa. As more than one participant indicated, they felt less isolated knowing that mothers from the other cultures shared similar challenges with postpartum depression. Finally, the technological sophistication of our two participant samples was quite equivalent. These similarities provide support for expanded US/Australia collaborative research on Web-based interventions.

The *MomMoodBooster* program is currently being tested in a feasibility trial that involves 50 depressed postpartum mothers—25 in Australia using the *MumMoodBooster* program and 25 additional mothers in Iowa using the *MomMoodBooster* program. While the content of the two programs is identical in meaning, each version uses country-specific language, and each has its own set of host videos for every session. The two programs use Personal Coaches and they also share video vignettes of mothers describing their implementation of some of the strategies using a mixture of American and Australian actors. It remains for the results of our feasibility trial and a subsequent fully powered RCT to establish the efficacy/effectiveness of the *MomMoodBooster* program. Results from our formative research have been highly encouraging and were instrumental in developing a program acceptable to mothers with PPD.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

BDI: Beck Depression Inventory
CBT: Cognitive Behavioral Therapy
CWD: Coping with Depression course
EPDS: Edinburgh Postnatal Depression Scale
IDCRC: Iowa Depression and Clinical Research Center
ORI: Oregon Research Institute
PHQ-9: Patient Health Questionnaire (9-item)
PIRI: Parent-Infant Research Institute
PPD: Postpartum Depression
PTSD: Post-Traumatic Stress Disorder
RCT: Randomized Controlled Trial
SUS: System Usability Scale

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Original Paper

Developing an Internet-Based Support System for Adolescents with Depression

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Abstract

Background: Depression is the most common mental health problem among adolescents. Despite policy guidance and governmental support to develop usable mental health services, there is still a lack of easily accessible and modern interventions available for adolescents in Finland's majority official language.

Objective: Our objective was to develop a user-friendly and feasible Internet-based support system for adolescents with depression.

Methods: The Internet-based support system for adolescents with depression was developed. To create this new intervention, some examples of existing interventions were studied, the theoretical basis for the intervention was described, and the health needs of adolescents identified. As an outcome of the process, the results were combined and the content and delivery of a new intervention will be described here.

Results: Six individual weekly Internet-based support sessions were delivered by a tutor over a 6-week period of time and developed to form an intervention called Depis.Net. This was an Internet-based support system for adolescents with depression tailored to improve self-management skills and increase awareness of their own well-being and mental health. The intervention was accessible via an electronic platform, which was secured and password protected for users. The intervention on the Depis.Net website consisted of elements identifying adolescents' needs, and offering self-monitoring, access to health information and self-reflective written exercises. An educated nurse tutor gave written feedback to each adolescent via the electronic platform.

Conclusions: An Internet-based support system for adolescents with depression was developed using a systematic approach with four steps. This was done to ensure that the intervention had a sound theoretical background and at the same time caters flexibly for the problems that adolescents commonly face in their daily lives. Its potential for adolescents visiting outpatient clinics will be evaluated in the next phase by means of a randomized controlled trial.

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KEYWORDS

adolescent, Internet, depression, development, intervention, support

Introduction

Mental health issues associated with adolescents have become a global public health problem [1,2]. It has been estimated that at least 20% of adolescents have some kind of mental health problem [3]. Depression is the most common mental health problem among adolescents with an estimated point prevalence of 4-6% [4]. In 2008, 8% of America's adolescents had at least one major depressive episode during the past year [5]. Depression is associated with suicidal ideations and attempts [6] causing pervasive and prolonged functional impairment, morbidity and predicts psychopathology in adulthood [2,7]. Although most adolescents recover from their first depressive episode, the probability of recurrence is from 20% to 60% in 1 or 2 years after remission and 70% after 5 years [8].

A Cochrane review by Merry et al (2011) found some evidence that tailored and universal depression prevention interventions may prevent the onset of depressive disorders compared with no intervention [9]. In recent years, such interventions have been developed more systematically using information technology (IT). The development has made the Internet a source of mental health information [10,11]. Internet-based health interventions have also been used with adolescents for depression prevention, anxiety prevention [12], and depression disorders [13]. However, according to systematic reviews, among adolescents they are still much more rare than with adults [14,15]. A national survey of young Australians found that 71% of respondents rated websites and books for mental health information to be helpful, which was less than for counseling, which generally involves face-to-face meetings in mental health services [16].

Internet-based interventions are nowadays a way to offer behavioral intervention in an environment in which IT is available and the population is adapt at using it [17]. In most Western countries, including Finland, IT is an integral part of people's lives and more than 80% of the people in this population are Internet users [18,19]. It is especially popular for adolescents' daily communication [20] and computers are often placed in adolescents' bedrooms [21]. We therefore assumed that Internet-based interventions could be integrated into adolescents' daily routines [22]. In Finland our new Health Care Act (2010/1326) highlights that health services should be near to users and also easily accessible for them [23]. In this paper we will describe a study in which we developed an Internet-based support system intervention for adolescents with depression who attend an adolescent outpatient clinic.

Previously, a variety of Internet-based devices have been developed and tested to support people with depression. These applications offer, for example, interventions treating depression online [24], increasing literacy among depression or reducing stigma and symptoms [25], Web-based cognitive behavioral therapy (CBT) [26], deducing symptoms using Internet support groups [27] or supporting people with depressive tendencies by a peer support social network service [28]. On the other hand, Internet-based methods [29] or other technical devices, such as mobile phones [30], have been less frequently used to help adolescents with depression. In 2012, Kauer et al [31] used mobile phones to facilitate self-monitoring for adolescents in their early stages of depression, while in 2009, Costin [32] used Health e-Cards to encourage help seeking. Further, van der Zanden and their group [13] developed an online group course for depression in adolescents and young adults in 2012.

However, devices to be used in depression have mostly been developed for speakers of English or for populous nations. Finnish is a relatively rare language compared to the fact that there are 5.4 million native speakers. Although Finnish adolescents generally nowadays have good English skills [33] helping them to integrate into the global world, services in Finnish, including mental health services has to be offered in Finnish language. Besides language, Finland is characterized by contrasting phenomena. For example, contradictions the education system is one of the best of the world and literacy in the skill of Finnish population is almost 100% [33]. The homogenous school system ensures that 97% of adolescents complete compulsory basic education [34]. At the same time, 5% of the age group between 15 and 29 years are excluded from the society, which means that they do not have a place to study, do not complete their education, or do not have a job [35]. Finnish adolescents also suffer from loneliness. It has been found that 9% of 8-9 graders had no close friends [36]. Other problems overshadowing Finnish adolescents include abuse of alcohol, which is related to low parental support and high parental alcohol abuse problems observed among depressed adolescent outpatients [37]. Other factors such as high divorce rates (2.5 divorces per 1,000 inhabitants) [38], high suicide rates for people ages 15-19 [39] also contribute to the high proportion of adolescents with depression compared to other countries. All these unique problems support a view that a culturally sensitive support system satisfying adolescents' needs in Finnish language should be developed.

Methods

Developing the Intervention

This intervention is an Internet-based support system designed for use in psychiatric adolescent outpatient clinics. In this intervention, we conducted measures in which the outcomes were synthesized and produced in the form of an Internet-based support system for adolescents with depression [40,41]. First, we reviewed the evidence for intervention development by searching the relevant literature on the topic. Second, we identified the most useful theories guiding intervention development. Third, we conducted interviews with professionals in social and health care services to gain a better perspective on adolescents' world, problems, or needs and possible solutions to these problems. Finally, we co-operated with nursing staff to ensure that the intervention would be adopted as part of the existing treatment environment and procedures, and that these newly developed interventions would benefit the adolescents, professionals, and services involved.

Reviewing the Evidence-Based Knowledge

Internet-based interventions are based on a variety of treatment ideologies and theoretical backgrounds, such as CBT [14], self-help [42], or problem-solving therapy [12]. The findings of a meta-analysis of the effectiveness of Internet-based

psychotherapeutic interventions provide strong support for the adoption of online psychological interventions [43]. There are also indications that IT is superior to waitlist and control assignments and the effects of IT are equal to therapist-delivered treatment across anxiety disorders [44]. Moreover, adherence to and satisfaction with computerized CBT interventions is good among patients despite the significantly reduced amount of contact with the clinician [45]. However, dropout rates are considerable [45] even though comparable to those reported in other psychological therapies [46]. The most common reason for dropout is that the participants were too busy or have a change in circumstance, with only a few trials reporting that the treatment was not useful as the reason for drop outs [46]. For IT to be effective, it must be technically reliable and robust, well accepted by clients and health care professionals, capable of producing services equivalent in quality to face-to-face consultations without undue disruption to practice patterns [47].

A number of Internet-based interventions for adult anxiety and depression have been developed and implemented, but there are fewer interventions for adolescents [14,15,43,48]. In Australia a randomized controlled trial study conducted by Calear et al examined the effectiveness of the MoodGym in a large sample of adolescents (N = 1477) in a school environment with the aim of targeting both anxiety and depressive symptoms. However, the effects on depressive symptoms were effective only in male participants in the intervention group at post-intervention and at 6-month follow up [49].

In addition to the present study, we found 4 registered clinical trials focusing on the use of IT among adolescents with depression. These registered studies were searched from the Clinical Trials Search Portal (search terms were adolescent AND depression AND information technology OR computer). This portal provides access to a central database containing the trial registration data sets provided by the most common registries. All these 4 studies [50-53] focus on CBT using IT. These studies targeted 546 adolescents with mild to severe depressive disorder. Interventions under investigation include self-directed programs and programs where adolescents receive counseling (Table 1). Based on this information, the knowledge base regarding the use of CBT will be strengthened. However, the present study investigated the use of IT as a method to increase self-management among adolescents with depression. The method is intended to support and strengthen the delivery of the treatment, not to replace it.

Table 1. Description of the registered randomized controlled trials considering the use of information and communication technology among adolescents with depression.

