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Protocol

An Internet-Based Counseling Intervention With Email Reminders that Promotes Self-Care in Adults With Chronic Heart Failure: Randomized Controlled Trial Protocol

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Abstract

Background: Chronic heart failure (CHF) is a public health priority. Its age-standardized prevalence has increased over the past decade. A major challenge for the management of CHF is to promote long-term adherence to self-care behaviors without overtaxing available health care resources. Counseling by multidisciplinary health care teams helps to improve adherence to self-care behaviors and to reduce the rate of death and hospitalization. In the absence of intervention, adherence to self-care is below recommended standards.

Objective: This trial aims to establish and evaluate a Canadian e-platform that will provide a core, standardized protocol of behavioral counseling and education to facilitate long-term adherence to self-care among patients with CHF.

Methods: Canadian e-Platform to Promote Behavioral Self-Management in Chronic Heart Failure (CHF-CePPORT) is a multi-site, double blind, randomized controlled trial with a 2 parallel-group (e-Counseling + Usual Care vs e-Info Control + Usual Care) by 3 assessments (baseline, 4-, and 12-month) design. We will identify subjects with New York Heart Association Class II or III systolic heart failure from collaborating CHF clinics and then recruit them (n=278) by phone. Subjects will be randomized in blocks within each site (Toronto, Montreal, and Vancouver). The primary outcome will be improved quality of life, defined as an increased number of subjects with an improvement of ≥5 points on the summary score of the Kansas City Cardiomyopathy Questionnaire. We will also assess the following secondary outcomes: (1) diet habits, depression, anxiety, smoking history, stress level, and readiness for change using self-report questionnaires, (2) physical activity level, current smoking status, and vagal-heart rate modulation by physiological tests, and (3) exercise capacity, prognostic indicators of cardiovascular functioning, and medication adherence through medical chart review. The primary outcome will be analyzed using generalized estimation equations with repeated measures on an intention-to-treat basis. Secondary outcomes will be analyzed using repeated-measures linear mixed models with a random effects intercept. All significant main effects or interactions in the statistical models will be followed up with post hoc contrasts using a Bonferroni correction with a 2-sided statistical significance criterion of $P<.05$.

Results: This 3.5-year, proof-of-principle trial will establish the e-infrastructure for a pan-Canadian e-platform for CHF that is comprised of a standardized, evidence-based protocol of e-Counseling.

Conclusions: CHF-CePPORT is designed to improve long-term adherence to self-care behaviors and quality of life among patients with CHF. It will demonstrate a distinct Canadian initiative to build capacity for preventive eHealth services for patients with CHF.

Trial Registration: ClinicalTrials.gov NCT01864369; http://clinicaltrials.gov/ct2/show/NCT01864369 (Archived by WebCite at http://www.webcitation.org/6Iiv6so7E).

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KEYWORDS

e-counseling; chronic heart failure; lifestyle intervention; Internet-based intervention; quality of life

Introduction

Chronic Heart Failure Syndrome

Chronic heart failure (CHF) is a progressive clinical syndrome in which the heart is unable to pump oxygenated blood sufficiently to meet metabolic demands during exercise or at rest [1]. It is a major cause of hospitalization and mortality, and it is the only major cardiovascular disease that is increasing in prevalence [2]. For example, in Canada, the age-standardized prevalence of CHF has risen from 1585 to 2510 cases per 100,000 over the past decade [3]. The 1-year hospital readmission rate is 40% [4], and the mortality rate after the first year of a CHF diagnosis is 25%-40%. Patients with CHF experience many symptoms such as shortness of breath and fatigue [5]. Self-care behaviors are critical to symptom management and quality of life. These behaviors include maintaining a healthy diet that is low in fat and sodium, limiting alcohol and fluid intake, maintaining a healthy body weight, exercising regularly, reducing stress, and smoke-free living [6].

A key challenge is to improve quality of life and long-term adherence to self-care behaviors for patients with CHF without overtaxing health care resources. In the absence of intervention, adherence to self-care is problematic with regard to medications (50%-96%), physical activity (9%-53%), dietary restriction of sodium (20%-71%), and daily monitoring of weight (20%-80%) [7]. Meta-analysis has shown that multidisciplinary counseling to promote self-care following hospital discharge for CHF reduces mortality (relative risk-RR=0.75, 95% CI 0.59-0.96), CHF-related hospitalizations (RR=0.74, 95% CI 0.63-0.87), and all-cause hospitalizations (RR=0.81, 95% CI 0.71-0.92) [8].

e-Counseling for Patients

We support the conclusions from recent meta-analytic reviews that call for further development of an e-Counseling strategy for patients with cardiovascular conditions, including CHF [8-10]. An e-Counseling strategy may be well suited to reinforce long-term adherence to self-care among patients with CHF, and in turn improve quality of life while reducing the high rate of hospitalization and mortality. The feasibility of this approach is underscored by the observation that 80.3% of Canadians reported having personal access to the Internet in 2010, including 70%-76% in the two lowest income quartiles, 80% who were between 45-64 years old, and 51% between 65-74 years old [11]. Moreover, we surveyed 100 patients with CHF about whether “It was easy for [them] to get access to a computer at home” (1=Strongly disagree, 5=Strongly agree) [12]. The mean response was 4.4, SD=1.1. In keeping with recent studies [13,14], these data indicate that e-Counseling is very likely to be used by patients with CHF in our clinics.

The primary objective of this trial is to establish and evaluate a Canadian e-platform for e-Counseling and education to enhance quality of life and to facilitate long-term adherence to self-care among patients with CHF. This proof-of-principle trial builds upon: (1) previous clinical trials in e-Counseling, telehealth, and telemonitoring, as well as observational studies by our team [12,15-28], and (2) our contributions to Canadian consensus guidelines for the clinical management of CHF [29-31]. This trial will be undertaken in collaboration with the

Consumer eHealth platform of the Heart and Stroke Foundation of Canada. Findings from the trial will help extend access to e-Counseling, interactive e-tools, and self-help information for patients with CHF.

Methods

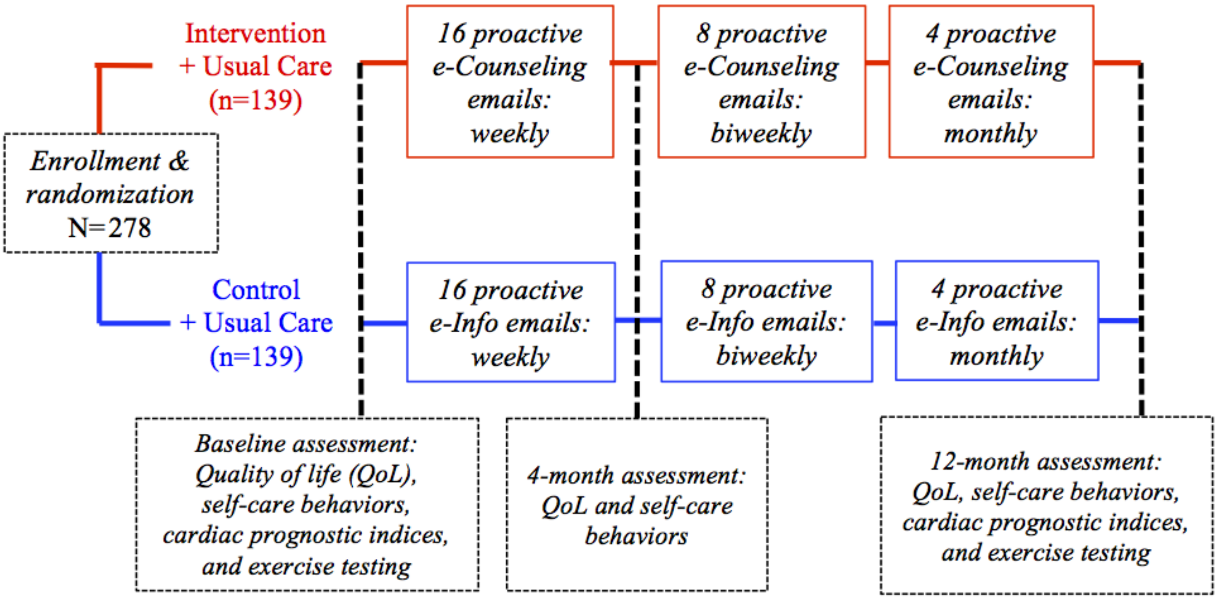
Procedures and Features

Procedures and features of our methods have been reviewed according to the Consolidated Standards of Reporting Trials (CONSORT) standards for clinical trials in eHealth [32,33]. It is reported here in accordance with the CONSORT-EHealth (v.1.6.1) checklist [34].

Trial Design

The Canadian e-Platform to Promote Behavioral Self-Management in Chronic Heart Failure (CHF-CePPORT) is a multi-site, double blind, randomized controlled trial (NCT01864369) with 2 parallel-groups (e-Counseling + Usual Care vs e-Info + Usual Care) and 3 assessment periods (baseline, 4-, and 12-month). Figure 1 shows the research design. This trial was modeled after 2 randomized controlled trials on telehealth and eHealth completed by our team [19,22,23], and after 2 exemplary trials of telehealth that are recently completed [35,36] or in progress [37].

Figure 1. Schematic summary of the trial design.



Hypotheses

Primary Hypothesis

Our primary hypothesis is that more subjects in the e-Counseling + Usual Care arm will experience significant improvement in the quality of life at the 12-month assessment than in the Control arm. This improvement will be defined as a clinically meaningful increase of ≥5 points [38] on the summary score of the Kansas City Cardiomyopathy Questionnaire (KCCQ) [39] from baseline.

Secondary Hypotheses

Our secondary hypotheses are that the e-Counseling + Usual Care arm will be associated with significant improvement in the quality of life, adherence to self-care, and psychological adjustment from baseline to 4- and 12-month assessments. These outcomes will be measured using the following objective and validated indices: (1) the KCCQ (≥5 points increase in the summary score at the 4-month assessment) for quality of life, (2) the Canadian version of the Diet History Questionnaire II (DHQ II) [40] for diet habits, (3) the mean 4-day step count (as measured by accelerometry) [41,42] and the Physical Activity Scale for the Elderly (PASE) questionnaire [43] for physical activity level, (4) the medication possession ratio (MPR) [20] for medication adherence, (5) the generalized anxiety disorder (GAD-7) scale [44] and Patient Health Questionnaire (PHQ-9) [45] for anxiety and depressive symptoms, respectively, (6) the Perceived Stress Scale (PSS) [46] for stress level, and (7) Prochaska’s algorithm [47] for readiness to change self-care behaviors.

In addition, we hypothesize that the e-Counseling + usual care group will perform better than the Control groups at the 12-month assessment on the following prognostic measures of cardiovascular functioning: (1) increased exercise capacity as measured by the 6-minute walk test (6MWT) [48], (2) increased vagal-heart rate modulation [44,45] as measured by electrocardiography (ECG), (3) decreased values of the Seattle Heart Failure Model (SHFM) [49-51], N-terminal pro-brain natriuretic peptide (NT-proBNP) [52,53], high sensitivity C-reactive protein (hsCRP) [52,54], and (4) increased VO_2 peak [55] during cardiopulmonary exercise testing.

Participant Inclusion/Exclusion Criteria

Patients with CHF will be eligible for the trial if they meet all of the following criteria: (1) male and female patients 18 years or older who are diagnosed with heart failure with reduced ejection fraction (systolic HF) that corresponds to New York Heart Association (NYHA) Class II or III for 3 or more months prior to enrollment, (2) documentation of left ventricular ejection fraction (LVEF) ≤40%, (3) if the patient has been stable throughout 12 months prior to enrollment, documentation will confirm impairment of LVEF by contrast ventriculography, radionuclide ventriculography, or quantitative echocardiography, (4) no worsening of CHF for 1 month prior to recruitment, as determined by the referring cardiologist, (5) confirmation by referring cardiologist that medical treatment includes an optimal and stable dose of angiotensin converting enzyme inhibitor, beta-blocker, and aldosterone antagonist where indicated for at least 1 month prior to enrollment in this study (Patients not treated with a beta-blocker will be enrolled if this was previously prescribed, but not tolerated by them. Use of digitalis or diuretic is optional), (6) subject is not *currently* enrolled in a formal exercise program, (7) comprehension of English or French, (8) subject is familiar with the use of and has access to a personal computer, email, and the Internet, and (9) subject provides informed written consent.

Patients with CHF will be ineligible if they fit with any of the following exclusion criteria: (1) documentation at enrollment of renal failure (serum-creatinine ≥300 micromoles/L, ≥3.0 mg/dL), significant liver disease (alanine transaminase >3-fold upper limit of normal), or poorly controlled diabetes mellitus (fasting blood glucose >10 mmol/L or hemoglobin A1c >8%, or current diagnosis of autonomic neuropathy, ketoacidosis, or hyperosmolar state), (2) current symptomatic hypotension and/or systolic blood pressure ≤85 mmHg, (3) persistent systolic or diastolic hypertension (systolic >170 mmHg or diastolic >100 mmHg despite antihypertensive therapy), (4) CHF secondary to any of the following conditions–primary uncorrected valvular cardiomyopathy, predominant right-sided heart failure, or noncardiac disease (eg, pericardial disease, complex congenital heart disease), (5) cardiovascular comorbidities/procedures that include stroke, acute myocardial infarction, or planned cardiac surgery within 4 weeks before enrollment, (6) severe obstructive, restrictive, or other chronic pulmonary disease, (7) previous heart transplant or is on a wait list for heart transplant at the time of enrollment, (8) diagnosis of major psychiatric disorder (eg, psychosis) or drug/alcohol abuse in past year, and (9) diagnosis of noncardiac disease (eg, cancer) that is likely to shorten life expectancy to <2 years.

Recruitment Procedure

Cardiologists, who are coinvestigators in this trial, will identify patients with CHF in their care who meet our recruitment criteria. A clinic staff member will introduce the study to the potential subjects and solicit their verbal consent to be contacted by our research team. The contact information of consented individuals will be sent via secure fax to the Behavioral Cardiology Research Unit at University Health Network (UHN), Toronto, Canada. Individuals will be telephoned by our research team to obtain verbal consent to participate and to schedule a baseline assessment appointment to be held at one of the three trial sites (Toronto, Montreal, and Vancouver). We will obtain written informed consent from subjects for trial participation, email communication, and review of medication history at the beginning of their baseline assessment appointment. Once they have completed their baseline assessment, subjects will be randomized into the intervention or control group. We have received ethics approval from our coordination site (UHN). At the time of manuscript submission, we are seeking ethics approval from the Vancouver and Montreal trial sites.

Intervention

Clinical/Theoretical Framework

New taxonomies of techniques for health behavior change have been reported [56,57]. Based on this work, our team has recently published a systematic review of how behavior change techniques are utilized in trials of e-Counseling [58]. Our key finding is that e-Counseling programs that were efficacious used a repertoire of at least six behavior change techniques that can be tailored to (or selected by) the individual user. Further, it is critical to present these techniques in an organized manner, within a framework of preventive counseling that is evidence-based and clinically relevant.

CHF-CePPORT is not “therapy” per se. However, our e-Counseling protocol incorporates key components of two foundational models of behavioral counseling: (1) motivational interviewing (MI) [59], and (2) cognitive-behavioral therapy [60-62]. MI was developed as a set of procedures [63] that build upon educational strategies used in Prochaska’s transtheoretical model [47,64]. The initial goal of MI is to validate the patient’s presenting stage of “readiness” and to tailor feedback or information accordingly. Therapeutic interactions and self-assessment procedures are designed to evoke positive “change talk,” [63] as the patient is directed to identify personally salient goals that are associated with potential change in a targeted behavior. As ambivalence about change is resolved, the patient is directed to “experiment” with behavior change. Goals for change and behavioral feedback are conventionally provided in a manner that is consistent with cognitive-behavioral therapy [60-62]. Strategies to sustain change are collaboratively reviewed to assist the patient in: (1) developing a repertoire of behavioral skills, and (2) building efficacy from performance-based feedback. Meta-analysis shows that in comparison to a standardized intervention or usual care, MI (alone or combined with cognitive-behavioral counseling) is associated with significantly greater reduction in body mass index, total cholesterol, blood pressure, adult smoking, and alcohol abuse, and with increased adherence to diet, exercise, and other “treatment” [65-67].

Intervention (e-Counseling + Usual Care) Group

The e-Counseling protocol in CHF-CePPORT builds upon evidence and know-how that we have shown in our previous trials. In the Community Outreach Heart Health and Risk Reduction Trial (COHRT) [23,68,69], we demonstrated that an evidence-based model of telehealth counseling with MI [59] added therapeutic benefit to a recommended standard of preventive counseling at a 6-month follow-up in people with or at elevated risk for cardiovascular disease. In the Internet-Based Strategic Transdisciplinary Approach to Risk Reduction and Treatment (I-START) [19,22,28], our e-Counseling protocol was independently associated with reduced systolic blood pressure, pulse pressure, and total cholesterol (but not with diastolic blood pressure), as well as with increased adherence to psychometrically assessed exercise and diet in people with hypertension. Through our ongoing trial, e-Counseling Promotes Blood Pressure Reduction and Therapeutic Lifestyle Change in Hypertension (REACH) [21], we are establishing whether our e-Counseling protocol independently reduces blood pressure and 10-year absolute risk for cardiovascular disease over a 12-month interval in people with hypertension. The CHF-CePPORT e-Counseling protocol builds upon this evidence [19,22,23,68,69], as well as guidelines from notable trials and reviews of telehealth and eHealth [14,35,37,70-72]. This trial will be a proof-of-principle study for patients with CHF.

The CHF-CePPORT e-Counseling protocol will be delivered in collaboration with the Consumer eHealth platform of the Heart and Stroke Foundation of Canada. It will send 28 emails proactively to each subject in the intervention arm over a 12-month interval (Table 1). Each email will link e-Counseling subjects to a restricted section of our e-platform where they will access multimedia materials and interactive e-tools. As noted above, the clinical method and content of this protocol is consistent with principles of MI. In keeping with I-START [19,22], the e-Counseling messages promote the following: (1) explicit validation of the subject's stage of "readiness" for behavior change via e-messaging and educational segments, (2) collaborative participation by means of subject-selected menus and explicit messaging to validate the subject's active participation, and (3) reinforcement of "change talk" [63] through peer modeling, dramatic vignettes, and self-help exercises that are designed to help resolve ambivalence to change. Additionally, MI is most efficacious when combined with other evidence-based counseling methods such as cognitive-behavioral therapy [66]. Accordingly, the e-Counseling protocol will maintain a user-centered approach by working collaboratively with each subject who reports appropriate motivation to change a behavior that they have identified as a priority for change. This includes interactive access to the following therapeutic tools: (1) self-help information and e-tools for self-monitoring self-care behaviors, and (2) developing cognitive-behavioral skills to build and strengthen efficacy [73] to initiate and maintain behavior change. The collaborative tone of the e-Counseling content is consistent with cognitive-behavioral guidelines to reinforce motivation [59,63] and efficacy [73]. Finally, subject engagement in this segment of the e-Counseling program will be reinforced through the use of short films that will complement the e-based self-help information and e-tools. These original short films have been written and produced by our research team, in collaboration with the Heart and Stroke Foundation of Ontario. e-Counseling subjects will continue to receive CHF-related medical care from their health care team during the course of the trial (ie, usual care).

Table 1. The 12-month schedule for proactive e-messaging for the CHF-CePPORT trial.

	Month 1-4	Month 5-8	Month 9-12
Schedule for proactive e-messages	Weekly	Biweekly	Monthly
Total # of proactive e-messages	16	8	4

Control Group

In addition to usual care, the Control group will be provided with e-messages following the same delivery schedule (Table 1). The e-messages will include brief articles that are randomly selected from the Healthy Living section of the Heart and Stroke Foundation of Canada e-platform. Each e-support article will provide information tailored for a CHF population, such as appointments with physicians and advice about heart healthy guidelines for exercise, diet, smoke-free living, symptom monitoring, and medications. This intervention will be distinct from the e-Counseling group in two ways: (1) information will not be tailored to each subject's stage of readiness for change, and (2) e-messages will not include e-tools and e-Counseling procedures to increase "readiness" and efficacy to adhere to targeted self-care behaviors.

Randomization and Blinding

Protection against bias will be accomplished by double blinding. Randomization will be done through a particular website which uses randomly permuted blocks to assign subjects to the e-Counseling group or to the Control group. This process will be conducted in blocks to ensure that group assignment is balanced across our recruitment sites (Toronto, Montreal, and Vancouver) for the overall trial. The individual who will be responsible for randomization at the Behavioral Cardiology Research Unit, UHN has no direct involvement in this trial. In addition, the randomization code will be hidden from trial subjects, as well as all those who will conduct assessments, data processing, and analysis. Thus, the CHF-CePPORT research team members and the trial subjects from the three sites will not be aware of the group assignment of the subjects.

Outcome Measures

Collection Materials in English and French

Data collection materials will be available in both English and French. All materials were developed in English. We will indicate if a published French version of a questionnaire is to be used. If none is available, our Montreal team will translate the English questionnaire into French using a standard back-translation protocol [74].

Primary Outcome

The primary outcome is quality of life improvement of subjects at the 12-month assessment, as measured by the number of subjects who demonstrate a clinically meaningful increase of ≥5 points [38] on the summary score of the KCCQ [39]. It is a

23-item questionnaire that assesses the patient's perception of CHF in terms of physical limitations, symptoms (frequency, severity, and recent change over time), self-efficacy, social interference, and quality of life over the past 2 weeks. The summary score ranges from 0-100, with the lower score reflecting poorer quality of life. Internal consistency is high for all domains (Cronbach alphas=.78-.95), except the 2-item self-efficacy scale (Cronbach alpha=.62). We will employ a validated French-Canadian version [39] of KCCQ in this trial.

Secondary Outcomes

The quality of life at the 4-month interval will be assessed by determining the number of subjects who demonstrate a ≥5-point improvement of the KCCQ total score [38,39].

The subjects' increase in adherence to the recommended intake of vegetables, fruit, dairy, and dietary fat will be evaluated at the 4- and 12-month assessments using the Canadian version [40] of the DHQ II [75], which is also available in French.

The physical activity level of the subjects will be measured in two ways: (1) mean step count, and (2) self-report questionnaire. We will ask subjects to document their daily step count for 7 days prior to their assessments at baseline, 4-, and 12 months. The step count will be measured using an accelerometer (LifeSource/A&D XL-18CN Activity Monitor) that we will provide to each subject. We will calculate the mean 4-day step count using data from the three weekdays and one weekend day that have the highest step count out of the 7-day record [76,77]. Adherence to physical activity over the past week will be measured by the PASE [78], which has been validated in persons with CHF [79]. We will use a French version that was translated by its publisher.

We will confirm the smoking status of those who self-report as a current smoker at the baseline, 4-, and 12-month assessments using salivary cotinine. The current smokers will be defined by having salivary cotinine level ≥10 ng/ml. These subjects will also be screened for the use of nicotine replacement therapy, which can confound their salivary cotinine result. Smoking history will be evaluated using questions from the Survey on Living with Chronic Disease in Canada [80] (ie, “Have you smoked at least 100 cigarettes in your life?”). The French version [80] of the smoking history questions will be also used in this trial.

We will estimate each subject's medication adherence using MPR [81]. It calculates the cumulative medication supply for *x* days, divided by the total days to the next refill or end of the observation period. MPR has been validated in a previous trial [20]. We will measure MPR with pharmacy refill data for a 4-month period that precedes each of the three assessments.

Anxiety will be measured using the GAD-7 scale [44]. Depressive symptoms will be assessed using the total score from the PHQ-9 [45]. Both questionnaires have been used extensively in health research and have been well validated, including in people with CHF [44,82]. French versions of the GAD-7 and PHQ-9, freely available on the Internet, will also be employed. These assessments will be made at the baseline, 4-, and 12-month intervals.

The 10-item PSS [46] is a commonly used instrument to measure the extent to which one's life is appraised as stressful. It has demonstrated adequate reliability (Cronbach alpha=.78). The PSS has been used in people with heart disease, including CHF [83]. We will use a validated French version of the PSS for this trial [84] at the baseline, 4-, and 12-month assessments.

Readiness for change in self-care will be assessed using Prochaska's transtheoretical algorithm [47] at the baseline, 4-, and 12-month intervals. This algorithm categorizes “readiness” to make behavioral changes in one of five stages: (1) precontemplation (do not intend to make a behavioral change in the next six months), (2) contemplation (intend to start making behavioral changes within the next six months), (3) preparation (ready to start making behavioral changes within the next 30 days), (4) action (have made changes to a behavior within the last six months), and (5) maintenance (continue with the new behavior that was changed six or more months ago).

The functional capacity of the subjects will be assessed using the 6MWT [85] at the baseline and 12-month intervals. In accordance with the American Thoracic Society's protocol, the test will use an indoor straight course of 30-40 meters and standard instructions to “walk as far as possible in six minutes.” Values will be expressed as the percent predicted value, rather than absolute distance, because the former is less susceptible to confounding factors [86].

Autonomic nervous system function of the subjects will be assessed using heart rate variability. A 10-minute recording will be collected using a three-lead ECG. The data will be sampled at 1000 Hz using LabView (version 7.1, National Instruments). A custom heart rate variability software will be used to analyze RR interval data using a fast Fourier transformation to obtain low frequency (0.04-0.15 Hz) and high frequency (0.15-0.50 Hz) spectral components. Only the Toronto sample will be asked to provide an ECG recording at baseline and 12-month intervals.

Peak aerobic power (VO_2 peak, oxygen consumption) and the VE/VCO_2 (rate of elimination of carbon dioxide) slope will be used to assess exercise capacity of the subjects at the baseline and 12-month intervals. The VO_2 peak has prognostic value [87]. It is associated with the quality of life [88], and it is sensitive to change following home-based training with telehealth in CHF patients [55]. We will be collecting this information on the subjects through medical chart review.

The SHFM provides a risk estimate that has been validated among patients with CHF [49-51]. It is derived from prognostic variables (diuretic dose/kg, systolic blood pressure, percent lymphocytes, haemoglobin, etiology, ejection fraction, cholesterol, uric acid, allopurinol, serum sodium, statin, NYHA class, age, and sex) that are easily obtained from medical charts. We will review the medical charts of the subjects to extract values for these abovementioned variables at the baseline and 12-month intervals. These will then be inserted into a freely available algorithm on the Internet. The generated SHFM score will be used in our analyses.

The brain natriuretic peptide (BNP) is a neurohormone that is synthesized in and secreted from the ventricular myocardium in response to elevated ventricular wall tension and stretch, and from the activation of the sympathetic and renin-angiotensin systems. BNP is increased in patients with CHF [89], and it correlates with risk for all-cause, cardiac, and pump-failure mortality. Proinflammatory hsCRP is elevated in CHF as the disease progresses [52,54]. We will extract these data, if available, from the medical charts of subjects at the baseline and 12-month assessments.

We will also collect the anthropometric variables such as age, sex, height and weight (for body mass index), waist circumference, medications, alcohol (drinks/day), and medical history for each subject at the baseline and 12-month assessments.

Data Collection

Data will be collected at three time points–baseline, 4-, and 12-month. Each subject will be asked to attend an in-person assessment appointment at the HF clinic from which he/she is recruited (Toronto, Montreal, or Vancouver) at each time point. During each assessment, subjects will be asked to complete specified physiological tests and self-report questionnaires (on paper or Web-based). There will be two exceptions: (1) subjects will complete the Web-based DHQ II, and (2) wear the accelerometer at home for seven days after their baseline assessment, and immediately prior to their 4- and 12-month assessments.

Subject Compliance Monitoring

As a quality control check, we will evaluate the number of emails sent to subjects versus the number of proactive emails that subjects have opened via automated reply. This will yield a ratio of adherence to treatment (number of emails sent/number of emails opened) that will be considered as a potential covariate in supplemental outcome analyses.

Problems with adherence/compliance to preventive counseling are often due to increased response burden that is disproportionate to perceived benefit [90]. To offset this problem, we will inform subjects that they can keep the accelerometer (approximate value=US $50) as a gesture of appreciation for their participation. Transportation/parking, up to US $21, will also be reimbursed. Finally, we expect to reinforce subject motivation to comply with trial procedures by maintaining a regular schedule of e-messages over 12 months, which are likely to be perceived as being supportive in nature.

Statistical Analysis Plan

Sample Size Estimation

Our sample size was not only estimated based on our own previous work, but also based on the seminal work from Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION). At the 12-month outcome in HF-ACTION [88], 53% (n=618, 95% CI 50%-56%) of subjects in exercise training had a clinically significant improvement (≥5 points) [38] from the baseline on the KCCQ [39], compared with 33% (n=386, 95% CI 30%-35%) in Usual Care. With type I error of .05 and power of .80, 93 subjects per group are required to replicate this effect. HF-ACTION was not an e-intervention, however, it utilized a 12-month home-based program to which only 40%-45% of subjects were adherent [91]. Consequently, there was only a small treatment effect for change in exercise capacity. This was correlated with KCCQ outcomes [88]-exercise group gained only 0.6 $ml \cdot kg^{-1} \cdot min^{-1}$ (interquartile range–IQR, −0.7 to 2.3) and Controls gained 0.2 $ml \cdot kg^{-1} \cdot min^{-1}$ (IQR, −1.2 to 1.4) [92]. This is likely due to low exercise intensity. CHF-CePPORT (in keeping with our previous trials of COHRT, I-START, and REACH) [23] [19,22,28] [21] is designed to improve the quality of life associated with increased self-care behaviors, including exercise. Therefore, a similar small change in exercise capacity as in HF-ACTION is expected, in association with an expected increase in the KCCQ score [39]. With alpha of .05 and power of .80, a sample of 115 subjects per group is required. Withdrawal or drop out (for any reason) has been below 6% in HF-ACTION [93] and in our previous telemonitoring trial [24]. When completion of repeated behavioral assessments are factored into subject loss, attrition was 19% in our telemonitoring trial [24] and 21% in I-START [19,22] Therefore, we conservatively plan for 21% attrition for CHF-CePPORT-final sample=278 subjects.

Our team will recruit subjects from CHF clinics in tertiary care hospitals where we hold senior positions. It is feasible to recruit 278 subjects across 3 sites: (1) Vancouver (St. Paul’s Hospital), (2) Toronto (UHN), and (3) Montreal (Montreal Heart Institute)–Years 1 and 2=248 subjects/3 hospitals/2 years=41 subjects per hospital, per year. Additionally, 30 subjects (10 per hospital) will be recruited in the first quarter of Year 3. The research clerk at the Behavioral Cardiology Research Unit, UHN, Toronto will perform coordination and monitoring of recruitment.

Statistical Analysis

This trial will use a 2 parallel-group design with 3 repeated assessments at baseline, 4-, and 12-months. A generalized mixed model (GMM) will evaluate the primary outcome, which is a binary code of whether the 12-month KCCQ [39] increases ≥5 points [38]. Predictors will include baseline KCCQ, age, sex, body mass index, and Group (e-Counseling vs Control). The primary outcome will be coded as a “failure” in the event of CHF hospitalization or mortality, but not for “elective” medical procedures (eg, cardiac resynchronization therapy). GMM with repeated measures will assess binary secondary outcomes across 4- and 12-month intervals (eg, KCCQ and smoking status). This analysis is optimal as it adjusts for serial correlations across repeated measures and between individual subjects in each group. Predictors will include baseline KCCQ, age, sex, body mass index, time (4- vs 12- month assessment interval), and Group (e-Counseling vs Control). Significant interactions or main effects will be followed by Bonferroni post hoc tests for significance, $P<.05$, 2-sided. Data missing at random will be handled by multiple imputations. For continuous secondary outcomes, linear mixed models (LMM) [94] for repeated measures with a random intercept will assess whether within-subject improvement across 4- and 12-month intervals is independently associated with our e-Counseling protocol. This analysis adjusts for serial correlations across repeated measures and between subjects in each Group. Predictors will include the baseline dependent variable, age, sex, body mass index, time (4- vs 12-month assessment interval), and Group (e-Counseling vs Control). LMM with a random intercept will also evaluate whether e-Counseling vs Control demonstrates improvement at the 12-month interval in VO_2 peak, NT-proBNP, hsCRP, and the SHFM.

Planned Subgroup Analysis

Subanalyses will explore whether therapeutic changes in primary or secondary outcomes following e-Counseling differ significantly within subgroups–sex, age, and income level. We will use GMM to evaluate the dose-response relationship between e-Counseling and improvement in our primary outcome; and LMM to evaluate this dose-response relationship for prognostic measures of CHF at the 12-month outcome using a ratio of adherence to treatment (number of emails sent/number of emails opened).

Quality Control and Quality Assurance Procedures

Three committees will be established for quality control and quality assurance purposes. The Steering Committee will hold teleconference meetings every 3 months to review trial progress, overall outcome rates, issues related to evaluation of primary or secondary outcomes, and response of research staff to any adverse incidents. This group will recommend whether our trial should continue without protocol modification, with modification, or whether it should be terminated. The Outcome Adjudication Committee will meet every 6 months by teleconference to adjudicate issues related to primary outcome status of subjects. The Safety and Monitoring Committee will meet annually with the option of expedited meetings in the event of an urgent issue or unexpected "serious adverse event."

Discussion

CHF-CePPORT Benefits to CHF Patients

It is critical for preventive eHealth care in Canada to establish a foundation upon which a pan-Canadian e-platform can be built for patients with CHF in order to improve the quality of life and adherence to self-care behaviors. It is reasonable to expect that CHF-CePPORT will provide data that is indispensible in helping investigators in Canada to develop a compelling Phase 3 trial where the independent benefit of e-Counseling for CHF can be evaluated with regard to decreasing HF hospitalizations and mortality-as has been shown for telehealth [35,70,95].

CHF-CePPORT Findings

Findings from CHF-CePPORT will also help guide the development of CHF e-Counseling services provided by the Heart and Stroke Foundation of Canada. Their Consumer eHealth platform offers visibility and accessibility for disseminating information and resources developed by CHF-CePPORT through its website. In 2011, this e-platform accommodated 395,044 users who searched for heart health information, while 160,600 users completed structured risk assessments. Second, our results will be submitted for presentation at national meetings and peer-reviewed publications. Third, the Heart and Stroke Clinical Update is an annual continuing medical education conference hosted by the Heart and Stroke Foundation of Canada for primary care physicians. Pending the results of this study, there is interest to develop a workshop for Canadian physicians and health professionals on the use of our e-platform to promote self-care in patients with CHF. As results become available, our team will develop a knowledge translation supplement grant.

The e-Platform in CHF-CePPORT

The proposed e-platform in CHF-CePPORT is designed to complement (rather than compete with) e-programs that are housed in collaborating institutions. Following our trial, our aim is to build supplementary e-links to specialized programs in participating CHF clinics within Canada. At the same time, we expect that the e-platform in CHF-CePPORT will evolve as an e-Counseling resource for CHF clinics through collaborations with other investigators. To that end, members of our research team are affiliated with societies that are engaged in knowledge dissemination and application. These affiliations will permit direct dissemination of study outcomes to key opinion leaders and facilitate uptake of new knowledge to a broader audience.

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Conflicts of Interest

The authors of this paper are also the developers of the Internet-based e-Counseling intervention being testing in this trial. GE is editor and publisher of JMIR Res Protoc, but had no role in assigning peer-reviewers; the protocol was also independently peer-reviewed at the funding agency.

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Abbreviations

6MWT: 6-minute walk test
BNP: brain natriuretic peptide
CHF: chronic heart failure
CHF-CePPORT: Canadian e-Platform to Promote Behavioral Self-Management in Chronic Heart Failure
COHRT: Community Outreach Heart Health and Risk Reduction Trial
CONSORT: Consolidated Standards of Reporting Trials
DHQ II: Diet History Questionnaire II
ECG: electrocardiography
GAD-7: generalized anxiety disorder
GMM: generalized mixed model
HF-ACTION: Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training
hsCRP: high sensitivity C-reactive protein
IQR: interquartile range
I-START: Internet-Based Strategic Transdisciplinary Approach to Risk Reduction and Treatment
KCCQ: Kansas City Cardiomyopathy Questionnaire
LMM: linear mixed models
LVEF: left ventricular ejection fraction
MI: motivational interviewing
MPR: medication possession ratio
NT-proBNP: N-terminal pro-brain natriuretic peptide
NYHA: New York Heart Association
PASE: Physical Activity Scale for the Elderly
PHQ-9: Patient Health Questionnaire
PSS: Perceived Stress Scale
REACH: Promotes Blood Pressure Reduction and Therapeutic Lifestyle Change in Hypertension
RR: relative risk
SHFM: Seattle Heart Failure Model
UHN: University Health Network

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Protocol

Evaluating a Brief, Internet-Based Intervention for Co-Occurring Depression and Problematic Alcohol Use in Young People: Protocol for a Randomized Controlled Trial

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Abstract

Background: Depression and alcohol misuse represent two of the major causes of disease burden in young adults. These conditions frequently co-occur and this co-occurrence is associated with increased risks and poorer outcomes than either disorder in isolation. Integrated treatments have been shown to be effective, however, there remains a significant gap between those in need of treatment and those receiving it, particularly in young people. The increased availability of Internet-based programs to complement health care presents a unique opportunity in the treatment of these conditions.

Objective: The objective of our study was to evaluate whether a brief, Internet-based, self-help intervention (the DEAL [DEpression-ALcohol] Project) can be effective in treating co-occurring depression and problematic alcohol use in young people (18-25 years old).

Methods: The evaluation will take the form of a randomized controlled trial (RCT), comparing the DEAL Project with an attention-control condition (HealthWatch). The RCT will consist of a four-week intervention phase and a 24-week follow-up. It will be entirely Internet-based and open Australia-wide to young people 18 to 25 years old. The primary outcomes will be change in depression symptoms and alcohol use at 5, 12, and 24 weeks post baseline. Secondary outcomes include change in general functioning and quality of life, anxiety/stress symptomatology, and a number of other depression/alcohol related outcomes. Process analysis will also measure engagement across the conditions.

Results: This study is currently ongoing with preliminary results expected in late 2014.