Intervention	Target group	Estimated enrollment	Country	Title, register, identification, and status
Computer guided, CBT delivered by a clinician-administered telephone intervention	Adolescents with major depressive disorder	150	US	Information Technology Enabled Treatment of Adolescent Depression ClinicalTrials.go NCT01582581 Recruiting
Stressbusters, computerized CBT program	Adolescents with low mood or depression	96	UK	A feasibility study and pilot trial of computerized CBT for depression in adolescents ISRCTN ISRCTN31219579 Recruiting
The computer-administered self-directed program is based on CBT	Adolescents with mild to moderate depressive symptoms	200	New Zealand	Youth e-therapy - Evaluation of a computerized CBT self-help program for adolescents with mild to moderate depression ANZCTR ACTRN12609000249257 Closed
A computer resource with a CBT-based guided self-help intervention with minimal supervision from a school guidance counselor or clinician	Adolescents with mild to moderate depression	100	New Zealand	Computerized delivery of a CBT-based self-help intervention for the treatment of depression in adolescents: development and pilot study ANZCTR ACTRN12606000142538 Recruiting

Theoretical Framework of the Intervention

As a theoretical framework we chose the self-determination theory (SDT) [54,55], which gave us guidance on how to support adolescents' natural or intrinsic tendencies to behave in an effective and healthy way. SDT focuses on the degree to which an individual's behavior is self-motivated and self-determined. In the context of an adolescent self-management intervention, the theory would suggest that adolescents' motivation to manage their own situations and well-being depends on their intrinsic motivation, which can be supported by increasing their positive feeling of autonomy, competence, and being connected [56,57]. In addition, a sense of connectedness should represent interpersonal acceptance and closeness. Thus, guided by the SDT we decided to plan our intervention so that at the beginning the adolescents should have a chance to identify and describe their own perceptions of their situations and possible concerns to ensure that adolescent' inner motivation and needs are identified from the start.

By so doing we were also more aware of what kind of information and support adolescents need to resolve in their individual situations. To support adolescents' competence and sense of autonomy, we focused on several areas, including knowledge-based awareness, self-monitoring, self-awareness (moods, feelings), social relationships (networking, friends, family relations), and life style (habits, circadian rhythm). In addition, a need for relatedness was supported by a person offering interpersonal acceptance, who is not too far away and close enough to be present and connected to the adolescent whenever needed, and who imparts a caring atmosphere without being too officious. The intervention then consisted of a variety of elements: identification of adolescent needs, self-monitoring, access to health information, and self-reflective written exercises. We also offered weekly positive feedback to promote feelings of competence. Positive feedback was previously shown to be effective in enhancing intrinsic motivations while negative feedback impairs them [58].

Interviews with Social and Health Care Professionals

To ensure that the support system intervention to be developed would satisfy the needs of suffering adolescents in their daily work (adolescent workers, police officers, staff from the emergency services and the family center, special teachers at school, and from the adolescent work of the Church), semi-structured interviews with only one theme were conducted in 2006. During the interviews, these 2 questions were posed to 17 participants: (1) What are the main problems that adolescents aged 15-17 years encounter? (2) What support do these adolescents need from a professional standpoint? The interview responses were analyzed using inductive content analysis [59].

The analysis revealed 5 key problems related to adolescent care. First, there was a lack of structure in adolescents' lives; they have no daily routines and rules and they have problems to cope with. They have irregular daily routines; they wake up late, have irregular meal times or do not have meals at all. Second, adolescents are obsessed with a single interest and activity. Third, many adolescents have issues with drug and alcohol abuse. Fourth, adolescents make no effort to excel in school. Finally, professionals are concerned about the interference and harassment associated with text messaging, email and Internet use. In particular, adolescents may not be aware that insults and threats communicated in text-messaging and emails are as abusive and threatening as other forms of such insults.

In light of the problems identified by the social and health care professionals, adolescents must be targeted with information about the importance of daily routines and rules, for example, how important they are to their physical and mental health. Adolescents need information about healthy sleep patterns and regular and healthy food for their health and well-being. Adolescents need information about the choices after comprehensive schooling, how these affect the rest of their lives, and the way they will be placed in society. Further, adolescents need information on good manners, how to interact well with other people. Additionally, they need information on legal aspects and rules on the use of modern technology and the Internet. Besides professionals, adolescents were also interviewed about their main informational needs and the topics in the support system were based on these themes.

Adaptation to the Intervention in a Specific Treatment Context

The intervention was to be adapted into the practice of 2 psychiatric outpatient clinics in southern Finland. The clinics serve over 2 million people in their catchment areas and offer specialized care for adolescents referred for psychiatric outpatient care. The clinics are specialized in the examination and treatment of adolescents less than 20 years old who are likely to be suffering from depression. There were in total 14 nurses, 8 psychologists, 7 social workers and 8 physicians working in these clinics.

To ensure that the intervention would be well integrated in the outpatient clinic an adaptation process was planned. It was based on the Technology Acceptance Model (TAM) [60], which posits that perceived usefulness of an intervention influences the perceived ease of use. These 2 components then determine an individual's intention to use and actual usage of a system. In practice, however, constraints in ability, time, environment, organization, and unconscious habits will limit intentions to act [61]. Therefore, we first arranged a series of educational sessions introducing background knowledge of Internet-based intervention use as a part of clinical care. Second, we conducted interviews to ascertain how useful nurses thought the intervention could be. Third, to ensure ease of use, the nurses were involved in different parts of the development process. They produced information on practical constraints and how these could be resolved. The aim of these actions was to support actual system use. Moreover, to promote nurses' intervention use, a manual for the intervention was developed including detailed descriptions of the background and principles of the intervention, as well the practical guidance on how to use the Depis.Net program.

The Intervention

As an outcome of the systematic development process an intervention called 'Depis.Net' was developed (Figure 1). At this stage, it was developed for adolescents who had received

a referral to an outpatient clinic. In a wider perspective, this can be used for adolescents with suspected depression or anxiety disorder, for example at school. This Internet-based support system intervention was developed to support adolescents' self-management, and to increase their awareness of issues associated with well-being and mental health. It was accessible via an electronic platform, which was secured and password protected for users. The intervention consisted of the following basic elements: identification of adolescent's concerns, self-monitoring, access to health information (Depis.Net website) and self-reflective written exercises . The intervention included 6 individual sessions to be delivered over a 6-week period. There was an introductory session, followed by sessions that focused on a different topic per week: (1) well-being, (2) home and family, (3) adolescent's rights and responsibilities, (4) adolescent depression, and (5) treatment of adolescents' depression (Figure 2). Adolescents had one week to process each topic. To ensure that the intervention was targeted at adolescents and user-friendly, volunteer adolescents were encouraged to take the photos included in the program, to design its external appearance, write the poems included in the program, and give feedback on the informational content of the support system. The content, exercises, and self-monitoring methods of each session are described in Table 2.

Table 2. Themes, exercises, and self-monitoring activities in the Internet-based support system.

Week	Theme	Exercises and self-monitoring
Introductory session	Introduction for independent working	Describe the focused problem
Week 1	Well-being	Working with focused problem
		Working with well-being theme
		Mood diary
		Question corner
Week 2	Home and family	Working with focused problem
		Working with home and family theme
		Network map
		Depression Scale (BDI-21)
		Mood diary
		Question corner
Week 3	Adolescent's rights and responsibilities	Working with focused problem
		Working with adolescent's rights and responsibilities theme
		Mood diary
		Question corner
Week 4	Adolescent depression	Working with focused problem
		Working with adolescent depression theme
		Rating sleeping diary
		Mood diary
		Question corner
Week 5	Treatment of adolescent's depression	Working with focused problem
		Working with treatment of adolescent's depression theme
		Assessment of sleeping diary
		Depression scale (BDI-21)
		Mood diary
		Question corner

The intervention was implemented in psychiatric outpatient clinics by trained tutors. Before the 6-week intervention there was a face-to-face discussion between each adolescent and a tutor. The aim was to provide basic information on the Depis.Net intervention. During the introductory session, the tutor supported the adolescent to write down his/her focused concern or problem so that he/she could work with it throughout the 6-week period from different angles. An intervention was followed by weekly accessible health information, self-monitoring exercises, self-reflective diaries and other exercises via a website in which the adolescent reflects his/her own life situation. Adolescents returned their diaries each week and the tutor offered support

and feedback via the website. Supportive text messages were sent to the adolescents once a week before the next topic started if they had not already visited it. Moreover, in case of serious concern based on adolescents' written texts and exercises (eg, suicidal indication), the outpatient clinic was contacted immediately. The regular and need-based support provided is described in Table 3 and Table 4.

Table 3. Regular support provided in the Internet-based support system.

Regular weekly support	Aim
Text message to continue to the next theme	To encourage use of the support system and communicate its progress
Individual feedback on Moodle	To encourage working on the support system
Reflecting on the participant's work in the support system when meeting the therapist face to face in the outpatient clinic	To integrate the theme and adolescent's work into the care process

Table 4. Need-based support provided in the Internet-based support system.

Needs-based support	Aim
Supportive text message if an adolescent had not done any weekly exercises	To motivate and avoid drop-out
Contact to the outpatient clinic in case of concern about adolescent's severe symptoms such as suicidal ideation	To ensure adolescent's safety and maintain quality support system

Figure 1. Depis.Net website.