Conclusions: This study, to our knowledge, will be the first RCT of a Internet-based treatment for comorbid depression and problematic alcohol use in any age group. If successful, the program represents a novel and innovative approach to addressing the significant harms associated with these conditions and will be an invaluable resource to those not receiving help elsewhere.

Trial Registration: Australian New Zealand Clinical Trials Registry; ACTRN12613000033741; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=363461 (Archived by WebCite at http://www.webcitation.org/6Mrg9VFX4).

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KEYWORDS

depression; alcohol; young people; Internet-based; comorbidity

Introduction

Alcohol Use Disorders and Depression

In the developed world, two of the top five leading global causes of years lost to disability are alcohol use disorders (AUD) and depression [1]. Young people bear a disproportionately large share of these burdens [2,3]. In Australia, the highest prevalence of 12-month AUDs in any age bracket occurs in those 16-24 years old (11.1%) [4]. In addition, this age bracket has the highest incidence rates for depression of any age group [5], half of whom will experience recurrent episodes of depression [6].

Comorbidity

Comorbidity across the disorder classes is common. Approximately one in four (22.2%) young Australians (16-25 years old) with current major depression also meet criteria for a 12-month AUD, while 14.3% of those with a 12-month AUD meet criteria for current major depression [7]. In treatment samples, rates of comorbidity are as high as 89% [8].

These comorbid conditions are associated with increased suicidality [9-11], symptom severity, and poorer social, interpersonal, and general functioning compared to those with a single disorder [12-14]. This group is also likely to report poorer quality of life [15] and increased treatment reliance [16-21]. Furthermore, these disorders tend to maintain and exacerbate one another [22]. As such, in recent years there has been increasing support for integrated approaches to comorbidity [23,24]. Baker et al [25] have demonstrated that concurrent treatment of depression and problem drinking is more effective than treating either condition alone and more effective than general counseling.

Hides et al [26], suggest that treatment integration is particularly relevant to youth, given “coping” is a key motive for substance use among young people with mental health issues. There have, however, been few such attempts made in younger populations [27-29]. Although early intervention is imperative to averting the development of more severe, ingrained morbidity [30,31], fewer than 25% of affected young people access traditional health services in a 12-month period [32].

Internet-Based Interventions

Internet-based interventions have been deemed to be particularly useful for those less likely to access traditional services, such as young people [33]. Advantages of these interventions include flexibility, anonymity, and accessibility, and as such, have the potential to overcome a number of structural and attitudinal barriers that frequently limit help seeking efforts in this population [34,35]. Furthermore, Internet use is widespread among young people [36,37]. Research suggests that the Internet helps to empower young people [38], and that young people are comfortable accessing both general health information and seeking specific mental health treatment via this medium [39,40]. Additionally, Internet-based treatments have the potential to reduce costs associated with treatment (by reducing contact time with the therapist), and increase treatment standardization and adherence to evidence-based practice [41,42]. Finally, this modality has also been shown to overcome imbalances in treatment seeking, access, and availability [43,44]. Such interventions have been shown to be effective and cost effective in treatment for depression and related disorders [45,46]. A number of recent meta-analyses have indicated that effect sizes for such interventions are small to moderate (0.28-0.78) [47-50], but roughly equivalent to traditional face-to-face therapy [51,52]. Similarly, recent meta-analyses have indicated that effect sizes for such alcohol interventions are small to moderate (0.22-0.48) [33,48, 53-55], again not dissimilar to brief in-person interventions [56,57].

To our knowledge, there has been no youth-focused Internet-based comorbidity interventions. Furthermore, in the general population only one computerized comorbidity intervention targeting these disorders has been evaluated. These evaluations of the computerized Self Help for Alcohol/other drug use and Depression (SHADE) resource indicate electronic forms of treatment for co-occurring disorders are viable and effective [58,59]. In two randomized controlled trials (RCTs), the SHADE program was associated with equivalent outcomes to that achieved by therapist-delivered treatment, with superior results as far as reducing alcohol consumption over 3- and 12-months.

Although unguided Internet-based interventions may not always be as effective as a face-to-face encounter with a skilled clinician, the reality is that a majority of those with depression and alcohol problems (especially young people) will never receive any face-to-face intervention. Fewer still will see a skilled clinician [32,60]. Internet-based interventions have the potential to engage young people through the use of new, interactive technology and may overcome the stigma associated with seeing a therapist.

Objective

The primary aim of the study is to evaluate whether a brief, Internet-based intervention—the DEpression-ALcohol Project (DEAL)—can be effective in treating co-occurring moderate depression and problematic alcohol use in young people (18 to 25 years old). This evaluation will take the form of a RCT comparing the DEAL Project to an attention-control condition and measuring participant outcomes across time. This will be, to our knowledge, the first RCT of an Internet-based treatment for comorbid depression and problematic alcohol use in any age group.

Methods

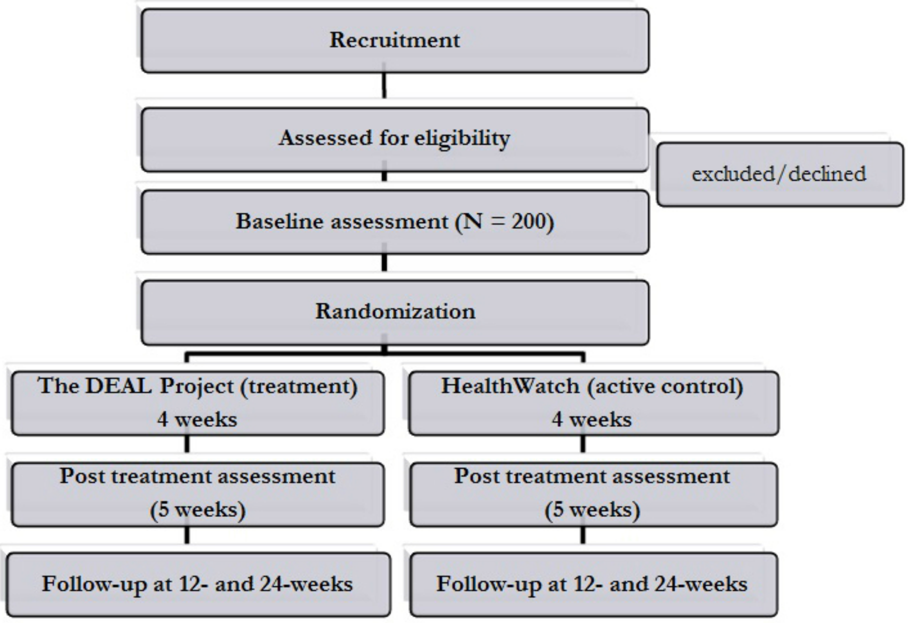
Study Setting

The study will be conducted Australia-wide and entirely Internet-based with minimal participant contact. All contact made will occur via email, with the exception of follow-up contact from a clinical psychologist if participants report experiencing particular distress and are suicidal (see Safety Protocol).

Study Design

The proposed RCT meets international standards for such trials. Figure 1 shows the design of the study and intended flow of participants. Initial contact with potential participants will be made via the Internet. Upon visiting the website, potential participants will complete an initial screening to determine eligibility. Eligible participants will receive a follow-up email to complete the full Internet-based baseline assessment, with randomization to one of the two treatment groups following assessment. Following randomization, participants will be provided with their login access code along with instructions about how to access the treatment website. Follow-up Internet-based assessment will occur across the two conditions at 5, 12, 24 weeks post baseline.

Figure 1. Flow of participants through the study.



Ethical Approval and Registration

The study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613000033741) and has ethical approval from the University of New South Wales Human Research Ethics Committee (HC12546). Consent will be obtained electronically from all participants and confidentially assured via rigorous data encryption.

Participants

We will aim to recruit approximately 200 participants. The trial has a purposive sample of young people reporting drinking at harmful levels with mild to moderate depressive symptoms. Young people will be informed that the study compares an Internet-based self-help program for depression and alcohol use with a healthy lifestyles program on a range of outcomes, and they will be randomly allocated to one of these groups. Recruitment will be Australia-wide, using extensive media coverage; including tertiary institutions and street press, Internet-based chat forums and blogs, government, youth-oriented services and websites, and paid Facebook and Google advertisements. The research team has been successful using similar strategies in previous studies [61]. They also have extensive experience recruiting large samples of participants with depression and alcohol use comorbidity (eg, 558 in 24 months in two states) [25,59].

Inclusion and Exclusion Criteria

Inclusion criteria include: (1) 18-25 years old, (2) current depressive symptoms (score of ≥7 on Depression Anxiety Stress Scale-21-DASS-21-Depression) [62], (3) harmful drinking as measured by the Alcohol Use Disorders Identification Test (AUDIT) (score of ≥8) [63,64], (4) ability to access the Internet (either in the private residence of the participant, or willingness to use the public library/other suitable venue with Internet access), and (5) Australian residency.

Exclusion criteria include: (1) psychotic symptoms screener score ≥3 [65], (2) non-English speakers, (3) serious risk of suicide (serious past 2-week thoughts of suicide and desire to act), and (4) daily use of cannabis/weekly use of amphetamines.

Randomization

Randomization will be automated within the program and therefore trial researchers will be blind to it. This process will occur immediately after the eligibility screener and baseline assessment have been completed and consent provided.

Safety Protocol

In any trial concerned with mental health or substance use there is the potential to uncover psychological distress in participants. In this population there is an increased risk, as the participants are mild-moderately depressed and drinking at harmful levels. As recruitment (and the trial itself) is entirely Internet-based, no contact (other than email) will occur between participants and the research team during the course of the study. In order to minimize risk, study participants will be provided with a contact email of a clinician upon commencement of the trial. A trained clinical psychologist and member of the research team will monitor this email. Upon email contact, the psychologist will make contact with the participant and initiate a dialogue and negotiate local referral options where appropriate.

Upon weekly login, participants will answer a screening question regarding suicidality (thoughts of suicide or a wish to commit suicide in the past week). On the basis of their answer, they are prompted to the email contact of the psychologist.

At the beginning and end of each periodic assessment, the participant will again be presented with this referral information for crisis care.

Interventions

Access to the treatment website for each of the following conditions will be for a period of 10 weeks from the point of randomization.

The DEAL Project program is a 4-week psychological treatment delivered entirely via the Internet. Participants access the Internet-based sessions from their home computer (or other preferred port for Internet access). Participant-selected pseudonym usernames/emails serve as their login code for the website. Content of the sessions is based on cognitive behavior therapy (CBT) and motivational enhancement theory and was developed from the SHADE resource [59]. Major modifications to the SHADE resource included length, language, reduction of text content, modified design and flow of program, and incorporation of youth vignettes. Participants are asked to complete each session of the DEAL Project intervention in sequence, a week apart, from the point of randomization. The website tracks participants' progress through each weekly module, with automated email reminders sent to the participant's nominated email address. However, participants are not "locked out" between sessions so they may complete at a faster rate.

There were 4 sessions of the HealthWatch program that were chosen for this study. This is an attention-control condition program first developed for the Australian National University WellBeing Study [66] in which participants read information about various health concerns and complete accompanying surveys. The purpose of this condition is to control for time spent interacting with an Internet-based program. The specific modules and surveys selected for the four weeks (from the complete 12-week set) were those deemed to be more relevant to younger people and include environmental health, physical and mental activity, nutrition, and relationships. These were redesigned to match the DEAL Project in appearance. Preliminary evidence from the WellBeing research trial suggests that the site is not associated with a reduction in depressive symptoms over time in adults.

Assessment and Outcome Measures

All assessment tools are frequently used in mental health and alcohol research and in Internet-based (nonface-to-face) formats. Table 1 shows the schedule of assessments.

Table 1. Intended assessments and administration frequency.

Assessment instruments		Baseline assessment	Endpoint self-assessment (5 wks post baseline)	Follow-up self-assessments (12, 24 wks post baseline)
Demographics		✓	-	-
Service utilization		✓	-	-
Depression				
	Patient Health Questionnaire (PHQ-9) [67]	✓	✓	✓
	DASS-21 [62]	✓	✓	✓
Alcohol				
	AUDIT [63]	✓	✓[a]	✓[a]
	TOT-AL [68]	✓	✓	✓
	World Health Organization (WHO) Composite International Diagnostic Interview (CIDI-Alcohol) [69]	✓	✓	✓
Other				
	Opiate Treatment Index (OTI-other drugs) [70][b]	✓	✓	✓
	Assessment of Quality of Life (AQoL) [71]	✓	✓	✓
	McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD) [72]	✓	-	-
Program feedback		-	✓	-

[a] AUDIT-consumption items only

[b] modified to collect only general drug use data

Administration of Assessments

Automatic email prompts to complete Internet-based follow-up assessments will be sent to participants at baseline, 5, 12, and 24 weeks post baseline. In line with best practice standards and our previous trial experience, the following strategies are employed to maximize retention in treatment and assessment: (1) email address required at program commencement, (2) individual email will be sent for each separate module, (3) reminder emails will be sent if participant does not complete assessment in six days, and (4) $10 iTunes voucher reimbursement provided for each scheduled assessments.

Primary Hypotheses

It is hypothesized that integrated treatment for depression and alcohol problems (the DEAL Project) can achieve greater reductions in: (1) depressive symptoms, and (2) alcohol use, compared to an attention-control condition at 5, 12, and 24 weeks post baseline.

Secondary aims include the examination of: (1) general functioning and quality of life, (2) depression/anxiety/stress symptomatology, (3) hazardous alcohol use, (4) AUD criteria, and (5) engagement across the conditions.

Primary Outcomes

Depressed mood is measured by the PHQ-9 [67], and alcohol use quantity and frequency is measured by the TOT-AL [68]. Prior experience with the target population suggests that both the treatment and attention-control groups are likely to show a decrease in these primary outcomes. We will also calculate reliable change indices (RCI) for depression and alcohol use at each time point relative to baseline to detect reliably significant change in primary outcome measures. RCI’s will be calculated using the methodology outlined in Jacobson and Truax [73], that is-$(Ss_{post} - Ss_{pre})/SE_{diff}$. Participants with an RCI of 1.96 or greater and who no longer meet the entry criteria for depression or hazardous/harmful alcohol use will be considered to have produced clinically and reliably significant change in these primary outcomes.

Secondary Outcomes

In this study, the AQoL measures general functioning and quality of life [71], and depression/anxiety/stress symptomatology is measured by the DASS [62]. Hazardous alcohol use is measured by the AUDIT [63], and AUD criteria are measured by the CIDI-alcohol [69]. Engagement will be measured by a process analysis using website visit data.

Data Analysis

As mentioned prior, the DEAL Project is based on the SHADE resource. Data from the SHADE trials indicate the program is associated with a 1.53 effect size change for depression and 0.86 for alcohol between baseline and 12-month follow-up assessments. However, given the SHADE intervention is therapist-guided and longer than that of the DEAL Project, we anticipate smaller effect sizes. Therefore, in line with other brief Internet-based alcohol multi-session modularized interventions with effect sizes of 0.56 [33], a more conservative medium effect size of 0.50 was used. These effects sizes were entered into GPower 3.1 [74] in order to estimate the sample sizes required to detect similar differences between the treatment and control conditions in the current study. Power was set at 80% and conservative 2-tailed tests were assumed even though a directional hypothesis is proposed. Based on this testing, a sample size of 64 per group was needed (total N=128). A conservative dropout rate is 35% of participants at follow-up. As such, we will aim to recruit 200 participants to the study. This will ensure that we will have sufficient power to conduct the analysis.

The authors, using available software packages, will carry out data coding and analysis. Data on screening, refusals, and dropout are coded and reported as per Consolidated Standards of Reporting Trials (CONSORT) [75], and primary analyses use intention-to-treat. Preliminary analyses check for any baseline or health service utilization differences that may confound with condition effects; later analyses control for these as necessary. Categorical and continuous measures of outcome will be examined using mixed or marginal longitudinal models (ie, mixed model repeated measures, generalized estimating equation modelling) as appropriate. These approaches enable the inclusion of participants with missing data, without using inferior techniques such as last observation carried forward, when data is missing at random [76]. A “completers” analysis on all participants completing at least 75% of the modules will be undertaken as a secondary analysis. In addition, comparisons on selected demographic and clinical characteristics will be made between “completers” and those who dropped out of treatment to help detect any biases in outcome measures. The potential effects of a number of covariates and confounders will be modelled in the major analyses (eg, borderline symptoms-MSI-BPD, medication status, drug use-modified OTI, gender, and involvement in additional mental health treatments) [72] [70].

Results

Recruitment is currently underway with preliminary results expected in late 2014.

Discussion

The Present Study

The present study will assess the effectiveness of an Internet-based comorbidity intervention for young people. It is expected that depression and alcohol use outcomes for participants who complete the DEAL Project program will be significantly better than for those allocated to the control condition.

Strengths and Limitations

A significant strength of the project is that it will be entirely Internet-based, without clinical guidance, thus, amplifying “real-world” applicability. This provides evidence on the feasibility of the intervention as a freely accessible program.

Previous trials of the SHADE program have used a guided approach [58,59], whereby therapists provide a one-session intervention at the commencement of treatment, along with 10-minute “check in” sessions at the conclusion of each computer session. This kind of approach has a number of advantages regarding therapeutic alliance, reduced dropout, improved utilization, and the ability to clarify concepts [77]. Unfortunately, such a technique is less likely to reflect real-world conditions.

A further strength of the proposed project is that the research design includes an active attention-control condition. The HealthWatch program will be used as the control, with participants being provided with a variety of health-related information. This active control [66] addresses limitations with previous clinical trials in which comparisons are allocated to a waitlist (no-treatment) control condition [78].

A potential challenge for this project will be participant dropout. Dropout rates from alcohol and other substance abuse treatment interventions are often high [79], similarly, Internet-based interventions, especially among young people, are also likely to compound these attrition rates [80]. It has been argued that a number of the strengths associated with Internet-based interventions (such as flexibility and anonymity) can quickly become weaknesses, as it may be much easier to neglect an appointment with an Internet-based program than a psychotherapist [81].

In a recent systematic review, Melville et al [82] found dropout rates from all Internet-based treatment programs for psychological disorders, which involved minimal therapist contact over a twenty year period, ranged from 2% to as high as 83%, with a weighted average of 31%. Interestingly, however, this weighted average was identical to that observed in face-to-face treatment for pathological gambling in the same review [82]. Therefore, assumptions that Internet-based therapies will automatically be associated with poorer adherence than face-to-face treatments appear contentious. Furthermore, the reasons for selective attrition are difficult to interpret as they may reflect the contradictory possibilities of dropout due to dissatisfaction, as opposed to dropout due to the individual feeling their needs have been met [83]. Nevertheless, attrition rates are a concern for any form of treatment and consequently the expansion of technology-based therapies demands researchers and developers consider innovative ways to engage individuals in therapy, particularly in younger populations. Feedback on the program will add to the knowledge base and aid future work in this area.

A related challenge is participant follow-up. Attempts to improve follow-up rates in the current study will include using a range of reminders, flexibility around timing of follow-up assessment (as it is Internet-based), obtaining a variety of contact details of significant others to help with locating participants, reinforcing to participants the importance of conducting follow-up, and financially compensating participants for the time required to complete the assessments ($10 vouchers for full completion of each assessment battery).

A final limitation is the program length. The program is considerably shorter than other interventions of this kind. However, brief interventions have been associated with significant effects for hazardous alcohol use outcomes compared to a variety of passive and active control conditions [84], especially among young populations [85]. A recent meta-analysis of 14 RCTs examined the effects of single-session personalized-feedback without therapeutic guidance on the reduction of problematic alcohol consumption in young adults [86]. The authors concluded such interventions were efficacious and cost effective and recommended the use of Internet-based approaches. This reiterated conclusions of an earlier review, which claimed that evidence supported the use of interventions that incorporated personalized feedback, either with or without practitioner support [87]. Similarly, in a systematic review of 22 RCTs of social norms-based brief interventions, Moreira et al [88] concluded that both computerized and individual face-to-face sessions appeared to reduce alcohol misuse.

Stice et al [89] reported that a four-week, group CBT-based intervention for adolescents at high-risk of depression was associated with significantly greater reductions in depressive symptoms, and a lower risk of developing depression, compared to bibliotherapy at 1- and 2-year follow-up. Scott et al [90] found primary care patients with depression who received six brief CBT sessions in combination with written educational material, recovered at significantly higher rates than those in standard care. These gains were maintained at 1-year follow-up. Similarly, a brief (4-6 sessions), solution-focused CBT treatment for depression was associated with a significantly greater reduction in symptom severity compared with standard care [91]. Brief (single session) interventions have also been found to be associated with comparable depression outcomes when compared to 10-sessions in samples with co-occurring alcohol problems [25].

Finally, in both depression and alcohol use interventions, young populations tend to be less likely to commit to the full course of sessions [92,93] and thus—especially in mild to moderate severity populations—it makes intuitive sense to adopt a brief-intervention approach.

Conclusions

Problematic alcohol use and depression are significant problems facing young people today, however, a lack of service utilization in combination with a lack of specialized treatments mean most affected young people do not receive treatment. Internet-based interventions have the potential to overcome many of the barriers to treatment in this population. This will be the first RCT, to our knowledge, of a psychological therapy in young people with co-occurring alcohol and depressive problems [27]. The proposed trial focuses on a common clinical problem that causes substantial functional, economic, and health impacts-comorbid depression and problematic alcohol use in young people. These conditions are currently undertreated, contribute significantly to the global disease burden, and are at their peak in this age range. Offering treatments of low cost and with wide reach to affected people will address current inequities of treatment access for these problems and provide a youth-appropriate modality of treatment delivery. These results will have implications for service design and health policy, and speak to important questions about the nature of treatment effects in general. In particular, the study is in line with current national and international initiatives in eHealth and addresses important questions with both clinical and scientific significance.

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Conflicts of Interest

None declared.

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Abbreviations

AQoL: assessment of quality of life
AUD: alcohol use disorders
AUDIT: Alcohol Use Disorders Identification Test
CBT: cognitive behavior therapy
CIDI: Composite International Diagnostic Interview
CONSORT: Consolidated Standards of Reporting Trials
DASS-21: Depression Anxiety Stress Scale-21
DEAL: DEpression-ALcohol Project
MSI-BPD: McLean screening instrument for borderline personality disorder
NDARC: National Drug and Alcohol Research Centre
NHMRC: National Health and Medical Research Council
OTI: Opiate Treatment Index
PHQ-9: Patient Health Questionnaire-9
RCI: reliable change indices
RCTs: randomized controlled trials
SHADE: self help for alcohol/other drug use and depression
WHO: World Health Organization

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Protocol

Nonsurgical Strategies in Patients With NET Liver Metastases: A Protocol of Four Systematic Reviews

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Abstract

Background: Patients diagnosed with neuroendocrine tumors (NETs) with hepatic metastases generally have a worse prognosis as compared with patients with nonmetastasized NETs. Due to tumor location and distant metastases, a surgical approach is often not possible and nonsurgical therapeutic strategies may apply.

Objective: The aim of these systematic reviews is to evaluate the role of nonsurgical therapy options for patients with nonresectable liver metastases of NETs.

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

Results: This study is ongoing and presents a protocol of four systematic reviews to assess the role of nonsurgical treatment options in patients with neuroendocrine liver metastases.

Conclusions: These systematic reviews, performed according to this protocol, will assess the value of noninvasive therapy options for patients with nonresectable liver metastases of NETs in combination with invasive techniques, such as percutaneous liver-directed techniques and local ablation techniques.

Trial Registration: International Prospective Register of Systematic Reviews (PROSPERO): CRD42012002657; http://www.metaxis.com/PROSPERO/full_doc.asp?RecordID=2657 (Archived by WebCite at http://www.webcitation.org/6NDlYi37O); CRD42012002658; http://www.metaxis.com/PROSPERO/full_doc.asp?RecordID=2658 (Archived by WebCite at http://www.webcitation.org/6NDlfWSuD); CRD42012002659; www.metaxis.com/PROSPERO/full_doc.asp?RecordID=2659 (Arichived by Webcite at http://www.webcitation.org/6NDlmWAFM); and CRD42012002660; http://www.metaxis.com/PROSPERO/full_doc.asp?RecordID=2660 (Archived by WebCite at http://www.webcitation.org/6NDmnylzp).

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KEYWORDS

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

Introduction

Neuroendocrine Tumors

Neuroendocrine tumors (NET) arise from neuroendocrine cells and are a heterogeneous group of neoplasms [1-3]. NETs originate from a wide range of anatomic sites, which are mainly located in the gastroenteropancreatic system (60%) and the bronchopulmonary system (>25%) [4,5]. With an incidence of 5.25 per 100,000 each year in the United States, NETs are considered to be rare tumors [4].

Patients with NET liver metastases either complain of abdominal pain due to the mass effect of the tumor or excessive hormone production leading to the carcinoid syndrome, which consists of diarrhea, cutaneous flushing, various hemodynamic alterations, and wheezing [6,7]. Moreover, up to 75% of patients with NETs (including midgut or hindgut origin) present with liver metastasis at the time of diagnosis [8].

A 5-year survival rate of 22% for patients with NET liver metastases has been described [5]. Surgical approach shows a benefit concerning overall survival as compared with the nonsurgical approach; however, curative surgery is only applicable in 10% of the patients [9]. Therefore, noninvasive alternatives, such as local ablation techniques, percutaneous liver-directed techniques (chemoembolization, bland embolization, and selective internal radiation therapy), peptide receptor radionuclide technique, chemotherapy, targeted therapy, and biotherapy are of great importance and their value has to be determined.

Local Ablative Techniques

Mechanistically, local ablative techniques such as cryotherapy, radiofrequency ablation (RFA), and percutaneous alcohol injection (PEI) rely on the cytotoxic effects of chemicals and induce nonphysiologic temperatures into the hepatic tissue [10,11]. Therefore, tumor location and extension in the liver influences the choice of treatment modality [12].

Percutaneous Liver-Directed Techniques

Treatment modalities involved in percutaneous liver-directed techniques, include bland embolization (BE), transarterial chemoembolization (TACE), and selective internal radiation therapy (SIRT). The principle of BE consists of inducing regional ischemia to the tumor. In TACE, chemotherapeutic substances are locally applied causing a cytotoxic effect. Due to the local embolization the intratumoral concentration of the cytostatic is as much as 20 times higher using TACE than in systemically applied chemotherapy [13]. In addition, systemic side effects can be minimized and cytotoxicity can be maximized [14]. SIRT uses intracorporal radiation through microspheres made of glass (Thera-Spheres) or of resins (SIR-Spheres). These microspheres are loaded with radioactive Yttrium-90 [2]. By virtue of their size, the microspheres obliterate the vessels and irradiate the tumor with a high radiation dose. The adjacent healthy tissue receives minimal dosage [2]. Unfortunately, these treatment modalities are difficult to compare due to the small number of patients and to heterogeneous inclusion criteria (eg, tumor staging, primary tumor location, etc). [15].

Peptide Receptor Radionuclide Therapy

Peptide receptor radionuclide therapy (PRRT), a combination of a somatostatin analog with a radioligand, a beta-emitter, is used to detect and treat NETs expressing somatostatin receptors. After systemic injection, the radioligand is internalized into the cells and transported to the lysosomes. The effect on tumor cell proliferation is based on the radiotoxicity of the radionuclide in the deoxyribonucleic acid of the target cell [16]. However, radionuclides should be applied cautiously since side effects, such as bone marrow toxicity, hepatic insufficiency, myelodysplastic syndrome, renal insufficiency, or hematological toxicity might occur. Secondary malignancies such as leukemia are rare, but may also occur [17-19]. Functional imaging (ie, octreoscan or gallium 68 Positron Emission Tomography [PET]) is required to identify the subgroup of patients eligible for PRRT [20,21].

Systemic Chemotherapy

The role of systemic chemotherapy for NETs with liver metastases has been discussed vigorously. In a prospective study, Moertel et al [22] evaluated streptozotocin as a chemotherapeutic monotherapy and found a significant response; however, the benefit was strongly limited by the renal and hematologic toxicity of streptozotocin, and therefore is not an acceptable treatment option. Studies combining streptozotocin with other agents have been conducted with the aim to decrease the dosage of streptozotocin, and thus reduce its toxicity [23]. For the therapy of metastatic pancreatic NETs, Kouvaraki et al [24] reported that a combined multidrug chemotherapy with fluorouracil, doxorubicin, and streptozotocin showed an acceptable response rate of 39% with responders having both increased progression-free survival and overall survival. However, patients with metastatic midgut NETs treated with this multidrug chemotherapy regimen showed the same survival rates as interferon-based therapy concepts [25]. Since poorly differentiated (G3) gastrointestinal NETs behave like lung neuroendocrine carcinomas (small-cell carcinomas) a platin-based chemotherapy is discussed [12].

Targeted Therapy

Targeted therapy includes multikinase inhibitors, mammalian target of rapamycin (mTOR) inhibitors, and monoclonal antibodies, which interact with various molecular pathways [26]. Sunitinib, an orally applied multikinase inhibitor, targets vascular endothelial growth factor (VEGF) receptors as well as platelet-derived growth factor receptors, which are often expressed in NETs [27,28]. Everolimus, an mTOR inhibitor, has also shown antitumor activity [29]. Bevacizumab, a monoclonal antibody against VEGF, inhibits angiogenesis in tumors and seems to reduce tumor perfusion [26,30].

Biotherapy

Biotherapy, using interferon-α and somatostatin analogues such as octreotide and lanreotide, prevents the synthesis of the polypeptide hormones and biogenic amines produced by functional NETs. This provides relief from endocrine symptoms associated with the carcinoid syndrome in 80% of patients [31-34]. The Placebo-Controlled, Double-Blind, Prospective, Randomized Study on the Antiproliferative Efficacy of Octreotide LAR in the Control of Tumor Growth in Patients with Metastatic Neuroendocrine Midgut Tumors reports treatment with octreotide (long-acting release) essentially delays the period to tumor progression in patients with both functionally active and inactive metastatic midgut NETs compared with the placebo-treated group. However, survival analysis could not be performed due to a small number of observed deaths [35].

The aim of these four systematic reviews is to determine evidence for the noninvasive treatment options in terms of symptom relief and tumor control in patients with nonresectable liver metastases of NETs.

Methods

Systematic Reviews

The following four systematic reviews dealing with the nonsurgical treatment options of neuroendocrine liver metastases attempt to address the following questions represented in Textbox 1.

Our research results will be reported in accordance with the standards of the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)[36].

The eligibility criteria for inclusion as well as for exclusion of studies are illustrated in Tables 1-4. Furthermore, the count and reason of exclusion will be revealed in a flow diagram, which will comply with the PRISMA Statement 2009 (Figure 1) [36]. The study types that will be included are randomized controlled trials (RCTs), prospective and retrospective comparative cohort studies, noncomparative cohort studies, case-control-studies, and case series.

These studies will provide the basis for the qualitative synthesis of this systematic review. Single-cohort studies will be collected in a separate database and will only be used for descriptive purposes. No publication date or language restrictions will apply.

Textbox 1. Questions regarding nonsurgical treatment options for neuroendocrine liver metastases.

1. When should locally ablative techniques (RFA, microwave, and cryotherapy) be used in patients with nonresectable neuroendocrine liver metastases?

- Do local ablation techniques (RFA, microwave, and cryotherapy) improve outcome (progression-free survival, overall survival, and quality of life) in patients with non–resection margin, tumor free (R0)/microscopic tumor lesions (R1) resectable NET liver metastases when compared with nonablative treatments (resection margin, macroscopic lesion [R2] liver resection, percutaneous liver-directed techniques, peptide receptor radionuclide treatment, chemotherapy, targeted therapy, and biotherapy)?
- Which local ablation technique (RFA, microwave, and cryotherapy) achieves the best outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases?
- Do local ablation techniques (RFA, microwave, and cryotherapy) in conjunction with a systemic treatment (peptide receptor radionuclide treatment, chemotherapy, targeted therapy, and biotherapy) improve outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases as opposed to a systemic treatment alone?
- What is the incidence of tumor dissemination in patients with NET liver metastases undergoing a local ablation technique? Does confirmation occur through imaging/biopsy during the follow-up?

2. When should percutaneous liver-directed techniques be used in patients with nonresectable neuroendocrine liver metastases?

- Do percutaneous liver-directed techniques (bland embolization, chemoembolization, and selective internal radiotherapy) improve outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases as opposed to R2 liver resection?
- Which percutaneous liver-directed technique (bland embolization, chemoembolization, and selective internal radiotherapy) achieves the best outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases?
- Do percutaneous liver-directed techniques (bland embolization, chemoembolization, selective internal radiotherapy) improve outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases in combination with a systemic treatment (peptide receptor radionuclide treatment, chemotherapy, targeted therapy, and biotherapy) when compared with a percutaneous liver-directed technique alone?
- What is the incidence of tumor dissemination in patients with NET liver metastases undergoing a percutaneous liver-directed technique? Does confirmation occur through imaging/biopsy during the follow-up?

3. When should peptide receptor radionuclide therapy be performed in patients with nonresectable neuroendocrine liver metastases?

- Does a peptide receptor radionuclide therapy improve outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases when compared with R2 liver resection?
- Does the outcome (progression-free survival, overall survival, and quality of life) for patients with nonresectable NET liver metastases undergoing a peptide receptor radionuclide therapy depend upon the size of liver metastases (>5- vs <5-cm diameter of the largest tumor) or their uptake on a diagnostic scan?
- Does the outcome (progression-free survival, overall survival, and quality of life) of a peptide receptor radionuclide therapy depend upon the percentage of liver volume involvement (eg, <75% vs >75%) for patients with nonresectable NET liver metastases?
- Does the outcome (progression free survival, overall survival, and quality of life) of a peptide receptor radionuclide therapy, for patients with nonresectable NET liver metastases, depend upon the site of the primary tumor?
- Does a peptide receptor radionuclide therapy in combination with percutaneous liver-directed techniques (bland embolization, chemoembolization, and selective internal radiotherapy) and/or local ablation techniques improve outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases when compared with peptide receptor radionuclide therapy as a single technique?

4. When should chemotherapy, targeted therapy, or biotherapy be used in patients with nonresectable neuroendocrine liver metastases?

- Does chemotherapy, targeted therapy and biotherapy improve outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases as opposed to R2 liver resection?
- Does outcome (progression-free survival, overall survival, and quality of life) of chemotherapy, targeted therapy, and biotherapy in patients with nonresectable NET liver metastases depend upon the size of liver metastases (>5- vs <5-cm diameter of the largest tumor)?
- Does outcome (progression-free survival, overall survival, and quality of life) of chemotherapy, targeted therapy, and biotherapy in patients with nonresectable NET liver metastases depend upon the percentage of liver volume involvement (eg, < 75% vs >75%)?
- Does outcome (progression free survival, overall survival, and quality of life) of chemotherapy, targeted therapy, and biotherapy in patients with nonresectable NET liver metastases depend upon the site of the primary tumor?
- Does chemotherapy, targeted therapy, and biotherapy in combination with percutaneous liver-directed techniques (bland embolization, chemoembolization, and selective internal radiotherapy) and/or local ablation techniques improve outcome (progression-free survival, overall survival, and quality of life) in patients with nonresectable NET liver metastases when compared with chemotherapy, targeted therapy, and biotherapy as a single technique?

Table 1. Eligibility criteria for review 1: when should locally ablative techniques be used in patients with unresectable neuroendocrine liver metastases?

Study characteristic	Inclusion criteria	Exclusion criteria
Patients population	Patients with nonresectable NLMs[a] Patients that underwent ablation or palliative resection	Children or adolescents (under the age of 18 years)
Intervention treatment	Palliative surgical resection Ablation (cryo[b], RFA[c], LITT[d], PEI[e]) Systemic treatment (chemotherapy, biotherapy, and targeted therapy)	
Intervention comparison	Surgical resection vs ablation Ablative techniques compared with others Ablation combined with systemic treatment vs ablation only	
Study design	RCTs[f] Prospective and retrospective single- or multicenter cohort studies Case series	Case reports
Reporting		Overall survival not mentioned

[a] Neuroendocrine liver metastases

[b] Cryotherapy

[c] Radiofrequency ablation

[d] Laser induced thermotherapy

[e] Percutaneous alcohol injection

[f] Randomized controlled trials

Table 2. Eligibility criteria for review 2: when should percutaneous liver-directed techniques be used in patients with nonresectable neuroendocrine liver metastases?

Study characteristic	Inclusion criteria	Exclusion criteria
Patient population	Patients with nonresectable NET liver metastases Patients treated with percutaneous liver directed techniques	Children or adolescents (under the age of 18 years)
Intervention(s)/ exposure(s)	Percutaneous liver directed techniques (bland embolization, chemoembolization, and selective Internal radiotherapy)	
Comparator(s)/ control	Palliative liver resection Percutaneous liver directed technique with or without systemic treatment	
Study design	RCTs[a] Prospective and retrospective comparative cohort studies Case-control studies Case series	Case reports
Reporting	Primary outcome: overall survival Secondary outcome: progression-free survival, quality of life	Studies that do not report the overall survival

[a] Randomized controlled trials

Table 3. Eligibility criteria for review 3: when should peptide receptor radionuclide therapy be performed in patients with nonresectable neuroendocrine liver metastases?