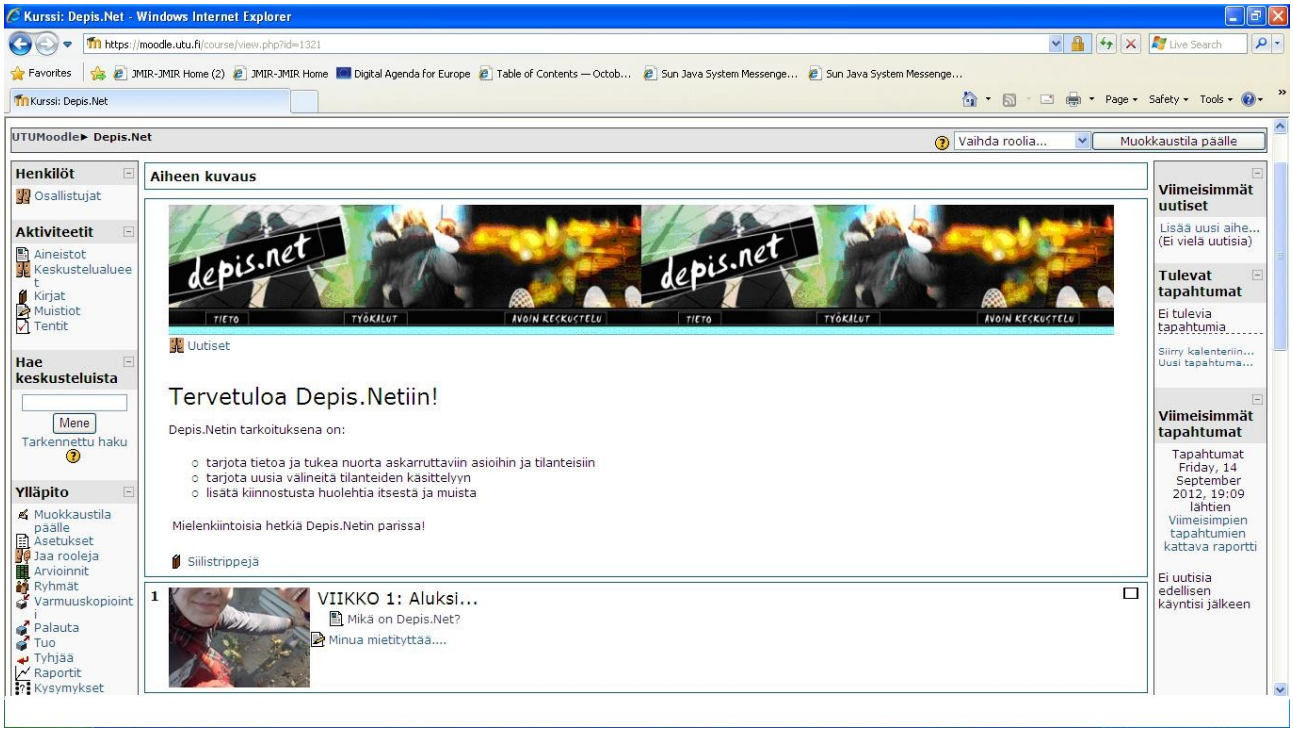
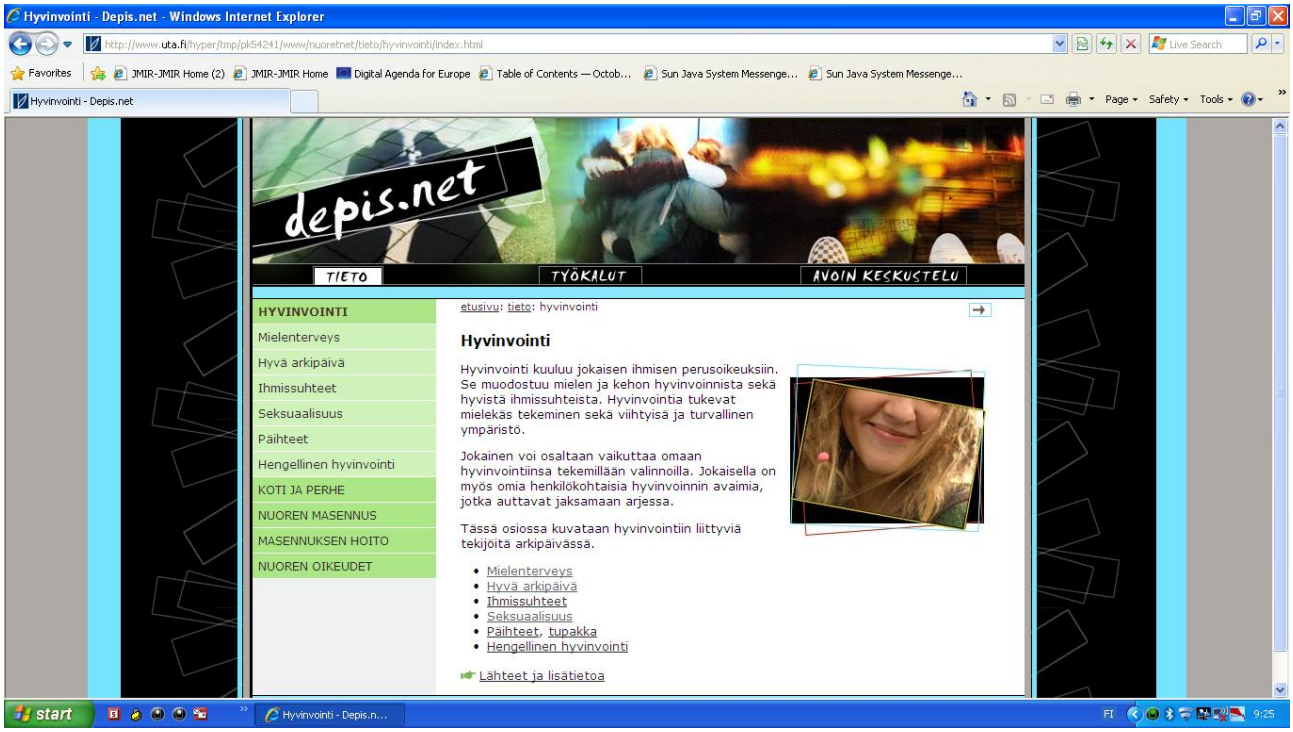


Figure 2. Different themes of the intervention on the Depis.Net website.



Discussion

This paper describes the process of developing an Internet-based support system intervention for adolescents. We included 4 steps to develop a need-based intervention for adolescents with depression treated in outpatient psychiatric clinics in Finland.

The theoretical framework chosen for the intervention, SDT [54,55], supported our intention to use such a method for several reasons. In SDT Ryan and Deci [56,57] posit 3 innate basic needs motivating human behavior: autonomy, competence and relatedness. First, autonomy refers to the feeling of being responsible for one's own actions. This supported our intention to use such a method, because it allows adolescents to work independently in the system and to discuss their achievements later on with their support person. Second, competence refers to being effective in dealing with the environment in which a person finds him/herself. In many cases, adolescents have poorer self-esteem and their sense of self-competence is weak [62]. Therefore it was important that through intervention activities, they should feel that they could cope with the assignments without stress. Third, relatedness represents interpersonal acceptance, closeness, and the universal desire to interact, be connected to, and caring for others. However, there are individual differences in the extent to which basic needs are satisfied or thwarted [58,59]. This convinced us that instead of a stand-alone online system, adolescents need a human interaction component in the system to feel support. [62].

TAM model was selected to structure the implementation process, understand acceptance, and use of IT among adolescents [60]. Moreover, by integrating the development process according to the TAM model, we were able to make the support system as usable and as acceptable as possible.

It is a limitation of the development process that no systematic literature review was conducted. The process of the systematic review is not appropriate in all literature reviews and therefore we considered using recently published reviews and study reports [40,41] for this. Moreover, even if adolescents were not actively involved throughout the whole development process, their opinions on content and layout were expressed in expert groups and considered in all phases of the Depis.Net intervention. The aim was to ensure that the intervention responded to the adolescent's needs and was perceived to be attractive.

The strength of the intervention is that it was developed on the basis of an established theoretical framework. The development process was conducted through several steps even though it was challenging to integrate different forms of information. The aim was to ensure that the intervention had a sound theoretical background yet flexible in the considerations for the problems that adolescents currently face in their daily lives. Although a number of Internet-based interventions have been developed and implemented for adult anxiety and depression, such interventions are scarce among adolescents with depression [14,15,43,48]. Therefore the recent literature led us to believe that an intervention of this sort would have great potential [22,46,50]. Moreover, integrating professionals' viewpoints into the existing knowledge base ensured that the intervention addressed topical concerns.

The potential of the intervention developed needs to be investigated, especially because there is still diversity in what is known about the effectiveness of these interventions [22] and a lack of consensus as to the effective components of these interventions [63]. Thus the potential of the Depis.Net intervention for adolescents attending outpatient clinics will be evaluated in the next phase by means of a randomized controlled trial (NCT00054925). As a practical consideration, in order for

an intervention for adolescent depression to be truly effective it must be accessible and desirable in a natural setting. It is important that adolescents make the decision to participate in it and make a commitment to follow an intervention on their own. Moreover, Internet-based interventions must be continuously maintained. The intervention will be further developed after evaluation of the results and feedback obtained in future studies.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
IT: information technology
SDT: self-determination theory
TAM: technology acceptance model

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Original Paper

Development and Formative Evaluation of a Visual E-Tool to Help Decision Makers Navigate the Evidence Around Health Financing

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Abstract

Background: There are calls for low and middle income countries to develop robust health financing policies to increase service coverage. However, existing evidence around financing options is complex and often difficult for policy makers to access.

Objective: To summarize the evidence on the impact of financing health systems and develop an e-tool to help decision makers navigate the findings.

Methods: After reviewing the literature, we used thematic analysis to summarize the impact of 7 common health financing mechanisms on 5 common health system goals. Information on the relevance of each study to a user's context was provided by 11 country indicators. A Web-based e-tool was then developed to assist users in navigating the literature review. This tool was evaluated using feedback from early users, collected using an online survey and in-depth interviews with key informants.

Results: The e-tool provides graphical summaries that allow a user to assess the following parameters with a single snapshot: the number of relevant studies available in the literature, the heterogeneity of evidence, where key evidence is lacking, and how closely the evidence matches their own context. Users particularly liked the visual display and found navigating the tool intuitive. However there was concern that a lack of evidence on positive impact might be construed as evidence against a financing option and that the tool might over-simplify the available financing options.

Conclusions: Complex evidence can be made more easily accessible and potentially more understandable using basic Web-based technology and innovative graphical representations that match findings to the users' goals and context.

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KEYWORDS

health care systems; financing; policy makers; software tools

Introduction

Against a background of calls for robust domestic health financing to attain and sustain increased service coverage [1], financing choices have seldom been so complex. The gradual removal of user fees is leaving a policy and funding vacuum in many low and middle income countries [2-4].

It is probable that the ideal health financing approach is a nuanced mix of methods appropriate to a given economic, social, political, and epidemiological context, and designed to best meet the most urgent health system priorities without significant negative consequences [5-7]. However, the pragmatic reality is that the process of defining and implementing this balance may create confusion and policy paralysis. This paralysis may be

further exacerbated by the breadth and heterogeneity of a relatively fast-growing body of evidence.

The last comprehensive review of the evidence on domestic health financing was conducted more than 7 years ago by Palmer et al [5], with Lagarde and Palmer [8] more recently reviewing the evidence on user fees. We build on this valuable evidence base in 2 ways- firstly we collate the evidence on a wide range of health financing methods to reflect the most current learning, and secondly we report on a broader set of impacts including service quality, poverty and equity, and revenue generation. Such reviews are generally not tailored to the needs of policy makers and other common users, and there is a recognized need to make that evidence more accessible [9].

In this paper we describe our development of an e-tool that summarizes the available literature quickly and easily in both graphical and tabular form, with the added ability to access the underlying evidence from anywhere within the tool. We describe the methods used to extract the literature, synthesize it into the e-tool and evaluate the overall usefulness of the final product. In the results we describe the final e-tool and briefly summarize the key findings of the literature review to provide the reader with a sense of the depth and complexity of the evidence incorporated into the Web-based platform. Finally, we reflect on the feedback from early users of the tool to highlight critical benefits, limitations, and lessons learned.

Methods

This section outlines the methods used for the literature review and synthesis of that evidence, the methods used to construct the e-tool using the review material, and the methods used to generate and synthesize user feedback.

Literature Review and Synthesis

Literature review methods were adapted from the EPPI-Centre [10] and Greenhalgh et al [11]. The following databases were searched using a consistent and comprehensive set of search terms: PubMed, Web of Science (Science Citation Index and Social Science Citation Index), Journal Storage (JSTOR), and Science Direct. References of articles retrieved from the initial search were then hand-searched. Websites of international organizations including the World Health Organization, World Bank, International Labour Organization, the United Nations, the United Nations Children's Fund, and the Social Science Research Network were also searched for relevant publications. The search was limited to papers published between January 1995 and June 2010.

In the context of our review, a heath financing mechanism (also referred to as method or tool) is defined as a mechanism intended to raise domestic revenue for health including national/government/social health insurance, taxation, community-based insurance, private insurance, user fees, and equity funds. Papers were only included if published in peer-reviewed journals, available in English, focused on low and middle income countries, and specifically evaluated or discussed the outcomes of at least one health financing method. Opinion papers, editorials, conference proceedings, and letters to the editor were excluded. Articles discussing the potential for the implementation of a method, evaluating willingness to pay or providing overviews or descriptions of health financing programs without discussing or evaluating the outcomes of implemented programs, were similarly excluded. Papers were not excluded on the basis of study design as research in this field uses a wide range of qualitative and quantitative methods. Similarly, papers were not scored on any quality of research metric as there are few widely accepted criteria for doing so in the field of economics that would span both qualitative and quantitative research outputs. Our intention was to avoid value judgments and conduct as inclusive a review as possible, given that users of the e-tool are able to identify the source of any evidence simply by hovering over a dot, and can access the paper itself with a single click.

From an initial shortlist of 151 papers, a total of 78 articles were included in the final database. A thematic analysis of the papers included in the final review was used to construct a data extraction form to systematically extract relevant information from each article reviewed. A subset of extracted data was independently reviewed by 3 researchers (JSW, GK, APB) to confirm that the extracted data accurately reflected the papers' content. This review thus takes a rigorous and systematic approach of searching, data extraction and synthesis, resulting in comprehensive findings that provide a valuable contribution to the existing body of knowledge in this area.

The possible outcomes of a health financing method were condensed into 5 domains or goals as shown in Table 1. For each article, we summarized the outcome of the financing mechanism on each of the goals in Table 1 by assigning 1 of 5 qualitative scores: "evidence against", "some evidence against", "no evidence of impact", "some evidence for", and "evidence for". We explicitly recorded if a goal was not considered as part of the study, to reflect where evidence was lacking.

Authors (ACP, JSW and APB) independently used the extracted summary information to assign impact or outcomes scores based on the conclusions of included studies. For instance, if a study concluded that a health financing tool reduced out-of-pocket payments then this was considered "evidence for" poverty reduction. If the authors had reported only slight reduction in these payments this would have been considered "*some* evidence for" poverty reduction. The 3 authors assigning scores then compared their findings, and resolved any discrepancies through group discussion. The final scores were transferred to Microsoft Excel to form the basis of the e-tool. During this process we did not make any judgements about the validity of conclusions regarding impact or program effect, nor did we make any assessment of study quality. Our scores are intended purely as a visual summary and an aid to further investigation. The decision to have a qualitative rather than a quantitative impact score is intended to make this clear to the user. The evidence available was qualitative, descriptive, and heterogeneous.

Table 1. Possible goals of a health financing policy.

Goal	Brief description
Promote equity	Incorporates references to relative poverty reduction, equity, the distribution of disease burden (eg, disability-adjusted life-years), the distribution of the financial burden (eg, the incidence of catastrophic health spending), and risk pooling.
Reduce poverty	Refers to changes in absolute poverty.
Improve quality	Refers to service quality and changes in health outcomes that may be a consequence, or indicator, of improved quality.
Generate revenue	Refers to either absolute or relative revenue generation at any tier of health service delivery. Assumes that increased revenue generation or retention is the desired outcome.
Increase use	Refers to the quantity of health services demanded, access to care and utilisation of health services.

Converting the Findings into a Scattar Plot

As the evidence for any financing method varied significantly by context, we sought to inform the user how closely the countries analyzed in each study matched their own. To this end, a subset of the study team (JSW and CP) produced an initial long list of country indicators relevant to health financing policy, and on which countries could be matched. It was considered important that indicators be easily available for most countries and transparent to users so that understanding these data did not constitute a barrier to using the tool. The long list was then reduced to a final set of eleven indicators judged by the full study team to provide independent information relevant to financing policy and appropriate for matching contexts.

These indicators, given in Table 2, were used to match a user's country to the evidence. We transformed the value of each indicator, *I*, into a value, *T(I)*, between 0 and 1 according to Figure 1, where the maxima and minima were taken across all low and middle income countries. Each country is thus characterized by a set of 11 values between 0 and 1, $\{T(I)_j\}$, where j runs from 1 to 11. These values can be thought of as a single point on an 11-dimensional graph, and we use the 11-dimensional distance, d_{YZ}, given in Figure 2, between 2 points as an estimate of how closely 2 countries Y and Z are matched.

Multimedia Appendix 1 gives a graphical example of the distance between 2 countries for 3-dimensions, and a plot of how 7 countries are placed in relation to an example country. The *context matching* criteria were checked for a subset of countries to ensure there was face validity but there was no formal validation of the measure. Again, the use of this measure was to aid the user to visually sort the available evidence (comparing *more closely matched* to *less closely matched* evidence). The exact ranking of countries with respect to their "context match" of another country was not intended to be an important output.

Figure 1. Equation to define T(I).

$$T(I) = \frac{I - \min(I)}{\max(I) - \min(I)}$$

Figure 2. Equation to define the distance function.

$$d_{YZ} = \sqrt{\sum_{j=1}^{11} \left(T(I_Z)_j - T(I_Y)_j \right)^2}$$

Table 2. Country indicators used for context matching.

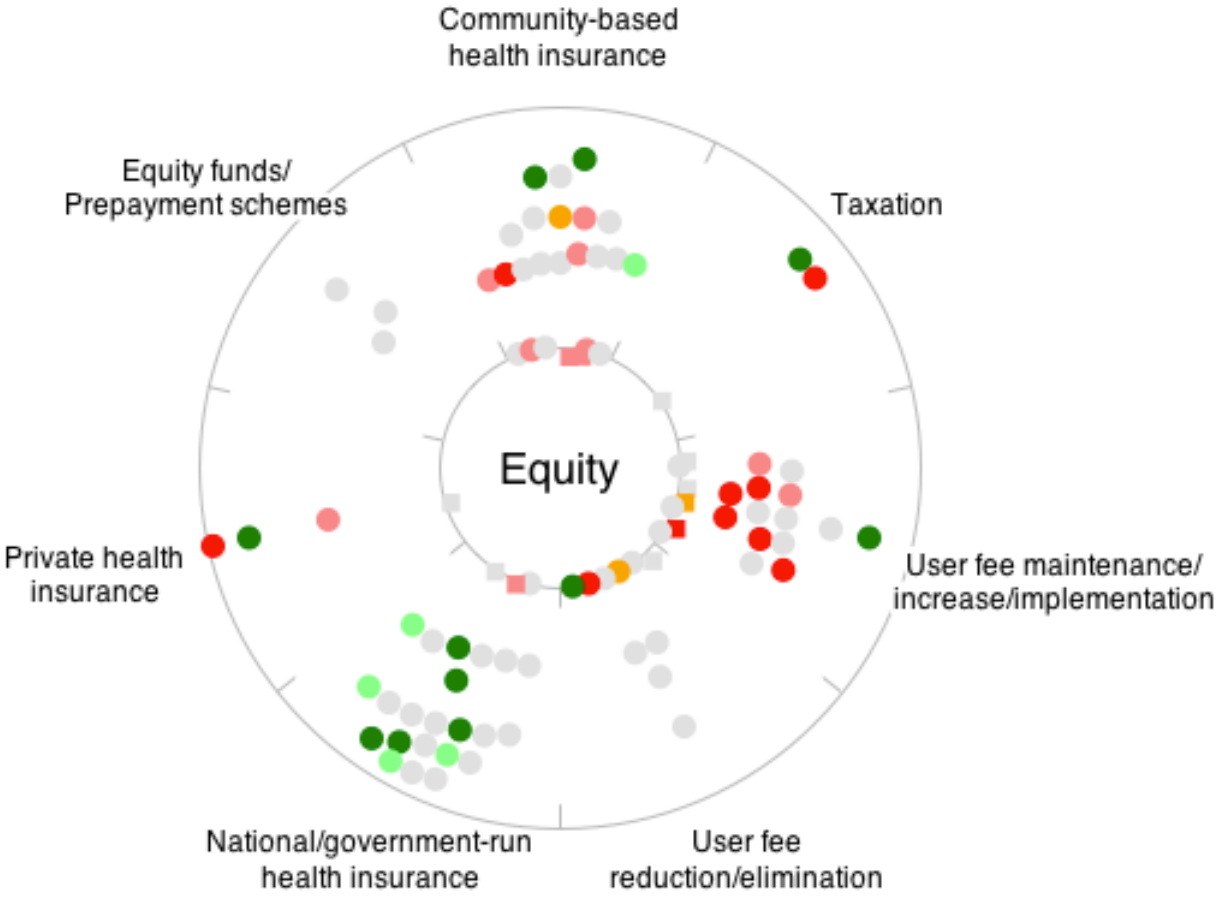
Indicator	Source (2008 data)
Health expenditure per capita ($)	World Bank
Maternal mortality ratio	World Bank
Under 5 mortality rate	World Bank
HIV prevalence	World Bank
Malaria incidence	United Nations
Education index	United Nations Development Program
GDP ($)	World Bank
Life expectancy at birth	United Nations Development Program
Proportion of the population living in an urban environment	World Bank
Proportion of the population living on less than $1.25 a day at 2005 international prices	World Bank
Population (log, base 10)	World Bank

The next stage in the process was to explore ways of displaying the available evidence in an intuitive and informative way. After several iterative discussions within the development team and experimentation with different ways of displaying the data, we developed a *scattar* plot, incorporating elements of both scatter and radar charts. Each such display focuses on one goal of a health financing policy and shows the evidence available for all 7 health financing mechanisms in the context of the (user-specified) country of interest. Figure 3 shows an example of how this would apply to the promotion of equity in Uganda.