Study characteristic	Inclusion criteria	Exclusion criteria
Patient population	Patients with nonresectable liver metastases treated with peptide receptor radionuclide therapy	Children or adolescents (under the age of 18 years)
Intervention–treatment	Peptide receptor radionuclide therapy Percutaneous liver directed techniques (bland embolization, chemoembolization, and selective internal radiotherapy)	
Intervention–comparison	Palliative resection vs peptide receptor radionuclide therapy	
Study design	RCTs[a] Prospective and retrospective comparative cohort studies Noncomparative cohort studies Case-control studies Case series	Case reports
Reporting		Studies that do not report the overall survival

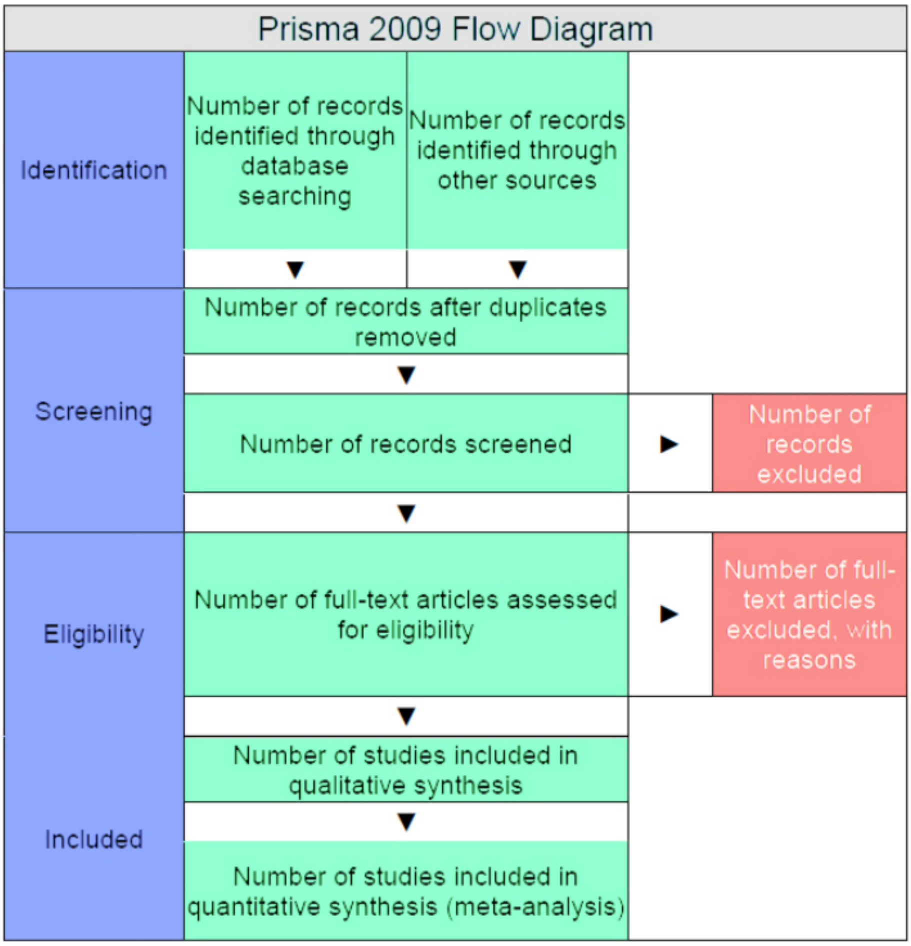
[a] Randomized controlled trials

Table 4. Eligibility criteria for review 4: when should chemotherapy, targeted therapy or biotherapy be used in patients with nonresectable neuroendocrine liver metastases?

Study characteristic	Inclusion criteria	Exclusion criteria
Patient population	Patients with nonresectable NET liver metastases Patients that underwent chemotherapy or biotherapy or targeted therapy or palliative liver resection	Children or adolescents (under the age of 18 years)
Intervention–treatment	Chemotherapy Biotherapy Targeted therapy Chemotherapy or biotherapy or targeted therapy with percutaneous liver-directed techniques (bland embolization, chemoembolization, selective internal radiotherapy) Chemotherapy or biotherapy or targeted therapy with locally ablative techniques	
Intervention–comparison	Chemotherapy or biotherapy or targeted therapy vs palliative resection Chemotherapy or biotherapy or targeted therapy with percutaneous liver-directed techniques vs single therapy Chemotherapy or biotherapy or targeted therapy with locally ablative techniques vs single therapy	
Study design	RCTs[a] Prospective and retrospective comparative cohort studies Noncomparative cohort studies Case-control studies Case series	Case reports
Reporting		Studies that do not report the overall survival

[a] Randomized controlled trials

Figure 1. Flow diagram according to PRISMA.



Search

The electronic search strategy to scan the databases and detect all relevant articles was developed by the librarians of the Medical Library Careum (University of Zurich, Switzerland). The search will be performed on the MEDLINE, EMBASE, and The Cochrane Library (Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, and Cochrane Central Register of Controlled Trials [CENTRAL]) databases. An endnote file, comprising all identified titles and, if accessible, the corresponding abstracts will be prepared for the investigators. Supplementary publications will be found by manual search or by reviewing reference lists. Two independent review group members will peruse titles and/or abstracts from studies, which were identified using the search profile. Afterwards, the entire text of these potentially eligible studies will be re-examined for eligibility. Any uncertainties will be discussed and resolved with a third member. A specially created Web-based, predetermined protocol will be used to extract data from the included studies for the study quality expertise and synthesis of medical findings.

Data Extraction

The data extraction parameters, include manuscript title, name of journal, first author's name, publication year, total number of patients, number of patients in the chemotherapy/biotherapy/targeted therapy group, number of patients in the nontreatment group, name of used substances, age (mean, standard deviation, median), male to female ratio, progression-free survival, overall survival, quality of life (containing side effects), study design, and targeting objective 1-5. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) will be used to grade the quality (level) of evidence and the strength of recommendations [37].

We will prepare a narrative synthesis of the findings from the included studies. A quantitative synthesis will be used if the included studies are sufficiently homogenous. We anticipate that there will be a limited scope for meta-analysis of a relatively large number of studies because of the range of outcomes measured across the small number of existing trials (such tumors are rare). Nevertheless, where studies have used the same type of intervention and comparator, with the same outcome measure, we will pool the results using a random-effects meta-analysis. We calculate a 95% CI and two-sided *P* values for each outcome.

Results

This study is ongoing and presents a protocol of four systematic reviews to assess the role of nonsurgical treatment options in patients with neuroendocrine liver metastases. Both noninvasive as well as invasive methods, such as percutaneous liver-directed techniques and local ablation techniques will be investigated.

Discussion

Several nonsurgical treatment options for neuroendocrine liver metastases have been reported. However, there is a lack of consensual data on the subject. These four systematic reviews described in this protocol aim to clarify the role of nonsurgical therapy modalities in patients with nonresectable NETs liver metastases. The systematic reviews will serve as a basis for developing clinical practice guidelines.

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Authors' Contributions

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

Conflicts of Interest

None declared.

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Abbreviations

BE: bland embolization
CENTRAL: Cochrane Central Register of Controlled Trials
GRADE: The Grading of Recommendations Assessment, Development and Evaluation
mTOR: mammalian target of rapamycin
NET: neuroendocrine tumors
PET: Positron Emission Tomography
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRRT: peptide receptor radionuclide therapy
R0, R1, R2: resection margin (R0: tumor free; R1: microscopic lesion; R2: macroscopic lesion)
RCT: randomized controlled trial
RFA: radio frequency ablation
SIRT: selective internal radiation therapy
TACE: transarterial chemoembolization
VEGF: vascular endothelial growth factor (receptor)

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Proposal

A Simple and Reliable Health Monitoring System For Shoulder Health: Proposal

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Abstract

Background: The current health care system is complex and inefficient. A simple and reliable health monitoring system that can help patients perform medical self-diagnosis is seldom readily available. Because the medical system is vast and complex, it has hampered or delayed patients in seeking medical advice or treatment in a timely manner, which may potentially affect the patient’s chances of recovery, especially those with severe sicknesses such as cancer, and heart disease.

Objective: The purpose of this paper is to propose a methodology in designing a simple, low cost, Internet-based health-screening platform.

Methods: This health-screening platform will enable patients to perform medical self-diagnosis over the Internet. Historical data has shown the importance of early detection to ensure patients receive proper treatment and speedy recovery.

Results: The platform is designed with special emphasis on the user interface. Standard Web-based user-interface design is adopted so the user feels ease to operate in a familiar Web environment. In addition, graphics such as charts and graphs are used generously to help users visualize and understand the result of the diagnostic. The system is developed using hypertext preprocessor (PHP) programming language. One important feature of this system platform is that it is built to be a stand-alone platform, which tends to have better user privacy security. The prototype system platform was developed by the National Cheng Kung University Ergonomic and Design Laboratory.

Conclusions: The completed prototype of this system platform was submitted to the Taiwan Medical Institute for evaluation. The evaluation of 120 participants showed that this platform system is a highly effective tool in health-screening applications, and has great potential for improving the medical care quality for the general public.

(JMIR Res Protoc 2014;3(1):e11) doi:10.2196/resprot.2584

KEYWORDS
health care service; network platform; shoulder health; scale design; PHP

Introduction

Around the world, some parts of the population live in areas distant from primary medical care facilities. Generally, these people have limited access to receiving proper preventive medical care, which often results in delayed treatment [1-4].

With the rapid advancement of telecommunication technology, some potential applications to certain medical practices, previously deemed infeasible and impractical, have recently been opened up. Further, this also allows an important channel for residents in rural areas to seek medical or diagnostic advice. For instance, with the advent of telecommunication technology, physicians are able to perform medical diagnostics, and enable medical devices (MRI, CAT scans, etc), using technologies such as video conferencing and the Internet, even though the patient is hundreds or thousands of miles away [5].

Internet-based medical technology has quickly become a critical part of modern health care systems and medicine [6-8]. Some good examples are in the fields of radiology, cardiology, dermatology, and family health [9-11].

The feasibility of using Web-based applications to perform medical diagnostics is limited [12,13]. This is due to the restricted capability and reliability of the program itself, and also the complexity and the nature of no 2 patients being identical. However, it is undeniable that Web-based medical applications can help a patient who lives in a remote location and has limited access to medical care facilities. In addition, it may also serve as a tool to alert a patient to seek care without delay.

The aim of this paper is to propose a simple, easy to implement, efficient, and reliable system for a telemedicine service as a preliminary medical diagnostic tool. The system is designed to enable the user to record the results of the diagnostic, and the results could be used by a physician in conjunction with future diagnostics. This is an application purposely built with a user-friendly, graphical interface and various services are implemented as dynamic Web pages. In addition, the application is developed with specific emphasis on patient privacy and ease of use. It is vital to create an environment in which the patient does not feel intimidated [14,15]. The system design considerations, the description of the system, and the results of the system validations are presented in the following sections.

Methods

System Design

The initial step was to conduct a comprehensive analysis of the study's scenario. Two types of users were identified to use the system: physicians in medical centers, which hosted the system platform, and patients located in remote and underserved areas that have concern for his/her health. Both users were required to have access to any active Internet connection and the ability to run popular Web browsers such as Internet Explorer and Mozilla Firefox. Since these Web browsers are supported by multiple operating systems, the users were able to access the application from any computer system with ease. In addition, the system design architecture was not limited to one unique type of medical symptom. The system design architecture was applicable to all types of medical symptoms or conditions with small updates to certain parts of the system. In this study, the medical symptoms due to neck and shoulder disorders were used as an example, and a proven Shoulder Fatigue Scale-30 Items (SFS-30) diagnostic scale [15] was used to determine the severity of patient neck and shoulder discomfort. In addition, we investigated how the SFS-30 scale was to be improved and applied, so this was not an experimental study, and it does not belong to randomized controlled trials.

System Management

We provide a hypothetical situation based on a patient who is suspected of suffering some form of neck and shoulder disorder, and is not sure the symptoms are severe enough to see a physician. This patient chose to get an initial diagnosis using a Web-based application from the medical center s/he preferred. The patient may have needed to pay a small fee to access the Web-based diagnostic application, and was required to input all the symptoms and a description of his/her concerns. Next, the data was submitted to the server for analysis and reviewed by the medical center's attending physician. The final diagnosis was then provided to the patient in electronic form. The patient accessed the Web-based system to see the diagnosis and determined if s/he was required to seek treatment.

Note that the system service platform also provided a link that the patient was able to use to communicate with the medical center's physicians. All Web-based medical diagnostic systems have certain limitations. Hence, when the final diagnosis was prepared, either comprehensive or broad, the patient was able to contact the medical center's physician swiftly to get additional information, clarification, and prevent further deterioration of the patient's medical-related conditions.

Interface Design

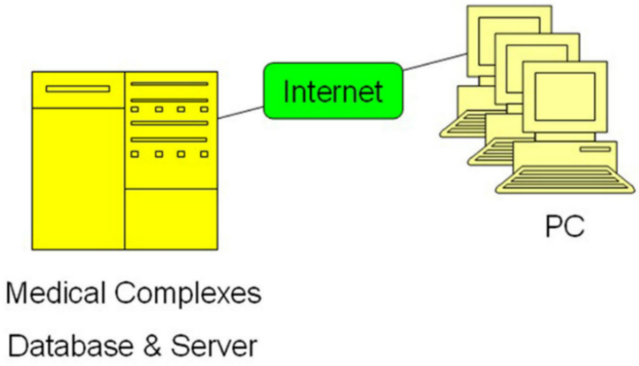
The system interface was designed with the assistance of 10 experts in the area of interface design, information system design, and prototype testing. The system's overall performance and satisfaction were acquired through questionnaires (questionnaires are available upon request). Lastly, the Heuristic Evaluation Method was used to determine the best method in diagnosing neck and shoulder pain symptoms, and also used to further refine and improve the overall system design.

Results

System Architecture

Figure 1 represents the different elements that make up the system architecture. The host center was located at the medical center's local server. This server was a database for the system platform, and designed to be accessed simultaneously by multiple personal computers. The system was accessible by all medical staff members and current registered patients of the medical center.

Figure 1. General architecture of the system.



System Service

The system performed two primary functions. The first function was to evaluate the data provided by the user. Next, the analyzed data was used to develop the final diagnosis and medical advice. In order to perform these functions, the three major components required for this system to perform its task were (1) data (inputted by the user), (2) database (storage and retrieval of data), and (3) personal computer and internet network (to complete the expert system; Figure 2).

Table 1, shows the comparison of three common types of testing platform design development. Simple platform design is selected for its low development cost, no geographical location limitation, and ability to output the final result in PDF format.

For this research, the system platform was developed using the Microsoft Windows XP operating system, and is designed for the Internet Explorer 6.0 or newer browser. The Web page is best viewed with 1024 × 768 screen resolution. The Pietty software package version 0.3.27 was used to develop the system platform. This software package was selected for its simple user interface, customizable window display, its support of multiple languages, and its advantage of direct drag and drop file upload.

The diagnosis data is reformatted using a PHP class that allows PDF files to be generated with pure PHP, also known as FPDF, and saved in a commonly used PDF format. This enables the user to store the file electronically and readily accessible. In addition, this reduces paper usage, which is beneficial for the environment. Next, a commonly used Java script was added to detect an incomplete input field. This was done to ensure all required input fields had been entered properly. To ensure the system platform could be displayed and function properly, additional PHP code was added to ensure compatibility with all types of browsers (Table 2).

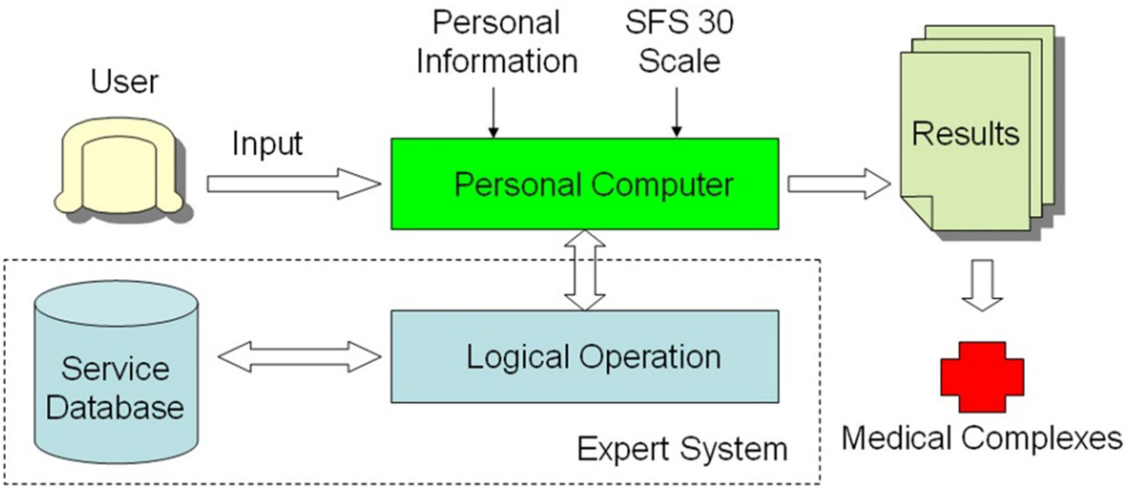
Table 1. Comparison of functional requirements in three types of testing platforms.

Functional requirements/types	Expert	Standard	Simple
Usage requirement	Physician	Onsite self-diagnostic	Web-based self-diagnostic
Target user	District hospital	Clinic	Public
Operating environment	Reside in user terminal	Reside in user terminal	Access through Internet
Programing language	JAVA	VB	PHP
Type of storage	None, printable	None, printable	PDF
Output format	Text, chart	Text, chart	Text, chart, figure
Development cost	High	Low	Low

Table 2. System development requirements of the testing platform.

Operating system	Ubuntu 4.1
Operating environment	Microsoft Windows XP Pro SP2
Browser	IE 6.0 and Newer
Development Tool	Pietty 0.3.27
Programming language	PHP/5.2.6-3, Apachie/2.2.11
Interface design	CSS
Chart design	Google Chart Tools, Flash
Data storage	MYSQL, FPDF
Testing	JavaScript
Analysis	SFS-30 questionnaire

Figure 2. System services.



System Access Management

Since this is a Web-based application, all data was transmitted through the Internet, and hence there was a potential risk of the data being intercepted or manipulated by someone other than the user. To ensure the safety and confidentiality of the database, all users were required to register and obtain permissions from the system administrator prior to accessing the system platform. For all registered users, s/he had the confidence of accessing the medical information easily and safely.

The system administrator was also responsible for establishing the database with relevant medical information and inputting from physicians. This was essential for the user to obtain complete, up-to-date, and accurate information.

Graphical User Interface

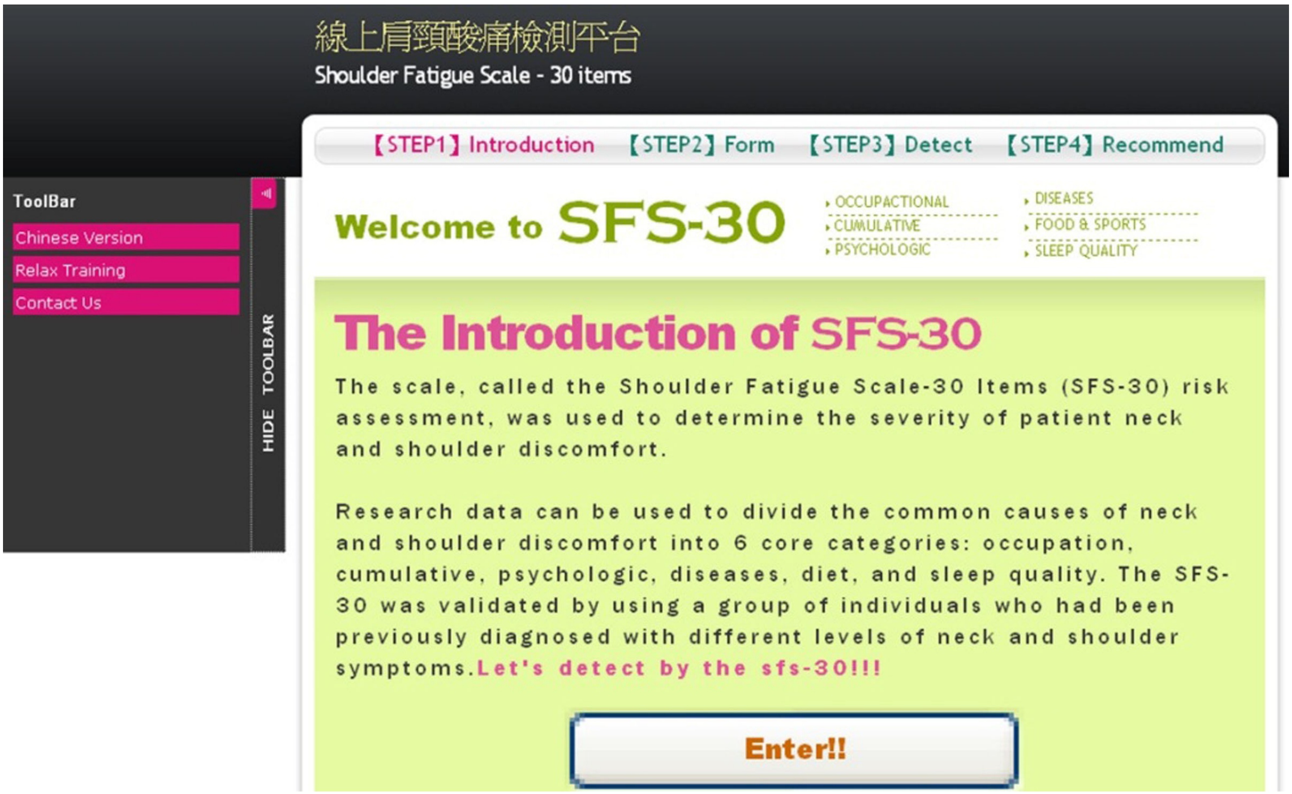
The user interface is a user-center graphical interface design. The first thing the user saw after launching the SFS-30 website is shown in Figure 3. From the main window, the steps are clearly labeled and progress is shown at the top edge of the window frame. At the left side of the window, under the tool bar there are additional buttons, which enable the user to switch Web content in languages between English and Chinese, and also medical center contact information.

In Figure 4, Step 2, the user clicked on the “Enter” button shown in “Step 1, Introduction” and proceeded to the user’s information input section.

Step 3 of Figure 5 is the input section required for the SFS-30 scale. Questions were asked regarding the user’s current body condition from level 1 to 7. The user was required to select/click the appropriate circle that best fits the user’s current physical condition.

Step 4 of Figure 6 presents the findings and recommendations. The results were presented in multiple layers to help the user understand his/her medical conditions with ease, and provided medical recommendations. All the information was presented in such a way that the user could make a decision for the next course of appropriate action to treat his/her medical conditions.

Figure 3. Main window.

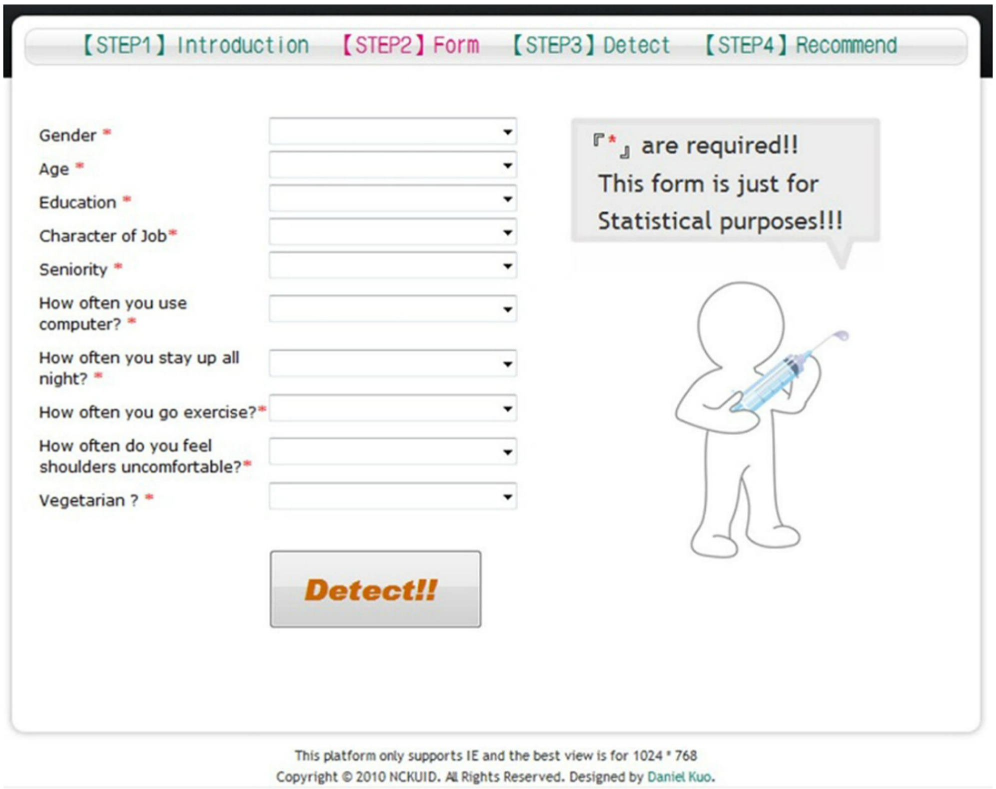


The Introduction of SFS-30

The scale, called the Shoulder Fatigue Scale-30 Items (SFS-30) risk assessment, was used to determine the severity of patient neck and shoulder discomfort.

Research data can be used to divide the common causes of neck and shoulder discomfort into 6 core categories: occupation, cumulative, psychologic, diseases, diet, and sleep quality. The SFS-30 was validated by using a group of individuals who had been previously diagnosed with different levels of neck and shoulder symptoms.Let's detect by the sfs-30!!!

Figure 4. Personal information.



Gender *	
Age *	
Education *	
Character of Job*	
Seniority *	
How often you use computer? *	
How often you stay up all night? *	
How often you go exercise?*	
How often do you feel shoulders uncomfortable?*	
Vegetarian ? *	

『*』 are required!! This form is just for Statistical purposes!!!

This platform only supports IE and the best view is for 1024 * 768
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Figure 5. SFS-30 Scale.

Occupational

01) I usually work by hand. ○○○○○●○
02) I usually sit during working. ○○○○●○○
03) I often use eyesight to work. ○○○○●○○
04) I need to concentrate my attention on working. ○○○○●○○
05) My job repeats the same movements frequently. ○○○●○○○
06) My dest is not hightly fit for me. ○○○○●○○

This platform only supports IE and the best view is for 1024*768
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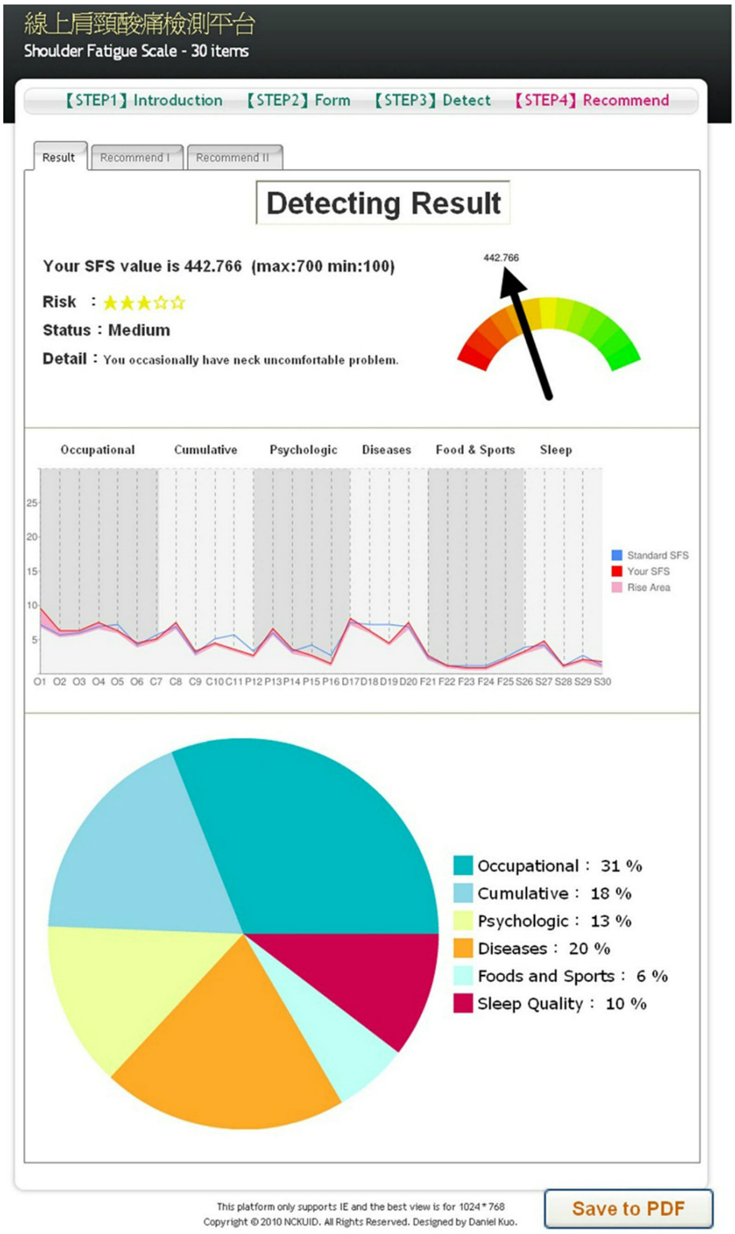
Figure 6. Results.



Detecting Result

Your SFS value is 442.766 (max:700 min:100)
Risk : ★★★☆☆
Status : Medium
Detail : You occasionally have neck uncomfortable problem.

Occupational : 31 %
Cumulative : 18 %
Psychologic : 13 %
Diseases : 20 %
Foods and Sports : 6 %
Sleep Quality : 10 %

This platform only supports IE and the best view is for 1024*768
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Validation and User Evaluation

When predicting or explaining the behavior of individuals, the “Intention model” is considered to be a complete model. The Intention model factors in attitude, beliefs, and affection, therefore predicting an individuals’ behavior. If someone wants to predict and explain whether a person will act in a specific manner, we have to understand their intentions.

Fishbein and Ajzen [16] proposed “Theory of Reasoned Action (TRA)”, which considers the antecedents of behavior is the Intention model, and impacts either or both of the “attitudes toward the behavior” and “subjective norms concerning the behavior”.

Based on the TRA and with the application of information system, Davis et al [17] proposed a model called “Technology Acceptance Model (TAM)”. This model contains two basic assumptions. The first is “perceived usefulness” (PU), where people think that using a particular system will be able to enhance performance. When the user perception level of usefulness of the system is higher, they will perceive the system more positively. The second is “perceived ease of use” (PEOU), in which people think that learning to use a particular system is easy. When users think learning the system is easy, they will also perceive the system more positively.

User evaluation and validation was conducted to evaluate the clinical trial of this system. The evaluation method used was a prototype system developed by Cheng Kung University Laboratory of Human Factors Engineering. The prototype system combined task-technology fit (TTF) and TAM models. Yen et al [18] combined and simplified the theory models of Goodhue and Thompson [19] and Dishaw and Strong [20]. Through the use of TAM and TTF to analyze the impact of the determinants of the subjects on the detection system, the system developed a more complete assessment. This prototype system was particularly suitable for this application. The validation was done using Structural Equation Modeling (SEM; LISREL version 8.51) to find the goodness of fit indices.

The evaluation and validation were conducted at Taipei Veterans General Hospital (Taiwan) in November 2010. There was a total of 120 patients who participated in this study. Among the 120 patients, there were 79 males and 41 females with an average age of 34-years old. Table 3 lists the demographic details of the patients.

The causal structure of the proposed research model was conducted using SEM. SEM is a modeling method that can handle a series or group of independent variables and the relationship between the dependent variable. In this study, LISREL 8.51 software was used to calculate the SEM fit indices. The recommended value and the numerical results of this study are listed in Table 4. From the table, most fit indices were found within the acceptable range. For instance, $\chi 2/df = 1.41$, goodness-of-fit index (GFI)=0.92, adjusted goodness-of-fit index (AGFI)=0.89, root mean square error of approximation (RMSEA)=0.026, and (expectation for a) constant factor index (CFI)=0.96 are consistent with expected values.

Table 3. Demographic information of the respondents.

Demographic information	n (n=120)	Percentage
Gender		
Male	79	65.8
Female	41	34.2
Age		
Under 20	5	4.2
21-30	53	44.2
31-40	22	18.3
41-50	24	20
51-60	13	10.8
Above 60	3	2.5
Education Level		
High school	5	4.2
College	74	61.7
Graduate school	39	32.5
Doctorate/PhD	2	1.7
Profession		
Typical white collar worker	51	42.5
Athlete	8	6.7
Service	31	25.8
Housewife	13	10.8
Porter	3	2.5
Other	14	11.7
Computer usage		
Do not use the computer	0	0
Less than 1 hour/day	13	10.8
1-4 hours/day	32	26.7
5-8 hours/day	55	45.8
More than 8 hours/day	20	16.7

Table 4. Measures of model fit for measurement model.

Measures of model fit	Recommended value	Recommended by	Research value
$\chi 2$	--	--	273.9
df	--	--	194
χ^2 / df[a]	<3	Hayduk	1.41
GFI[b]	>0.9	Scott	0.92
AGFI[c]	>0.8	Scott	0.89
CFI[d]	>0.9	Bagozzi & Yi	0.96
RMSEA[e]	<0.05	Bagozzi & Yi	0.026

[a] Chi-square value divided by the degrees of freedom

[b] Goodness-of-fit Index

[c] Adjusted Goodness-of-fit Index

[d] (Expectation for a) constant scale factor index

[e] Root mean square error of approximation

From the reliability analysis, the overall scale of the Cronbach α value was found to be 0.946 (n=120). This indicated that the result of this questionnaire (questionnaires available upon request) had good internal consistency.

Next, composite reliability (CR) was conducted to check the consistency of internal dimension. The higher the CR value, the higher the correlation between the observed variables. Hair et al [21] pointed out the confirmatory factor analysis of SEM, the reliability of each dimension must be greater than 0.7. From Table 4, all six dimensional CR values were found greater than 0.7. These CR values indicated that the dimensions of this questionnaire were in good internal consistency.

Average variance extracted (AVE) is a measure of the shared or common variance in a latent variable (LV), and the amount of variance that is captured by the LV in relation to the amount due to its measurement error. In another words, AVE is a measure of the error-free variance of a set of items. Per Fornell and Larcker [22] the recommended AVE value should be greater than 0.5. From Table 5, the AVE values for all six dimensions were found to be greater than the recommended value of 0.5. This showed that the questionnaire has a certain convergent validity.

Discriminant validity was used to calculate the degree of difference in dimensions and trait. Hair et al [21] indicated that if the square root of mean variance is greater than the correlation matrix, the various dimensions have good discriminant validity. Table 6 shows the coorelation coefficient matrix of LV.

The last stage of the validation process was to use LISREL to calculate the γ and β values. These values are used to explain the observed variables and LV, and relations between each LV. Table 7 summarizes the hypothesis, and Figure 7 demonstrates the results of the verified hypothesis.

Textbox 1 shows the results of the verification of the following hypotheses that are supported.

Textbox 1. Supported hypothesis results.

H1: User PU and BI show positive correlation.

H2: User PEOU and PU show positive correlation.

H3: User PEOU and BI show positive correlation.

H7: The TECH and user PEOU show positive correlation.

H8: The TECH and user PU show positive correlation.

H9: The TASK of improving the user’s neck and shoulder pain symptoms and the TTF show positive correlation.

H10: The TECH of improving the user’s neck and shoulder pain symptoms and the TTF show positive correlation.

Figure 7. Integrated theoretical model of TTF and TAM [15].

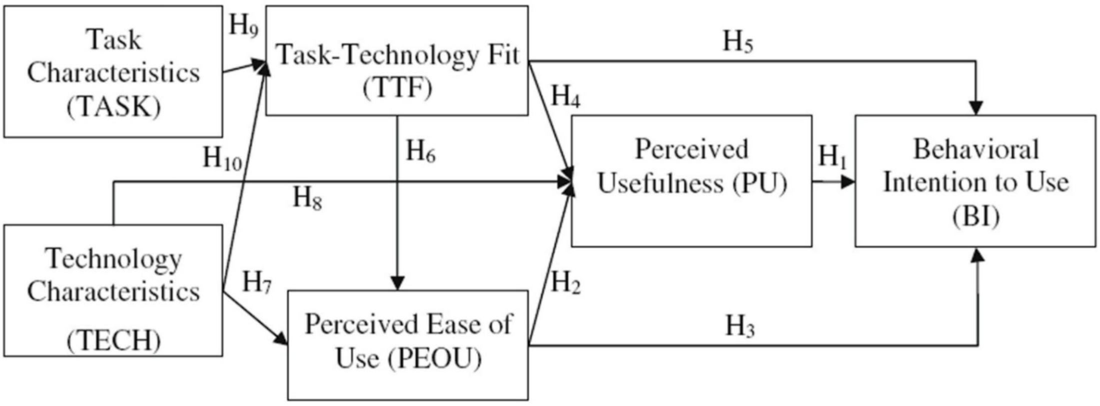


Table 5. Reliability analysis.

Latent variable	Observed variable	Factor loading	Measurement error	Composite reliability	Average variance extracted
Behavioral intention (BI)					
	BI1	0.86	0.24	0.872	0.773
	BI2	0.83	0.18		
Perceived usefulness (PU)					
	PU1	0.61	0.03	0.939	0.857
	PU2	0.57	0.15		
	PU3	0.67	0.07		
	PU4	0.72	0.18		
Perceived ease of usefulness (PEOU)					
	PEOU1	0.84	0.22	0.924	0.781
	PEOU2	0.79	0.17		
	PEOU3	0.9	0.29		
	PEOU4	0.86	0.27		
Task-technology fit (TTF)					
	TTF1	0.75	0.25	0.898	0.754
	TTF2	0.63	0.26		
	TTF3	0.72	0.19		
	TTF4	0.78	0.24		
Technology characteristics (TECH)					
	TECH1	0.65	0.16	0.927	0.840
	TECH2	0.52	0.12		
	TECH3	0.68	0.11		
	TECH4	0.56	0.07		
Task characteristics (TASK)					
	TASK1	0.87	0.24	0.879	0.646
	TASK2	0.79	0.27		
	TASK3	0.84	0.28		
	TASK4	0.85	0.75		

Table 6. The correlation coefficient matrix of the latent variable.