Literature reviews are differentiated from evaluation-style studies in an attempt to reduce the risk of double-counting evidence. Review studies are thus shown in square dots on the inner ring while all other studies are represented as round dots. The distance of the dots from the inner ring within the *scattar* plot indicates how closely the countries within each study match the user-specified country (eg, Uganda in Figure 3). Round dots on the inner circle correspond to studies that consider exactly the country chosen by the user.

The colour of each dot indicates the impact of the financing mechanism on the chosen goal (eg, promoting equity) as reported in the cited study. These colours range from green for positive impact to red for negative impact, with orange indicating that there was definite evidence of no impact. Dots coloured in grey correspond to studies that considered a given health financing tool but did not consider the impact on the goal under consideration. We felt it was important to include these on the graphical display as they give an indication of where evidence is lacking. All possible plots would always have the same number of dots (since all studies are shown on every plot). The position of the dots within the ring will change according to the user-specified country and the colour of the dots will change according to the user-specified goal.

Figure 3. Example of a 'scattar' plot showing the available evidence of impact of each financing tool on promoting equity in Uganda. Each dot represents a single study and its colour represents the reported impact on the specified goal.



Eliciting and Analysing Feedback from Users

In September 2011, the tool was launched by Save the Children, through an email to policy makers, international agencies, and researchers. Feedback was collected using a mixed methods approach including an online survey (n=19) and semi-structured key informant interviews (n=8). Due to the small quantitative sample, the results will be treated qualitatively and only percentages over 50% will be reported in the findings. The small sample of survey respondents is acknowledged as a limitation of this study and it is further acknowledged that the survey respondents may not constitute a random or representative sample of potential users of the tool. However, despite the small number of respondents to the survey, we were able to obtain responses from a wide spectrum of stakeholders including government policy advisors, consultants, staff from national and international non-governmental organisations (NGOs), as well as students and academics. Key informants included respondents from:

- United Nations Children's Fund
- World Health Organisation
- The UK Department for International Development
- The Bill and Melinda Gates Foundation
- Imperial College London
- NGOs including; Research 4 Development, Oxfam, World Vision, Save the Children UK (Zimbabwe, South Africa and Ethiopia country teams)

The findings from the key informant interviews were synthesised using thematic analysis.

Results

Summary of Literature Review Results

From an initial shortlist of 151 papers, a total of 78 articles were included in the final analysis. The health financing methods included in the tool, together with the number of papers providing evidence of impact of this tool on a health financing goal are as follows:

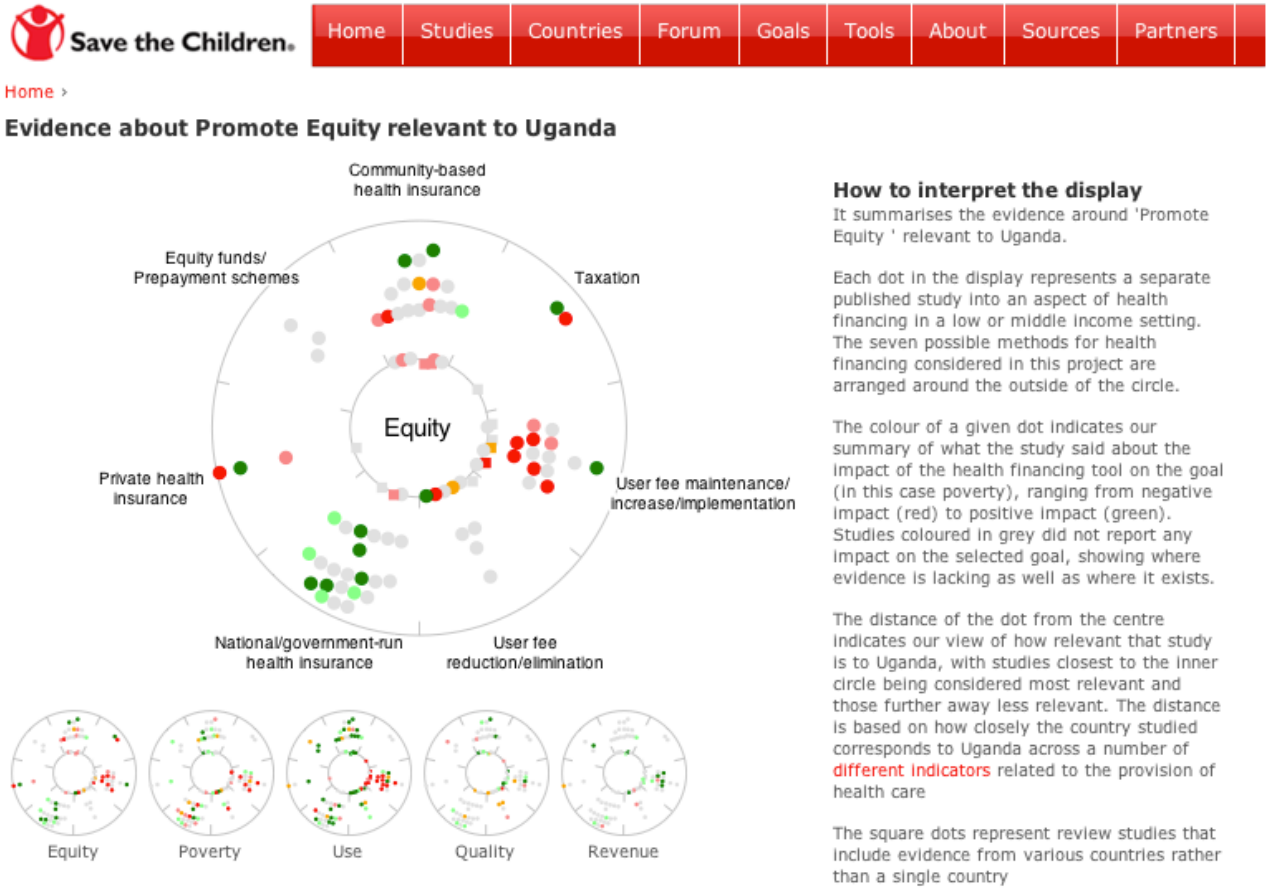
- Equity funds and discount cards (2 papers)
- Tax-funded systems (2 papers)
- Private health insurance (4 papers)
- User fees - which we segmented into: (1) the implementation, increase, or maintenance of fees (21 papers), and (2) the reduction or elimination of fees (10 papers)
- Community-based health insurance (CBHI) (24 papers)
- National/government-run health insurance (NHI) including social health insurance (25 papers)

This review provided an opportunity to update the evidence on a wide range of health financing methods, generating a number of key insights. Firstly, the breadth of the review highlighted that the weight of evidence is unevenly distributed between health financing methods. In particular, little has been written since 1995 about the impact of tax-based financing despite the recognition that most countries that have achieved universal risk protection have done so through tax financed systems. Secondly, no single method emerges as having the greatest positive impact on utilisation, service quality, equity and risk pooling, poverty, and revenue, although the tool highlights the positive and negative impacts of each method on these goals. Importantly, no financing method effectively removes or redresses the indirect costs faced by the poor when accessing health services. Thirdly, the small body of evidence on private health insurance raises concerns about adverse, unintended consequences. Fourthly, the large body of evidence on CBHI and NHI offers a mixed perspective on their use. Compared to Palmer et al [5] the new evidence on CBHI reviewed in our paper indicates, in general, that there is an increase in access and utilisation of health services amongst member households, although this increase may not be among the poorest. The new evidence on NHI indicates that in many cases, coverage of these schemes does not reach the most vulnerable groups of a population and utilisation of services remains low outside major urban centres due a lack of health facilities.

Finally, compared to Lagarde and Palmer [8], a substantial number of new papers on the implementation of user fees have been included in this review without adding very significant new insights about any positive impact. User fees did contribute to revenue generation, but this varied significantly between settings. Overall the implementation of user fees had a negative impact on equity. The evidence we reviewed about the impact of the removal of user fees on quality of services was mixed, and confounded by simultaneous health system strengthening measures. The narrow evidence base on the removal of user fees shows potential for improvements in equity and use.

In Figure 4, the user can quickly see that there is most evidence around national and community health insurance and the implementation of user fees. There is some evidence directly related to Uganda (round dots on the inner circle). The large number of gray dots shows that many studies did not consider the impact of the health financing method on equity. Looking at the colours of the dots, the evidence suggests that national health insurance schemes have a positive impact on equity, user fee implementation a negative impact, and that the evidence on community-based health insurance is mixed. The 2 studies where community-based health insurance had a positive impact on equity are least well matched to Uganda's context (the dots are close to the outer ring), but 2 community-based health insurance studies directly related to Uganda show some evidence of a negative impact.

Figure 4. Screenshot of the website's graphical summary. As for Figure 1, the chosen country is Uganda and the chosen goal is "Promote Equity".



The Tool and the Scattar Plots

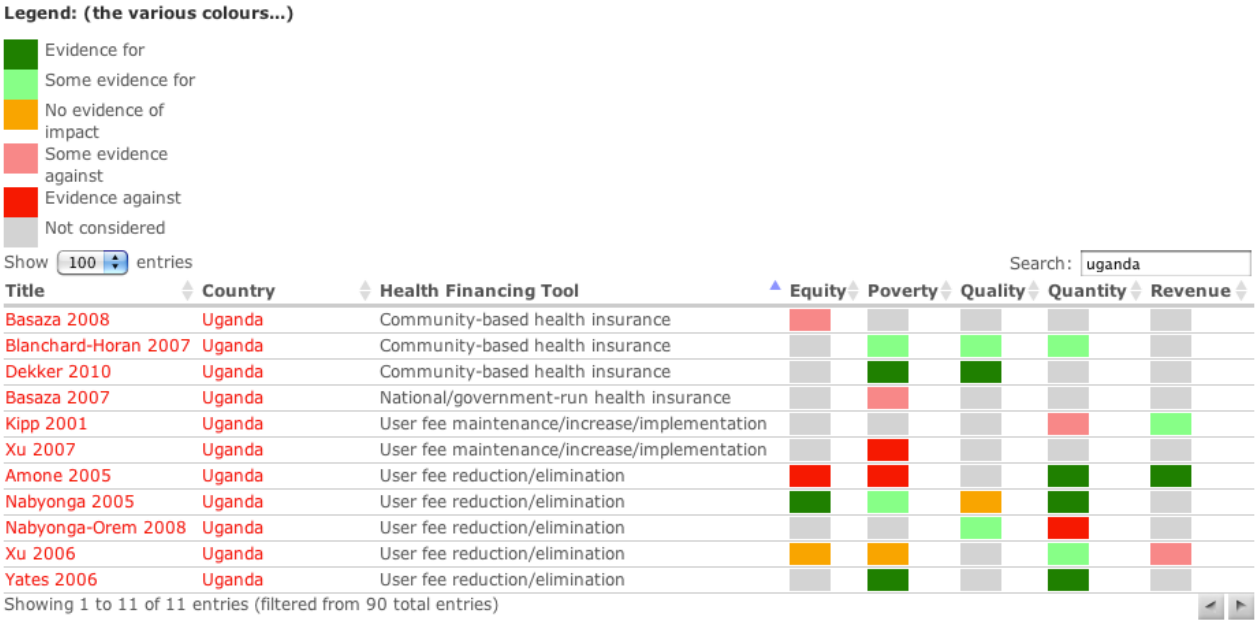
After consulting informally with potential users, it was decided that the most accessible platform for the tool would be a website where users could navigate easily between different countries and goals. Additional advantages of an online tool were that it presented a familiar interface to users-it would be easy to access, it would be easy to update and maintain version control, and it provided an ideal environment to cross-reference between studies, countries, tools and goals. The website was registered under Save the Children's branding, since they funded and commissioned this work [12].