	BI	PU	PEOU	TTF	TASK	TECH
BI[a]	0.88					
PU[b]	0.73	0.93				
PEOU[c]	0.69	0.74	0.88			
TTF[d]	0.58	0.66	0.72	0.87		
TASK[e]	0.37	0.62	0.52	0.57	0.80	
TECH[f]	0.77	0.76	0.76	0.71	0.51	0.92

[a] Behavioral intention

[b] Perceived usefulness

[c] Perceived ease of usefulness

[d] Task-technology fit

[e] Task characteristics

[f] Technology characteristics

Table 7. Structural model results.

Hypothesis	Hypothesis (H)	β	t Statistic	Results of hypothesis testing
PU[a]→BI[b]	H1	0.52	7.46	Supported
PEOU[c]→PU	H2	0.26	3.52	Supported
PEOU→BI	H3	0.21	3.16	Supported
TTF[d]→PU	H4	0.12	1.32	Not supported
TTF→BI	H5	0.19	2.92	Not supported
TTF→PEOU	H6	0.13	1.30	Not supported
TECH[e]→PEOU	H7	0.47	4.28	Supported
TECH→PU	H8	0.35	3.33	Supported
TASK[f]→TTF	H9	0.22	3.30	Supported
TECH→TTF	H10	0.64	8.65	Supported

[a] Perceived usefulness

[b] Behavioral intention

[c] Perceived ease of usefulness

[d] Task-technology fit

[e] Technology characteristics

[f] Task characteristics

Discussion

Self-Diagnostic Tool

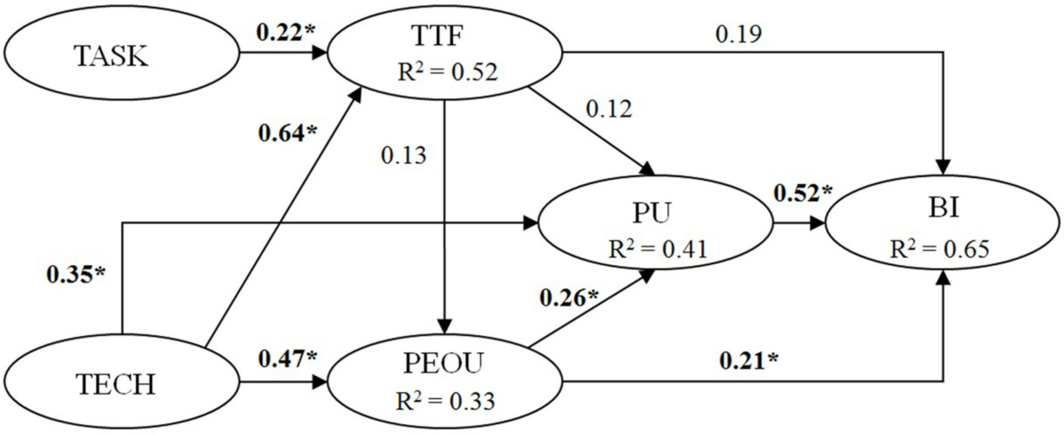
Historically, a simple medical self-diagnostic scale tends to have low accuracy and minimal reference value. This type of self-diagnostic scale is also not readily available and printed on paper. At the present time, patients have limited options in receiving a proper medical diagnosis without seeing the physician in person. Hence, the Web-based, self-diagnosis system developed in this study will be a great alternative available to the patient.

The main finding of this study was achieved in developing a self-diagnosis system architecture that is beneficial to the general public. The system was developed with the primary objective in providing a low cost, self-diagnostic tool and can be accessed through any personal computer that is connected to the Internet. Further, the tool is developed with a user-friendly interface that is simple and intuitive to use without special instructions. Another important feature of the tool is that it enables users to save a copy of the diagnosis for their personal records, and can be used as a reference for future visits with the physician.

The proposed system was tested using a hypothesis model developed by Yen et al [15]. The hypothesis model was based on TAM and TTF (Figure 8). This method was used to determine the factors that influenced the user’s decision to use the detection system. According to the result of the hypothesis testing, PU and PEOU had positive relations with BI. This shows that under the circumstances the detection system was not only easy to use, but will also boast the user's desire to continue to use the detection system. Next, TECH significantly predicted the subject's PU and PEOU. Thus, hypothesis H7 and H8 are supported. This result was not surprising due to the fact that previous studies, such as TAM, had shown that there is a significant relationship between PU and PEOU. Next, H8 indicated that the TECH is one of the external variables that significantly predict PU. This result contributes to previous research in which the effect of technology on PEOU is emphasized, but the relation between technology and PU is unnoticed [15].

On the other hand, hypotheses H4, H5, and H6 are not supported. Per TTF model definition, this is used to measure the degree to which a technology can assist an individual in carrying out his/her tasks. The findings suggested that users themselves may already know the causes of his/her neck and shoulder pain symptoms, and this is probably due to bad habits, or an undesirable working environment that he/she has limited or no control over it. Therefore, the user does not feel compelled to use the diagnostic system in treating his/her problems, even with knowing the system is simple and beneficial.

Figure 8. Structural model results (*correlation is significant at the 0.01 level).



Study Limitation

The accuracy of any diagnostic test depends on the inputs. Often, the user might not select the correct response and this could result in an inaccurate diagnosis. However, Liu's [15] research indicated that an assessment scale could serve as a health-screening tool. Hence, even if the diagnosis may not be accurate; it can still provide some sort of warning message and the state of severity of the user's current medical conditions. The physician can use the warning message from the diagnosis for a reference as well.

Conclusions

The purpose of this study was to develop a medical, self-diagnostic system for neck and back pain patients. This system is supported by the inspection database, expert systems, and a decision-support mechanism. Upon the completion of the diagnostic, the system will generate a report consisting of charts, level of severity, and recommendations in a PDF format. Note that this report contains information based on research from medical doctors; hence, the information can be used to assist patient's attending physician in developing the proper treatments.

In addition, the diagnosis identifies the potential root cause of the user's neck and back pain symptoms, and provides recommendations that the user can choose to pursue in alleviating his/her conditions perhaps due to environmental factors or poor personal habits. In doing so, the diagnosis can aid the user in preventing his/her neck and back pain symptoms from becoming a health risk.

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Conflicts of Interest

None declared.

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Abbreviations

AGFI: adjusted goodness-of-fit index
AVE: average variance extracted
BI: behavioral intention
CR: composite reliability
CFI: (expect for a) constant scale factor Index
FPDF: a PHP class that allows PDF files to be generated with pure PHP
GFI: goodness-of-fit index

LV: latent variable
PEOU: perceived ease of usefulness
PHP: hypertext preprocessor
PU: perceived usefulness
RMSEA: root mean square error of approximation
SEM: structural equation modeling
SFS-30: Shoulder Fatigue Scale-30 Item
TASK: task characteristics
TAM: Technology Acceptance Model
TECH: technology characteristics TRA: Theory of Reasoned Action TTF: task-technology fit
TRA: Theory of Reasoned Action
TTF: task-technology fit

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Proposal

Texting to Increase Physical Activity Among Teenagers (TXT Me!): Rationale, Design, and Methods Proposal

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Abstract

Background: Physical activity decreases from childhood through adulthood. Among youth, teenagers (teens) achieve the lowest levels of physical activity, and high school age youth are particularly at risk of inactivity. Effective methods are needed to increase youth physical activity in a way that can be maintained through adulthood. Because teens text a great deal, text messages promoting walking, a low cost physical activity, may be an effective method for promoting sustainable physical activity.

Objective: The objective of our study was to determine the effect of pedometers, self selected step goals, and texts grounded in the self-determination theory (SDT) on physical activity among the teens.

Methods: “TXT Me!” was a 12 week intervention that texted 14-17 year olds to increase their daily physical activity by increasing the number of steps they take each day. The intervention was grounded in the SDT. Formative research with the teens helped construct the intervention and develop the texts. A total of 84 texts were developed (12 to set a step goal, and 72 promoting autonomy, competence, and relatedness). The pilot evaluation used a four group, randomized design (n=160). After baseline data collection, the participants were randomized to one of four conditions (no treatment control, pedometer only, pedometer + weekly prompts, pedometer + weekly prompts + SDT grounded texts). Data were collected at baseline and immediately upon completion of the study. The primary outcome was physical activity, measured by 7 days of accelerometry. Basic psychological needs, physical activity motivation, process evaluation, and program satisfaction data were also collected.

Results: To our knowledge, this is one of the first studies to explore the use of stand alone, SDT grounded texts, supported by pedometers and prompts to set a self selected step goal, as a method for increasing physical activity among teens.

Conclusions: This pilot study will contribute valuable information regarding whether theoretically grounded text messages show promise as an effective method to increase physical activity among teens.

Trial Registration: Clinicaltrials.gov NCT01482234; http://clinicaltrials.gov/ct2/show/NCT01482234 (Archived by WebCite at http://www.webcitation.org/6NYvRMOoq).

(JMIR Res Protoc 2014;3(1):e14) doi:10.2196/resprot.3074

KEYWORDS

physical activity; pedometers; text messages; self-determination theory; adolescents

Introduction

Obesity and Chronic Diseases

Obesity has reached epidemic proportions both in the United States and other countries [1,2]. This is a major public health concern primarily because obesity increases the risk of developing chronic diseases [3], such as certain cancers [4,5], cardiovascular disease [6], and type 2 diabetes mellitus [7]. Obese adolescents are more likely to become obese adults [8], thus increasing current and future risk of chronic disease. Therefore, preventing obesity during adolescence would be of major public health significance.

Decreased Physical Activity in Adolescence

Physical activity (PA) has been inversely related to adiposity [9] and decreases risk for cardiovascular disease [10], type 2 diabetes [11], and certain cancers [12]. However, research demonstrates that PA steadily decreases from childhood through adolescence [13]. Between the ages of 6 and 16, PA decreased approximately 50%, with a continued decrease into adulthood [14]. Between early and late adolescence, moderate to vigorous PA decreased substantially among both boys (6.7 hours per week to 5.1 hours per week) and girls (5.9 hours per week to 3.5 hours per week) [15], suggesting that adolescence is a particularly vulnerable time for PA. Finding ways to avoid this decline would have a significant impact on adolescent PA and obesity risk.

Walking is a popular form of PA [16]. Walking is convenient, inexpensive, and can be easily incorporated into everyday life [17,18] in multiple ways (eg, leisure time PA, active transport) [19]. Increased walking is likely a sustainable form of PA that could be maintained over time [20]. Interventions that encourage simple activities such as walking could make substantial inroads into increasing sustainable PA [18]. Brisk walking is equivalent to moderate intensity PA [21-24]. Given the potential public health significance of walking [18], research is needed to identify effective methods for promoting walking in groups at risk of low levels of PA, such as adolescents.

Pedometers monitor daily steps, thus providing a convenient way to set goals, self monitor PA, and serve as a reminder to be active [25]. Pedometer use has been associated with increased PA in adults [26] and youth [27]. Having a step goal has been associated with decreased body mass index in adults [26]. Among youth, pedometers alone may not be enough to increase PA; other strategies to augment pedometers may be needed to promote sustained PA [27]. As there is a shortage of youth pedometer based studies, there is a need to identify effective methods for incorporating pedometers into interventions promoting walking and to evaluate the long term effectiveness of these interventions [27].

Texting and Teenagers

Cellphone ownership and texting are high among teenagers (teens) [28]. A recent study found that 77% of 12-17 year olds had a cell phone, and that texting is the primary way 14-17 year olds communicate with others (eg, friends, family) [28]. Teens are prolific users of SMS text messaging (short message service, SMS), with a median of 100 texts sent and received each day [28]. Since texting is a familiar, convenient, and acceptable way that teens communicate with others, texting may be an effective way to increase PA in this at risk group. A number of reviews of cell phone based studies suggest this intervention mode is promising [29-32]. Some characteristics of text message based interventions that appeared to enhance effectiveness were matching text message frequency to expected frequency of behavior (eg, daily PA), tailoring to selected characteristics (eg, personal values), and interactivity (eg, ability to communicate with research team) [31]. A limitation that was cited was that few of the randomized control trials using texts were theory based [32].

The Self-Determination Theory

Interventions that are based on psychological theories increase the likelihood of achieving behavior change [33]. The self-determination theory (SDT) [34] posits that three basic psychological needs underpin behavior: (1) competence (ie, skills, ability), (2) autonomy (ie, choice, control), and (3) relatedness (ie, connection to self and others). Need satisfaction (as related to the SDT) integrates the behavior into one’s sense of self (ie, how one defines him/herself). The higher the need satisfaction, the greater the integration with sense of self, thus increasing motivation to perform the behavior, behavioral performance, and the likelihood the behavior will be maintained over time [34]. The SDT has guided PA focused studies in both youth [35-44] and adults [45]. A systematic review of adult studies concluded the evidence supported the SDT as a framework for identifying key factors that influence and promote exercise [45]. Promising evidence is also emerging from youth studies. The SDT predicted autonomous motivation and step counts in youth [36], as well as intention to engage in leisure time PA [37]. The SDT explained changes in motivation to engage in school physical education in the transition from elementary to middle school [40]. An intervention with teens that focused on need satisfaction (ie, autonomy, competence, relatedness) enhanced cardiovascular fitness and was well received by youth [35]. Satisfaction of the basic psychological needs was also associated with autonomous motivation and PA in children [42]. Therefore, the SDT informed interventions promoting PA to youth that emphasize the basic psychological needs might be of particular utility in enhancing motivation to engage in PA, and, ultimately, PA.

Behavioral interventions should be systematically developed and tested [46] to maximize resource effectiveness and increase the likelihood of success. Ideally, interventions should be focused on behaviors that can be changed, evidence based, appropriate for the target population, and focused on realistic, achievable goals [46]. This paper describes the rationale, design, development, and methods for a systematically developed pilot intervention using pedometers, prompts to set a step goal, and SDT grounded text messages promoting walking (ie, increased daily steps) to teens.

Methods

Overview

This research included two phases: (1) formative, to develop the intervention and construct the text messages, and (2) pilot to assess the feasibility of this approach. Both of these phases are described below.

Participants

Teens for both phases of the research were recruited using the volunteer database at the Children's Nutrition Research Center. The standard recruitment methods, (eg, newsletter and website announcements, distribution of flyers in community locations likely to be visited by parents and teens) were also used. The parents provided written informed consent for their teen to participate in the study, and teens provided written assent. The teens that participated in the formative phase of the program were not eligible to participate in the pilot study.

Eligible participants were 14-17 years old, fluent in English, with Internet access, an email address, and access to a cell phone with unlimited text messaging. Exclusionary criteria included mental (eg, learning impairments) or physical (eg, blindness, deafness, inability to be physically active, medical conditions that limited PA) conditions that impaired their ability to fully participate in the program and/or complete data collection. The families that were interested in participating in the study contacted the Children's Nutrition Research Center's Recruitment Coordinator. She explained the study in detail, screened interested families, and routed eligible teens to the study coordinator.

Intervention

Focus

This program encouraged walking (eg, attaining a certain number of daily steps), a low cost PA that does not require special equipment, membership fees (eg, gym), or a high level of fitness [17,18]. It is also an activity that has the potential to be maintained over time [20].

Formative Research

There were thirty 14-17 year olds, stratified by gender (male, female) and race/ethnicity (black, Hispanic, white) that were invited to participate in two rounds of formative research. During each round of formative research, the teens completed a Web-based survey and then participated in a telephone interview with trained research coordinators to discuss the survey responses. Probes were used to clarify and understand responses and to ensure responses were interpreted as intended.

Formative research revealed that teens had positive reactions to wearing a pedometer to help them keep track of the number of steps they took each day and to receiving daily texts to help them attain a step goal. The teens thought that attaining 12,000-15,000 steps a day would be "easy." Most of them wanted the study to set a step goal for them, and they wanted to text their daily steps to the study. The most common reasons teens wanted to be physically active were related to appearance (eg, lose weight, be fit, appeal to opposite gender) and sports/athletics. Most of them reported having unlimited texting plans and having to adhere to family (eg, no profanity, violence, sexting) and school (eg, no texting during class) rules about texting. They also reported talking with parents, friends, especially close friends, and others, such as coaches and teachers about PA. All the teens believed that teens have control over whether they are physically active, although the amount of control they exert over whether they are physically active varied from some to total control. Most thought 6 a.m.-8 a.m. would be the ideal time to receive texts about PA.

The teens suggested keeping the text messages short (<160 characters); ensuring messages were positive, straightforward, and promoted realistic behaviors; and conveyed emotion through the use of emoticons [47], (eg, :D) and exclamation points (!). Other suggestions included ensuring the texts did not nag (eg, "Don't forget...you're in charge of meeting your step goal."), or sound like school (eg, "Having a problem meeting your step goal? Make a list of ways to get extra steps. You've got what it takes!"). The teens also suggested not using words like "problem solving" or "brain storming," text abbreviations (eg, "gr8" for "great"), or suggestions that were unrealistic, unclear, or too formal. In other words, the teens wanted straightforward, realistic text messages that focused on facts.

There were two types of text messages that were developed: (1) reminders to set a weekly step goal (eg, prompts), and (2) SDT grounded text messages emphasizing the basic psychological needs (ie, autonomy, competence, relatedness). The texts were vetted by the teens and a professional panel of experts in psychology, behavior change, PA, and SDT prior to use in the pilot study. Examples of modifications after the texts were reviewed by the teens are presented in Textbox 1.

Autonomy was operationalized as having choice or control over PA, while competence focused on having the skills or abilities to meet step goals and be physically active. Relatedness was operationalized as a sense of connectedness to self and important others (ie, family, friends). Connectedness to self was promoted by relating step goal attainment to personal values [48,49]. During formative assessment, the teens were shown a list of personal values that was used in a previous intervention with youth [49]. The values receiving the highest ratings were; "being healthy and fit", "being responsible", "being successful", "getting good grades", and "being a good person". The teens did not relate to messages attempting to connect meeting a daily step goal with "being a good person". Further, since "healthy" and "fit" are slightly different concepts, they were split and promoted separately. The final values used to promote a sense of connectedness to self were; "being healthy", "being fit", "being responsible", "being successful", and "getting good grades". Examples of how "relatedness to self" was operationalized are presented in Table 1.

Using the formative research described above as a guide, texts were <160 characters, straightforward, realistic, and conveyed emotion through emoticons and exclamation points, actual words, rather than text abbreviations, were used. A total of 84 texts were finalized for the pilot feasibility study, 12 prompts to set a step goal, and 72 SDT grounded texts. The SDT grounded texts were evenly divided between those promoting autonomy, competence, and relatedness. Relatedness was further divided into text messages promoting a connection with self (ie, personal values) and others (ie, friends, family). Prompts were sent once a week (Sunday), and SDT grounded texts were sent 6 times a week (Monday-Saturday).

Textbox 1. Sample messages after formative research with teens.

Modifications to a text prompt reminding teens to set a step goal-

Original-“It’s that time again. What will your daily goal be this week?”

Teen reactions-Suggested adding an emoticon, shortening, and removing “it’s that time again.”

Revision-“What will your step goal be this week? :D”

Modifications to a SDT grounded text promoting autonomy-

Original-“You are in control of your life's choices; meeting your step goal today is your choice.”

Teen reactions-Liked this text, felt empowered; liked the implied conclusion; suggested shortening it.

Revision-“Your steps, your choice, your life! You're in charge!”