On the site, the user begins by choosing the country and health financing goal, before being taken to a page showing the relevant *scattar* plot (see Multimedia Appendix 2 for a screencast). We thought it important that the user is asked to choose a goal first to highlight the fact that while more than one goal may be of interest, the impact of a health financing mechanism is not necessarily the same for all 5 goals. On the right hand side of the page showing the *scattar* plot is an explanation of how to interpret the display (Figure 4). Thumbnails of all 5 goals are given at the bottom of the main plot allowing the user to switch easily between goals and giving an immediate visual impression of the distribution of the evidence.

The user always has access to the evidence on which the summaries are based. Hovering over any dot displays the authors, paper title, and country studied (Multimedia Appendix 2). Selecting a dot will bring the user to a separate page in a new tab with the full reference, a link to the publisher, the published abstract, and our summary of the evidence of impact for all 5 goals. There are also separate webpages within the site providing a searchable and sortable list of studies used, with summaries of impact (Figure 5) and context-matching indicator values for each country.

In several places on the website, the simple and qualitative nature of the impact assessment of studies is stressed, as well as the overall aim to help users navigate the evidence. We stress in the online explanations that our summaries are not considered a suitable basis for action without further investigation. By making it easy for the user to access the evidence used for this tool from many places on the site and according to different criteria (eg, country, goal, health financing mechanism), we hope that we have made clear its exploratory intent. In a sense the website is intended as a directional magnifying glass to help users identify the evidence that they might find useful quickly according to their particular questions and interest.

Figure 5. Screenshot of the list of studies showing summary of impact. Any search term could be used (here: Uganda), or the gray arrows at the top of each column used to sort the entire list. The text in red represents links to the extended information on the given studies and country.



Title	Country	Health Financing Tool	Equity	Poverty	Quality	Quantity	Revenue
Basaza 2008	Uganda	Community-based health insurance					
Blanchard-Horan 2007	Uganda	Community-based health insurance					
Dekker 2010	Uganda	Community-based health insurance					
Basaza 2007	Uganda	National/government-run health insurance					
Kipp 2001	Uganda	User fee maintenance/increase/implementation					
Xu 2007	Uganda	User fee maintenance/increase/implementation					
Amone 2005	Uganda	User fee reduction/elimination					
Nabyonga 2005	Uganda	User fee reduction/elimination					
Nabyonga-Orem 2008	Uganda	User fee reduction/elimination					
Xu 2006	Uganda	User fee reduction/elimination					
Yates 2006	Uganda	User fee reduction/elimination					

Showing 1 to 11 of 11 entries (filtered from 90 total entries)

Feedback from Users

Feedback from the survey was very positive, with 90% (17/19) of respondents stating that the website was either very or extremely easy to navigate. The most commonly used features of the website were the graphical summaries (53%, 10/19) and the country information (68%, 13/19). Respondents particularly liked the graphical summaries and the summary tables and found the colour-coded system useful and intuitive. Although most respondents had not visited the website with a particular question in mind, 90% (17/19) of respondents did find the website helpful and 63% (12/19) of respondents are either very or extremely likely to recommend the website to others.

Findings from the in-depth interviews supported this positive view, although a number of constructive criticisms and suggestions were proposed. Firstly, there was concern that a lack of evidence might be construed as evidence against a financing option. There were calls for the tool to more clearly distinguish between negative evidence and lack of evidence. Secondly, respondents expressed a concern that the tool might encourage users to take an over-simple view of financing options as it does not offer the option of integration or mixing financing methods and does not take into account of the context in which they are implemented. This is indeed a limitation of the tool imposed on the production team by the paucity of evidence on mixed methods financing approaches. Thirdly, it was suggested that the power of the tool is not immediately obvious and that a guide or manual available online might be a useful resource. Finally, one respondent suggested that new literature might already have emerged which would warrant inclusion on the site. This latter point was considered critical by the team producing the tool and has been a consideration from the outset of the project.

Discussion

The health financing debate is moving on in low and middle income countries, from asking whether user fees should be removed, to exploring how to finance healthcare to achieve universal risk protection whilst achieving equity, efficiency, and quality of care. A conventional literature review will always be challenged by the breadth and complexity of the evidence on health financing, and the need to condense that evidence into a single journal article. Additionally, a published literature review is not necessarily the easiest way for a policy maker, or other user outside of academia, to access the evidence. We have developed a new e-tool that helps users (whether policy makers, NGO workers, or academics) to navigate the complex evidence by focusing on a single intelligent snapshot of the literature. Our tool is easy to access, and provides a rapid search of the evidence by country and goal. The tabular summary also allows the user to search the evidence according to a variety of criteria such as finance mechanism, country, or impact among others. Given its structure and Web implementation, the tool is also designed to be easily updated as new evidence emerges and country indicators change. These positive aspects of the tool were mentioned in the feedback received from early users during the evaluation stage of this process.

That said, to structure the tool in a comprehensible and navigable form, it was necessary to make certain simplifications or groupings within the evidence–particularly with regards to the assignment of impact. We attempted to minimize the loss of detail by allowing users to link through to the original articles. This loss of complexity is a common tension when synthesising evidence and is highlighted in the feedback from users as a risk of our tool (ie, that users might think only in the discrete and mutually exclusive categories of health financing options presented in the tool, forgetting that a mix of financing methods might be the most appropriate solution for their context). Understanding more fully how users interpret and use the output

of a tool such as this may be a rich area for future research. However, while we needed to simplify the evidence somewhat, we would argue that this form of e-tool requires less simplification than a static journal article. We would also argue that our tool is evidence based, and the failure of our tool to shed light on the benefits of mixing financing methods reflects a failure of the academic literature to shed light on this option.

At every stage in building the tool we tried to be transparent about our assumptions and methods and always provide links for the user to the original evidence. Thus, the tool is intended to be used for exploration, allowing users to drill quickly down to the evidence most relevant to their needs, and not to make any finite recommendations for policy or health financing mechanism for a given country. While the tool has only been recently launched, it is hoped that it will become an important supplement to the existing literature on health systems financing. We also hope that this methodology could be used to bridge the gap between academic knowledge and practice for other complex policy questions.

Acknowledgments

This project was funded by a grant from Save the Children.

Conflicts of Interest

The funder of this study, Save the Children, advocates for services to be available free at the point of use and for financing mechanisms to offer universal risk protection

Multimedia Appendix 1

Context matching of the studies.

[PDF File (Adobe PDF File), 8KB - resprot_v1i2e25_app1.pdf]

Multimedia Appendix 2

Screencast of how a user might navigate the tool.

[MOV File, 7MB - resprot_v1i2e25_app2.mov]

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Abbreviations

CBHI: community-based health insurance
NGO: non-governmental organisation
NHI: national or government-run health insurance

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Protocol

Lifetime Occupational Physical Activity and Musculoskeletal Aging in Middle-Aged Men and Women in Denmark: Retrospective Cohort Study Protocol and Methods

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Abstract

Background: Physical function is essential for performing most aspects of daily life and musculoskeletal aging leads to a decline in physical function. The onset and rate of this process vary and are influenced by environmental, genetic, and hormonal factors. Although everyone eventually experiences musculoskeletal aging, it is beneficial to study the factors that influence the aging process in order to prevent disability. The role of occupational physical activity in the musculoskeletal aging process is unclear. In the past, hard physical work was thought to strengthen the worker, but current studies in this field fail to find a training effect in jobs with a high level of occupational physical activity.

Objective: The aim of this study is to examine the influence of lifetime occupational physical activity on physical function in midlife. The study follows the "occupational life-course perspective," emphasizing the importance of occupational exposures accumulated throughout life on the musculoskeletal aging process taking socioeconomic and lifestyle factors into consideration.

Methods: This study is a retrospective cohort study including a cross-sectional measurement of physical function in 5000 middle-aged Danes. Data was obtained from the Copenhagen Aging and Midlife Biobank (CAMB) which is based on three existing Danish cohorts. Using questionnaire information about the five longest-held occupations, the job history was coded from the Danish version of the International Standard Classification of Occupations (D-ISCO 88) and a job exposure matrix containing information about occupational physical activity in Danish jobs was applied to the dataset. The primary outcomes are three tests of physical function: handgrip strength, balance, and chair rise. In the analyses, we will compare physical function in midlife according to accumulated exposure to high levels of occupational physical activity.

Conclusions: We have a unique opportunity to study the influence of work on early musculoskeletal aging taking other factors into account. In this study, the "healthy worker effect" is reduced due to inclusion of people from the working population and

people who are already retired or have been excluded from the labor market. However, low participation in the physical tests can lead to selection bias.

(JMIR Res Protoc 2012;1(2):e7) doi:10.2196/resprot.2191

KEYWORDS

Occupational exposure; work load; physical fitness; musculoskeletal system; aging

Introduction

Physical function is essential for performing most aspects of daily life and it is a predictor of morbidity and mortality [1,2]. Musculoskeletal aging leads to a decline in physical function [3], the onset and rate of which vary and are influenced by environmental, genetic, and hormonal factors [4]. Leisure-time physical activity is important for maintaining physical function and is recommended by authorities in many countries [5], but the role of occupational physical activity (OPA) is more controversial [6]. Until the 1980s, manual workers were considered stronger than non-manual workers because of OPA. Since then, muscle strength and endurance have been shown to be lower in manual workers than in non-manual workers [7-10]. The absence of an observed training effect of OPA on physical function has been explained by a lack of an optimal combination of intensity, frequency, and duration of job tasks [7,11].

Since the 1980s, few studies have focused on prolonged exposure to strenuous physical work as a predictor of loss of muscle strength and impaired physical function. One study found no association between lifetime OPA and handgrip strength [11], but other studies have shown a training effect of OPA on shoulder muscle strength [12] and physical capacity in the upper extremities [13]. Three studies in older people with a history of manual labor showed that overall lifetime OPA may be associated with significantly higher rates of disability, lower physical function, and reduced muscular strength [14-16]. Two factors influence the associations found in these studies of accumulated physical activity and later physical function: exposure assessment and confounding factors.

The exposure assessment is essential. Most of the studies previously cited rely on self-reports of workload because self-reports provide the simplest and most cost-effective method of measuring physical exposure in large epidemiological studies [17]. Although the validity of self-reports vary [18], they are useful for detecting relative differences in physical workload among occupational groups. To supplement self-reports of physical exposure, expert judgments and job exposure matrices (JEMs) have been used in occupational epidemiology [19,20]. JEMs are databases based on expert judgments, registers, or measurements and use coded job titles to assign exposures in epidemiologic studies [21]. They are useful for retrospective exposure assessment in population-based studies in which many types of jobs are represented. Several research groups have used expert ratings and established JEMs for assessment of physical exposure [22,23], but the imprecise definition of OPA and the lack of accurate measurements can affect the validity. The use of a panel of experts for assessment of exposure improves the validity of the judgments [24], but misclassification is still possible because a JEM is a group-based assessment and individual differences in exposures because of variation in job tasks among people with the same job title and differences in ergonomics and capacity are not taken into account [25]. A recent study found high validity of reported job histories comparing information from questionnaires and interviews, whereas self-reports of work-life OPA levels showed varying validity (Møller et al, unpublished data, 2012). Therefore, this study uses a JEM on occupational physical activity based on expert ratings to supplement the exposure assessment.

In the previously mentioned studies, differences in physical function among older people could be attributed to confounding factors throughout life. Using a life-course perspective on aging and functional decline, factors such as socioeconomics, lifestyle, and genetics are relevant to take into consideration [4]. However, it is not always possible to follow trajectories of confounding factors in life-course analyses although they can influence outcomes such as physical function in midlife [26-28].

There has been little focus on occupational exposures in life-course studies of physical function [29]. Thus, it is not known how occupational exposures during the course of life influence the musculoskeletal aging process and the decline in physical function. Our hypothesis is that a high level of OPA affects the timing and/or the rate of the musculoskeletal aging process. In this study, the term “occupational life-course perspective” is used and the aim is to examine the influence of lifetime occupational physical activity on physical function in midlife.

Methods

Study Design

This study is a retrospective cohort study including a cross-sectional measurement of physical function in midlife. Data will be obtained from the Copenhagen Aging and Midlife Biobank (CAMB) [30], which is based on three existing Danish cohorts aimed at determining the importance of prenatal and perinatal factors, factors in childhood, and factors in early adulthood for early signs of aging in late midlife. Physical examinations of the cohort are planned for the future, but not yet funded.

Study Population

This study utilizes data from two of the three CAMB cohorts: The Metropolit Cohort and the Danish Longitudinal Study on Work, Unemployment and Health. From these cohorts, 12,656 middle-aged men and women living in Denmark were invited to participate. Data collection took place between April 2009 and March 2011. Of the initial 12,656 invitations, 39.97% (5059/12,656) answered the postal questionnaire and 30.48% (3858/12,656) attended the examination. Presently, the CAMB

database is being prepared for analysis. The analyses will begin in the spring of 2012 when the database will be available for further research and the job exposure matrix has been established.

Description of the Cohorts

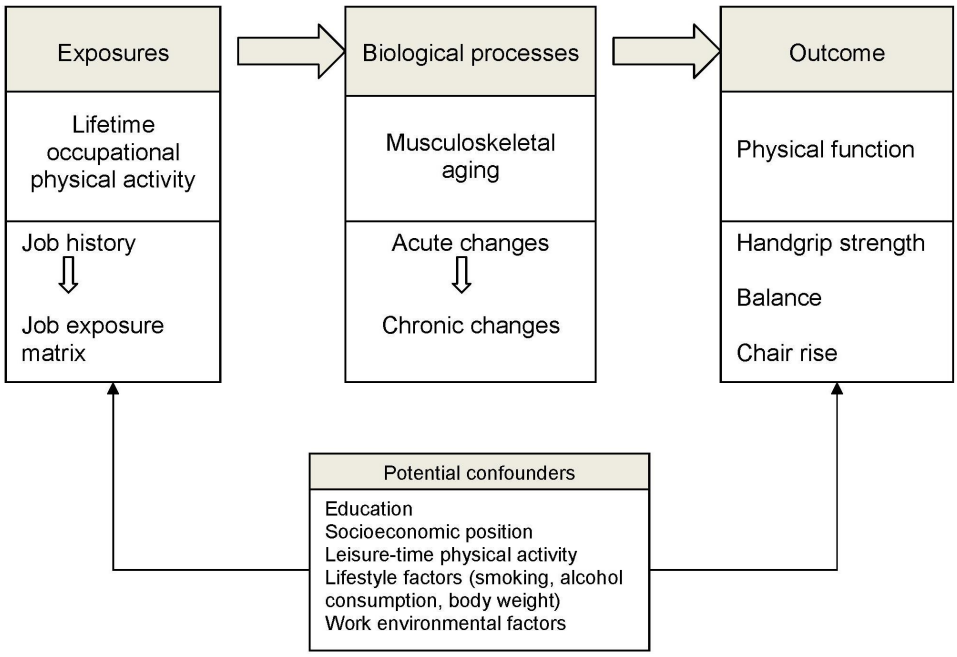
The Metropolit Cohort is defined as the 11,532 men born in 1953 in the Copenhagen Metropolitan area and living in Denmark in 1968. The cohort has been described in detail elsewhere [31]. Data from birth certificates, including information on dimensions at birth and the father's occupational status at the time of birth, were manually collected for all members of the original study population in 1965. That same year, 7987 (69.26%) of these males participated in a school-based survey that included a questionnaire administered by their class teachers. The questionnaire included tests of cognition and questions regarding leisure-time activities and social aspirations. In addition, data from conscription board examinations between 1971-1976, including measurements of height, weight, and cognitive function, were collected from archives in 2004. In 2004, 6292 members of the cohort responded to a health questionnaire. The Metropolit Cohort provides a unique opportunity to study early biological and social influences on the development of a number of social and health outcomes [32-34].

The Danish Longitudinal Study on Work, Unemployment and Health is a prospective population study that began with a baseline postal survey in the spring of 2000 in a stratified random sample (n = 15,227) consisting of two population groups: (1) individuals between 40 and 50 years by October 1, 1999 (7588/11,082, response rate 68.47%), and (2) individuals between 36 and 54 years who were unemployed at least 70% of the time between October 1, 1996 and October 1, 1999 (2350/4200, response rate 55.95%). Both samples were drawn initially from the "Anvendt Kommunal Forskning" (AKF) Longitudinal Register maintained by the Danish Institute of Governmental Research. The AKF Longitudinal Register comprises 100% of the Danish population aged 15 years and older. Data on non-participation was derived from the register. Non-participants included a significantly higher proportion of men, non-native-born Danes, individuals living on transfer income, and individuals with lower education levels (untrained or semi-skilled). In 2006, a follow-up questionnaire was sent to the surviving respondents, now aged 44-62 years (n = 8916) and a completed questionnaire was returned by 6151 respondents (response rate 68.99%). Data included a number of demographic, socioeconomic, psychosocial, and behavioral measures because socioeconomics and the consequences of unemployment were two of the main fields of investigation [35-37].

Conceptual and Analytical Model

Figure 1 illustrates the conceptual model used in this study. The research hypothesis is that prolonged exposure to high levels of OPA is associated with lower levels of physical function in midlife. The physiological link between exposure and outcome is the underlying biological processes, where acute changes in the musculoskeletal system turn chronic because of insufficient time for recovery [38,39] and a cumulative effect of physical wear and tear over the years influences the onset and rate of the musculoskeletal aging process [13]. At the same time, other factors throughout the course of life are associated with the exposure to occupational physical activity and physical function in midlife, which are potential confounders in our conceptual model.

Figure 1. Conceptual model of study.



Exposure Assessment

Occupational physical activity is the main exposure in this study. We define occupational physical activity as "work including mostly standing and walking at work combined with daily lifting of heavy burdens."

Self-reported Measures

The questionnaire provides data on the five longest occupations held plus the current occupation. The job titles were coded using the 1988 revision of the Danish version of the International Standard Classification of Occupations (D-ISCO 88) registration system by a coder with a broad knowledge of the Danish labor market. The International Standard Classification of Occupations (ISCO) was developed by the International Labour Office in 1958 and is a standardized classification and rating system of job types according to skills and education requirements [40].The D-ISCO contains classifications for more than 2000 Danish job titles as four-digit codes and it is used primarily for statistical analysis and research.

The questionnaire provides information about exposure during working life to dust, noise, chemicals, heavy lifting, working with the back bent, about the psychosocial work environment, and OPA. The OPA is categorized into four groups: sedentary work (eg, office work); mainly standing and walking at work (eg, teachers or machine operators); moderate physical exertion (eg, car mechanics or cooks); and hard physical work including lifting and pushing/pulling (eg, furniture movers or bricklayers). For all types of exposures, the respondent has to include a summation of their years of exposure.

Job Exposure Matrix

A job exposure matrix, the occupational physical activity matrix (OPA matrix), was applied to the dataset. The OPA matrix is based on an existing Danish job exposure matrix called the Knee-Hip Matrix [41] that is based on expert judgment of physical exposures associated with risk of osteoarthritis (eg, sitting, standing/walking, whole-body vibration, kneeling, and lifting of heavy objects). Firstly, all jobs in the D-ISCO classification considered more than minimally exposed to at least one of the exposures of interest were collapsed into homogeneous exposure groups (HEGs). Of the 2227 possible, 689 job titles were collapsed into 121 HEGs containing from 1-34 different occupational titles. For example, the HEG “people working in the printing industry” includes bookbinders, machine operators, and printers; “people working with food preparation in different kitchens” includes different types of cooks and managers in cafés and cafeterias.

Expert Rating

In keeping with international recommendations for expert ratings, a panel of five raters (experienced occupational physicians) independently assessed the 122 HEGs. They rated the duration of sitting, standing/walking, kneeling, and whole-body vibration throughout a normal working day. Furthermore, a rating of daily lifting (kg/day) and number of lifts over 20 kg per day were assigned to each HEG. A final consensus meeting was held to discuss outliers and discrepancies in the ratings and the method was validated internally and externally [41].

The OPA Matrix

The division of job titles in the HEGs and the average rating of the experts on physical activity (eg, hours standing/walking per day and lifting frequency and intensity per day) came from the Knee–Hip Matrix. Job groups not included in the HEGs were assigned as “unexposed.” Years of exposure to standing and walking and lifting were calculated according to the following definitions: (1) standing year (SY) defined as 6 hours of standing and walking at work each day in 1 year; (2) lifting year (LY) defined as lifting more than 20 kg at least 10 times per day in 1 year; and (3) ton year (TY) defined as 1000 kg of heavy lifting per day in 1 year. Each participant’s job history was converted to D-ISCO job titles covering the 0–5 previous longest occupations. Finally, data on exposure from the OPA matrix was assigned to the respective job titles and a summation of exposure was calculated.

Outcome Assessment

Test Protocol

Participants in CAMB attended an examination at the National Research Centre for the Working Environment (NRCWE), which involved a review of the previously completed questionnaire, measurement of weight and height, a battery of physical tests, cognitive tests, blood sampling, and information about health status with respect to some of the results of the examination. The battery of physical tests included tests of handgrip strength, trunk extension and flexion, jump height, flexibility, chair rise, and balance. General exclusion criteria for participation in the physical tests were high blood pressure, self-reported signs of angina pectoris, and use of prescribed heart/lung medication.

Objective Measures of Physical Function

Three signs of early musculoskeletal aging were used as outcome measures: handgrip strength, balance, and chair rise.

Handgrip strength was measured during a maximal voluntary isometric contraction with an electronic version of the Jamar dynamometer [42]. The participant sat upright on a chair with the elbow flexed 90 degrees and was instructed to squeeze the dynamometer as fast and as forcefully as possible. From a total of 3-5 attempts, the highest force value was used as the handgrip strength.

Balance was measured on an Advanced Mechanical Technology, Inc (AMTI) force platform during a one-legged stance with eyes open and arms across the chest [43,44]. The participant focused on a dot on the wall and stood as steady as possible for 30 seconds. Balance was defined as the sway area (95% confidence ellipse measured in cm^2). A lower sway area indicates better balance. Three 30-second attempts were given and the lowest sway area of the three attempts was used. Some participants were unable to maintain their balance for 30 seconds; therefore, the outcome was also dichotomized as a “yes/no” answer regarding completion of the test.

The ability to rise from a chair was determined by a chair rise test. Participants were instructed to rise and sit as many times as possible over 30 seconds [45]. Only one attempt was given because of the tiring nature of the test. An electronic switch placed under the seat of the chair counted the total number of chair rises.

Confounders and Intermediate Variables

Information about various confounders was available from the CAMB questionnaire:

1. Chronic diseases. Number of chronic diseases are registered and grouped into three groups: no chronic disease, one chronic disease, and two or more chronic diseases. Relevant diseases were asthma, diabetes, hypertension, angina pectoris, stroke, myocardial infarction, bronchitis, emphysema, osteoarthritis, cancer, anxiety, depression, other psychiatric diseases, and back pain.

2. Pain. A general pain score was calculated from answers about pain levels in 9 parts of the body.

3. Leisure-time physical activity. Information about weekly physical activity during leisure-time was reported in two ways. Duration of housing and gardening work plus walking and bicycling (including transportation to work) is summated and categorized as less than 3 hours per week, 3–6 hours per week, and more than 7 hours a week. Another question included a more specific description of the intensity of physical activity during leisure time and was categorized as low, medium, or high intensity.

4. Smoking. Smoking was reported as smoker/non-smoker including a smoking history in pack years (defined as 20 cigarettes or an equal amount of tobacco smoked each day for 1 year).

5. Alcohol consumption. Alcohol consumption was categorized in units of alcohol per week.

6. Education. School education was categorized into three groups: no exam, primary education, and secondary/higher education. Vocational education was categorized into five groups: unskilled, skilled manual worker, and short, medium, or long further education.

7. Occupational social class. Information about current occupation and education was used to categorize participants into eight socioeconomic classes.

8. Psychosocial work environment. Information about psychosocial work environmental factors (eg, demands, feedback, support, and influence) was also included in the analyses as confounders.

9. Physical measures. Height, weight, and lean body mass were measured at the examination. Body mass index (BMI) was categorized into four groups: <18.5, 18.5–25, 25–30, and >30 kg/m^2.

Statistical Analysis

The primary outcome is signs of early musculoskeletal aging, measured as performance in the three physical tests.

The following null-hypothesis will be tested: in 3 tests of physical function, there is no difference between middle-aged Danes according to their level of lifetime occupational physical activity.

Because prior studies hypothesized a positive association between manual workers and handgrip strength, we will analyze handgrip strength in a separate analysis. Analyses will be stratified for gender due to differences in physical capacity.

First univariate analyses of the cumulative exposures to standing and lifting and the associations with the three outcome measures will be calculated using logistic regression analyses. Analyses will be repeated using self-reports of exposure. Afterwards multiple regression analyses with stepwise forward selection of variables will be used.

Dropout analyses will be done with the CAMB database to study attrition by using information on socioeconomic status, health, and lifestyle factors from previous questionnaires and registers.

Power Calculation

The power calculation is based primarily on the studies of Kuh et al of a British birth cohort of comparable age and size (2797 individuals age 53 years) [29,46]. Work is included as a dichotomized covariate (manual/non-manual) in their multivariate regression analyses. We expect to find larger differences in our study using a more specific exposure assessment. The following power calculations were performed in SAS version 9.2 PROC POWER. It is assumed that 20% of the population has a job history that includes a moderate to high level of OPA, and we are aiming for a power of 90% (beta = .1) with a significance level of 5% (alpha = .05) in the following calculations.

Handgrip Strength

Kuh et al found a non-significant difference of 0.3 kg in handgrip strength between manual and non-manual male workers [29]. A significant difference of 4 kg between manual and non-manual workers was found in the Il SIRENTE study [14], in which hard physical work was a primary exposure but included older participants. Presuming a relevant difference of 4 kg and the previous assumptions, 2375 participants are needed to show a statistical difference.

Chair Rise Test

Kuh et al measured time to complete 10 chair rises and found a difference of 0.3 sec^{-1} (SD 3.3) between manual and non-manual workers. This is a small difference. A slightly larger difference of 0.5 sec^{-1} is more appropriate, so that manual and non-manual workers use 22 and 20 seconds, respectively. Given this and the other assumptions described previously, n is calculated to be 2870.

Balance

In the British birth cohorts, balance was tested at home and the results are not comparable to our test of balance using the AMTI platform.

From the power calculations in SAS PROC POWER, we will find significant differences (alpha = .05) between manual and non-manual workers in the three physical tests if we include at least 3000 persons.

Discussion

Prevention of decline in physical function due to working conditions is important to the individual worker and to society as a whole in order to maintain the ability to work and prevent disability later in life [47]. More knowledge is needed about the associations between lifetime workload and midlife physical function.

Measurements of physical function are more valid measures than self-reports of pain or disability. The three physical tests were chosen to study functional limitations instead of specific diseases. These outcome measures have been used mainly in gerontological studies [1,2]. There is an association between handgrip strength and mortality in elderly people and handgrip strength and mortality due to all causes in midlife have recently been shown to be associated [2].

Strengths and Limitations

CAMB is a population-based cohort and inclusion is not based on symptoms or diseases [24] which reduces the "healthy worker effect." Cohort members are invited and included regardless of their status in the labor market. Therefore, the cohort includes middle-aged Danes who are still working, on disability pension, unemployed, sick-listed, or have retired early. All have their occupational history recorded through the questionnaire. However, health and physical capacity during youth is not taken into account in our analyses. We hope to be able to include data on chronic diseases in youth in later analyses in order to study selection into jobs or into the labor market. A low participation in CAMB among those invited can lead to selection bias; therefore, dropout analyses are crucial.

We introduce an individual summation of exposure to occupational physical activity in working life using self-reports of job history and expert judgments of exposure to OPA and the exposure assessment is strengthened by a combination of dose (level of physical activity) and time (duration of occupation) [48]. However, there is a risk of misclassification due to generalization of physical demands in job groups (HEGs) in the JEM. By using the five longest-held jobs plus the present job in the exposure assessment, we take account of the fact that deterioration of physical function may be a chronic process and symptomatic workers are more likely to change jobs from high exposure to low exposure [22,49].

Changes in lifestyle factors and socioeconomics throughout life are not taken into account in this study, but historic data about exposures during childhood and adulthood will be included in future analyses. Because the participants did not have a physical examination during their youth, we cannot make conclusions about causal relationships with respect to changes in physical function.

Impact of Results

In Danish public opinion, OPA is considered to have detrimental effects on health. Work-related exposure is thought to be the primary cause of decline in physical function and ability to work in midlife. We hope to investigate this using the occupational life-course perspective on musculoskeletal aging and physical function. At the same time, it is important to prevent early exit from the labor market due to demographic changes in the Western world. This study will help pinpoint targets for such prevention strategies.

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The CAMB study was approved by the Regional Committee on Biomedical Research Ethics, Capital Region, Registration Number H-A-2008–126.

Authors' Contributions

AM was the first author of the manuscript and participated in the design of the study. OSM, JHA, PS, and SR designed the study in collaboration with KA. TSE and JHA participated in establishment of the job exposure matrix and in drafting and revision of the manuscript. LLA participated in collection of data in CAMB and was involved in the drafting and revision of the manuscript. KA, RL, MO, and AMH made substantial contributions to establishment of CAMB and to collection of data, and participated in drafting and revision of the manuscript. UC, RL, and MO contributed by administration of the two cohorts and participated in drafting and revision of the manuscript. All authors have read and approved the final manuscript and contributed to the revision of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AKF: Anvendt Kommunal Forskning (“Danish Institute of Governmental Research”)
AMTI: Advanced Mechanical Technology, Inc.
BMI: body mass index
CAMB: Copenhagen Aging and Midlife Biobank
D-ISCO: the Danish version of ISCO
HEG: homogeneous exposure groups
ISCO: International Standard Classification of Occupations
JEM: job exposure matrix
LY: lifting year (lifting more than 20 kg at least 10 times per day in a year)
NRCWE: National Research Centre for the Working Environment
OPA: occupational physical activity
SY: standing year (6 hours of standing and walking at work per day in a year)
TY: ton year (1000 kg of heavy lifting per day in a year)

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