Modifications to a SDT grounded text promoting competence-

Original-“You are capable of using strategies like problem solving and self monitoring, to help you meet your step goal.”

Teen reactions-Wordy; sounds like school; unconversational.

Revision-“You are capable of using strategies to reach your step goal! Success is yours!”

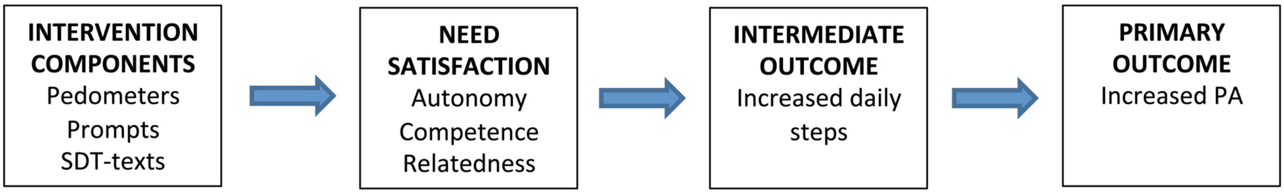
Table 1. Texts connecting personal values to meeting step goal.

Personal value	Text message
Being healthy	“Meeting your step goal shows being healthy is important to you.”
Being fit	“’Step’ towards fitness. Meet your step goal today!!”
Being responsible	“Meeting your step goal shows you take responsibility for your health.”
Being successful	“Experience success! Meet your step goal today. :D”
Getting good grades	“Meeting your step goal shows you know how to achieve your goals, like getting good grades.”

Conceptual Model

Figure 1 shows a conceptual model of the intervention. The intervention components include pedometers (to self monitor, promotes competence), prompts (to set a self selected step goal, promotes autonomy), and SDT informed text messages emphasizing the basic psychological needs within the context of daily steps (promotes autonomy, competence, relatedness). Emphasizing the basic psychological needs in the context of taking more daily steps enhances motivation to take more daily steps, which leads to increased daily steps, and ultimately, increased PA. The pilot study tests the feasibility of this approach.

Figure 1. Conceptual model guiding the intervention. Self-determination theory (SDT); physical activity (PA).



Pilot Study Design

A four group design was employed: (1) no treatment control, (2) pedometer only, (3) pedometer + weekly texts to set a step goal (ie, prompts), and (4) pedometer + weekly texts to set a step goal + SDT focused text messages. This design is expected to provide insight into the additive effects of intervention components (pedometers, prompts, SDT focused text messages). Data were collected at baseline and upon completion of the 12 week intervention (post 1 data collection). The primary outcome was objectively measured PA. Randomization occurred after baseline data collection using a random numbers table. After obtaining written informed consent/assent, the participants began baseline data collection. Institutional review board approval was obtained from Baylor College of Medicine (H-27537). The study was registered with Clinicaltrials.gov prior to initiation (NCT01482234).

Procedures

Intervention

Although the formative assessment with the teens indicated their desire to have the study set a daily step goal for them, the teens were not assigned a daily step goal by the study. Goals set by others are inconsistent with the SDT and the development of higher levels of PA motivation (ie, autonomous motivation) [34]; autonomous motivation is more likely to lead to sustained PA (ie, increased daily steps) [45]. Rather, each teen's average daily step count was extracted from baseline activity monitor data. When they were notified of their group assignment and sent a pedometer, all the teens except those randomized to the control group were told that experts recommend teens attain a daily step count of 12,000 to 15,000 [50]. They were then given their average daily step count and told that increases should be gradual. This was deemed to be general knowledge instead of a goal, since it did not adhere to the characteristics of a goal (ie, specific, moderately difficult, temporal) [51], much like the recommendation to attain 60 or more minutes of PA a day [52]. The teens in the control group received their average daily baseline step count, a pedometer, and the recommended guideline at the end of the study.

A browser based administrative software application was developed to manage participants, send texts, and view messages received from participants. The management application enabled the research team to enter participants into their assigned group after randomization. A database of the text messages (ie, prompts and theory based messages) was created and an algorithm was developed to connect message type with group. Each morning at 8 a.m., the algorithm driven application was automatically executed to query the database by group, and identify whether texts were to be sent to each group that day, and if so, which texts to send. The application then communicated with an SMS gateway provider (Clickatel), via their Web-based application programming interface to automatically send the messages. Prompts were sent each Sunday, and SDT focused texts were sent Monday-Saturday.

An additional feature in the administrative application enabled preformatted messages to be manually texted to participants by the research team through the SMS gateway. Examples of preformatted messages included texts to let the teens know that it was time for data collection and/or that the activity monitor had been sent to them by prepaid courier service. These messages were texted to all participants on an as needed basis by the research staff, regardless of group assignment.

The teens could also send texts to the research team through the SMS gateway. Research staff could manually respond to texts received by the teens during the data collection or intervention period through the SMS gateway. Although the teens were not asked to text their step goal or step attainment to the research team because of its inconsistency with the SDT, some chose to text this information to the team anyway. Examples of other types of texts received from the teens included questions, texts to let the research team know they had received a package, or other types of general communication with the research team.

The administrative management application and the SMS gateway were hosted on secure servers and accessed via a Secure Socket Layer connection. An automatic log was maintained to track all activity of the application, which included both manual and automated messages sent by the research team, message delivery (both automated and manual), messages received from the study participants, and any technical issues encountered during message delivery (automated, manual).

Data Collection

Objectively measured PA was assessed with 7 days of accelerometry (Actigraph, Limited Liability Corporation; Model GT3X+). Self reported data included the Basic Psychological Need Satisfaction Questionnaire [53], PA motivation (intrinsic, extrinsic) as measured by the expanded Behavioral Regulation in Exercise Questionnaire [54], social desirability of response [55,56], program satisfaction (post 1 only), and standard demographics (baseline only), these data were collected using a secure, password protected website. Process data were collected using the framework of Baranowski and Jago [57]. The areas emphasized included recruitment, retention, and program delivery; process data were recorded in an Access database maintained by study staff. A log of technical issues was also maintained, as was a record of texts sent to and received from participants.

Beta Testing

Extensive internal beta testing was conducted with the research staff and programmers prior to the feasibility study. A one month test of the procedures and text messages with participants who participated in the formative research was also conducted and served as a final beta test of intervention, messages, and procedures prior to the feasibility study. No technical or procedural issues were identified during the one month beta test.

Results

Pilot Study

A 12 week pilot study was initiated in August 2012 and completed in August 2013. There were one hundred and sixty 14-17 year olds that were enrolled (40/group) using the volunteer database (ie, families interested in participating in research studies) at the Children's Nutrition Research Center and also using standard recruitment procedures (posting of flyers, posting of study details on recruitment websites and/or electronic newsletters). The teens were randomized after completing a baseline data collection. The baseline characteristics indicated that 51.9% (83/160) were female, and 60.6% (97/160) were at the lower end of the age range (ie, less than 16 years old). The sample was ethnically diverse (35.6%, 57/160 black; 31.3%, 50/160 white; 26.9%, 43/160 Hispanic; and 6.3%, 10/160 mixed/other), respectively. The teens wore an activity monitor for 7 days to obtain an objective measure of PA; they also completed Web-based self report questionnaires. Baseline psychometric values of the measurement scales (Cronbach alpha) were within acceptable ranges [58] (Psychological Need Satisfaction in Exercise, .87; expanded Behavioral Regulation in Exercise Questionnaire, .84). Data are currently being analyzed to determine feasibility of this approach to promote PA to teens.

Expected Outcomes

Although the pilot study was not powered to detect statistically significant differences, the group receiving pedometers + weekly prompts + SDT text messages is expected to have the greatest increase in moderate to vigorous PA and average daily steps. They are also expected to have the greatest increases in basic psychological needs, and the greatest movement towards higher levels of PA motivation. The group receiving pedometers + weekly prompts is expected to have the next greatest increase in moderate to vigorous PA, steps, psychological needs, and PA motivation, followed by the group receiving pedometers only. The control group is expected to exhibit no change in moderate to vigorous PA, steps, basic psychological needs, or PA motivation. It is also expected that recruitment goals will be met, attrition will be low, and that we will be able to collect complete data (Web-based self report, 7 days of accelerometry) in at least 75.0% (120/160) of study participants at post 1, regardless of group assignment. It is also anticipated that few technical issues will limit distribution of SMS text messaging; that program satisfaction will be high among participants, particularly in the group that received daily messages; and that the internal consistency of self report measures will be acceptable (>.70).

Discussion

Teenagers and Physical Activity

Teens are at risk of low levels of PA [15]. This is a major public health concern because low levels of PA, particularly during adolescence, have been shown to track into adulthood [14], thus increasing the risk of obesity [9] and multiple chronic diseases [10-12]. Effective interventions are needed to increase PA among this at risk group. Because walking is an activity that can be relatively easily incorporated into one’s other daily activities [17,18], interventions encouraging teens to take more steps throughout the day may be an effective way to enhance sustainable PA in this at risk group.

An Intervention for Teenagers

The intervention described here provides teens with a pedometer to self monitor their daily steps, encourages them to set a self endorsed daily step goal through once a week texts, and sends daily texts emphasizing the basic psychological needs. It extends the literature in several important ways. First, it systematically varies the intervention components (none, pedometers only, pedometers + prompts, pedometers + prompts + SDT informed texts), which will provide information on whether adding prompts or SDT informed text messages increase daily steps and PA over pedometers alone. Second, it will add to the body of literature on whether SDT informed interventions are an effective way to promote PA among teens. Text messages promoting obesity prevention behaviors have been shown to be acceptable and feasible with obese teens; however, their effect on behavior was not assessed, and they were developed as an adjunct to a weight management program rather than as a stand alone intervention [59]. The current research extends this by examining intervention effects on daily steps; specifically, it examines whether an SDT informed text message based intervention focusing on the basic psychological needs is feasible, acceptable, and influences average daily steps, motivation, and PA in teens. Third, it adds further support to the importance of conducting formative research with teens to help ensure the intervention meets their expectations [60]. Ultimately, this could enhance intervention effectiveness by designing interventions that are developmentally appropriate and relevant to the target audience, an important lesson learned for researchers conducting research with teens. Fourth, it extends the evidence regarding the relationship between pedometers and PA in teens [27]. And finally, it extends the literature on texting as a stand alone intervention modality versus as a supporting component. Although reviews provide suggestive evidence that text messages may be an effective way to promote health enhancing behaviors [29-32], few have examined it as a stand alone intervention method. A text message based intervention to increase PA in teens showed promising results; however, PA was self reported, and the intervention only lasted two weeks [61]. The current study will extend this research by using a stronger measure of PA (objectively measured), and sending text messages for 12 weeks.

Conclusions

Teens are heavy users of texting [62]. Therefore, a text based intervention encouraging teens to take more steps during the day may be an effective way to encourage them to be more physically active in a manner that has the potential to be sustained throughout life [20]. This is an important area of research; a text message based intervention would be easy to disseminate at a relatively low cost, using a familiar and convenient technology. Thus, this research ultimately has the potential for public health significance by increasing PA in an at risk group in a familiar, convenient, and relatively low cost manner.

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Authors' Contributions

DT was principal investigator and oversaw all aspects of the project; DC oversaw recruitment, data collection, intervention delivery, and assisted with message and intervention development; RBhatt managed the project during message and intervention development; TB was a coinvestigator and provided guidance on message design; TB, WR, RJ, and BA comprised the expert panel and provided assistance with text message design; YL is the study biostatistician; JM provided medical oversight during recruitment; RT architectured the message database schema, and built the administrative management application; RBuday oversaw and guided the work of RT and assisted with development of the overall structure and function of the message database and administrative application.

Conflicts of Interest

None declared.

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Abbreviations

PA: physical activity
SDT: self-determination theory
SMS: short message service
teens: teenagers
USDA/ARS: United States Department of Agriculture, Agricultural Research Service

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Original Paper

Use and Appreciation of a Web-Based, Tailored Intervention (E-health4Uth) Combined With Counseling to Promote Adolescents' Health in Preventive Youth Health Care: Survey and Log-File Analysis

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Abstract

Background: Health promotion for adolescents is important in the prevention of mental health problems and health-risk behaviors. We implemented two interventions in a preventive youth health care setting. Adolescents in the E-health4Uth group received Web-based, tailored messages on their health behavior and well-being. Adolescents in the E-health4Uth and counseling group received the same tailored messages, but were subsequently referred to a school nurse for a consultation if they were at risk of mental health problems.

Objective: This study evaluated the use and appreciation of these Web-based, tailored messages and additional consultation with a school nurse. Differences in use and appreciation according to demographics (ie, gender, level of education, and ethnicity) of the adolescents were also assessed.

Methods: Two youth health care organizations participated in this study and conducted the interventions in 12 secondary schools. In total, 1702 adolescents participated; 533 in the E-health4Uth group, 554 in the E-health4Uth and counseling group, and 615 in the control group (ie, care as usual). Adolescents completed an evaluation questionnaire assessing the use and appreciation of the tailored messages immediately after receiving these messages and at a 4-month follow-up. After the consultation, adolescents and nurses completed an evaluation questionnaire on the use and appreciation of the consultation.

Results: The majority of the adolescents (845/1034, 81.72%) indicated they had read the tailored messages. Most items on the use and appreciation of the tailored messages and the program were scored positive (overall satisfaction on a scale from 1, most-negative, to 10, most-positive: mean 6.70, SD 1.60). In general, adolescents in vocational training, girls, and adolescents of non-Dutch ethnicity, indicated they used the tailored messages more often and appreciated the content of the messages better than adolescents receiving preuniversity education, boys, and adolescents of Dutch ethnicity, respectively (all $P<.05$). In the E-health4Uth and counseling group, 18.6% (103/553) of the adolescents were referred to a nurse. Adolescents in vocational training and girls were more often referred to a nurse than adolescents receiving preuniversity education ($P=.007$) and boys ($P=.03$), respectively. Adolescents and nurses positively evaluated the consultation (overall satisfaction of adolescents: mean 8.07, SD 1.21). Adolescents in vocational training attended the consultation more often ($P=.047$) and considered the consultation a more valuable addition to the tailored messages than adolescents receiving preuniversity education ($P=.034$).

Conclusions: The Web-based, tailored messages and additional consultation were used and appreciated positively by adolescents and nurses. The consultation seems a valuable addition to the tailored messages. However, the tailored messages might need further improvement since adolescents did not rate all evaluation items about these messages explicitly positive. As these interventions were already interweaved with the existing practice of the preventive youth health care, they are especially promising for future implementation.

Trial Registration: Netherlands Trial Register Number (NTR): NTR3596; http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=3596 (Archived by WebCite at http://www.webcitation.org/6LryL42zH).

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KEYWORDS

adolescents; youth health care; Web-based tailoring; eHealth; Internet; counseling; health care evaluation; health promotion

Introduction

Mental health problems often have their first manifestation during adolescence [1], and many health-risk behaviors, such as excessive alcohol consumption, cigarette smoking, drug use, and unsafe sex, are acquired during adolescence [2]. These mental health problems and health-risk behaviors often persist into adulthood, thereby affecting not only current health but also health later in life [3-8]. Therefore, adolescents are an important target group for health promotion.

Promoting good health and a healthy lifestyle is a task of the preventive youth health care [9]. The aim of preventive youth health care is to improve and protect the health, growth, and development of young people. In the Netherlands, all children and adolescents are invited for preventive periodic health examinations at set ages until the age of 13 years [10]. From the age of 5 years, these examinations often take place at school. The examinations focus on growth, development, health functioning, and behavior of infants, children, and adolescents. Given the rapid maturation in adolescence and the mental health problems and health-risk behaviors associated with this developmental period, it is desirable to implement an additional preventive health examination between ages 15 and 16 years [11,12].

Furthermore, with an increasing demand for adolescent health promotion by the government and preventive youth health care in the Netherlands [11,12], and the current financial strain on preventive health care, greater efficiency is required. Providing health information through the Internet (eHealth) can be beneficial for achieving this. For example, the Internet is very efficient for data sampling and offers the opportunity to give immediate computerized, tailored messages on health and health behavior [13,14]. Web-based, tailored messages eliminate (as far as possible) information that is not personally relevant [13,15-17] and are therefore more likely to be effective in changing behavior compared with nontailored messages [15]. Various studies have shown that Web-based tailoring is a promising technique to promote health behaviors of adolescents [18-23]. Additionally, it provides the opportunity to enhance the efficiency of face-to-face counseling by collecting information on adolescents' health prior to the consultation, which could support the nurse during the consultation [24-28].

However, currently eHealth is not broadly applied in preventive youth health care, even though earlier research indicates that Web-based, tailored interventions can be combined with current daily practice of the preventive youth health care [28-30]. Therefore, we implemented two interventions in preventive youth health care using Web-based, tailored messages (E-health4Uth and E-health4Uth and counseling) [31]. These Web-based, tailored messages focused on topics related to health risk behaviors (eg, alcohol consumption, smoking) and well-being (eg, mental health status, suicidal thoughts). Both interventions used the same messages, which were developed for adolescents (aged 12-18 years) in an earlier study [32,33]. In the E-health4Uth and counseling group, adolescents who were at risk of mental health problems were also referred to a school nurse for a consultation. With adolescents' knowledge, the nurses received information regarding adolescents' health and health behaviors from the E-health4Uth tool, to facilitate communication during the consultation [28].

Evaluating use and appreciation of Web-based, tailored interventions and the consultation is important to guide improvement of interventions to increase intervention's effectiveness [34]. Successful use and appreciation of an intervention are prerequisites for active information processing, which is necessary for achieving behavioral change [35,36]. Because demographic variables (gender, level of education, and ethnicity) have shown to influence the use of eHealth tools in general [37,38], research on the use and appreciation among specific demographic subgroups can provide insight into the usability of Web-based tailoring among such specific groups.

Taken together, the aim of this study was to evaluate the use and appreciation of the Web-based, tailored messages, and the use and appreciation of the subsequent consultation applied by the preventive youth health care in schools. Differences in use and appreciation according to demographics of the adolescents (by gender, level of education, and ethnicity) are explored.

Methods

Study Design

The study design is a three-armed cluster randomized controlled trial (RCT), with two intervention groups (E-health4Uth and E-health4Uth and counseling) and a control group (ie, care as usual). The interventions were applied by preventive youth health care in secondary schools. School classes were the unit of randomization, because randomization at the individual level (ie, the level of the adolescents) may lead to contamination of the control group [39]. For allocation of the school classes (clusters) to one of the study arms, a computer-generated list of random numbers was used. Randomization sequence was stratified with a 1:1:1 allocation using random block sizes of three. The computer-generated random number list was prepared by an investigator with no involvement in the trial. The random number list was applied by the researchers in the order schools committed to participate. This paper reports on the use and appreciation of the Web-based, tailored messages and counseling conducted in 2012 and 2013. Further details about the study design and the interventions are described in a design paper published elsewhere [31]. The Medical Ethical Committee of Erasmus Medical Center has declared that the Medical Research Involving Human Subjects Act (also known by its Dutch abbreviation WMO) does not apply to this research proposal. The Medical Ethical Committee had no objection against the execution of this research proposal (MEC-2012 - 337).

Sample and Setting

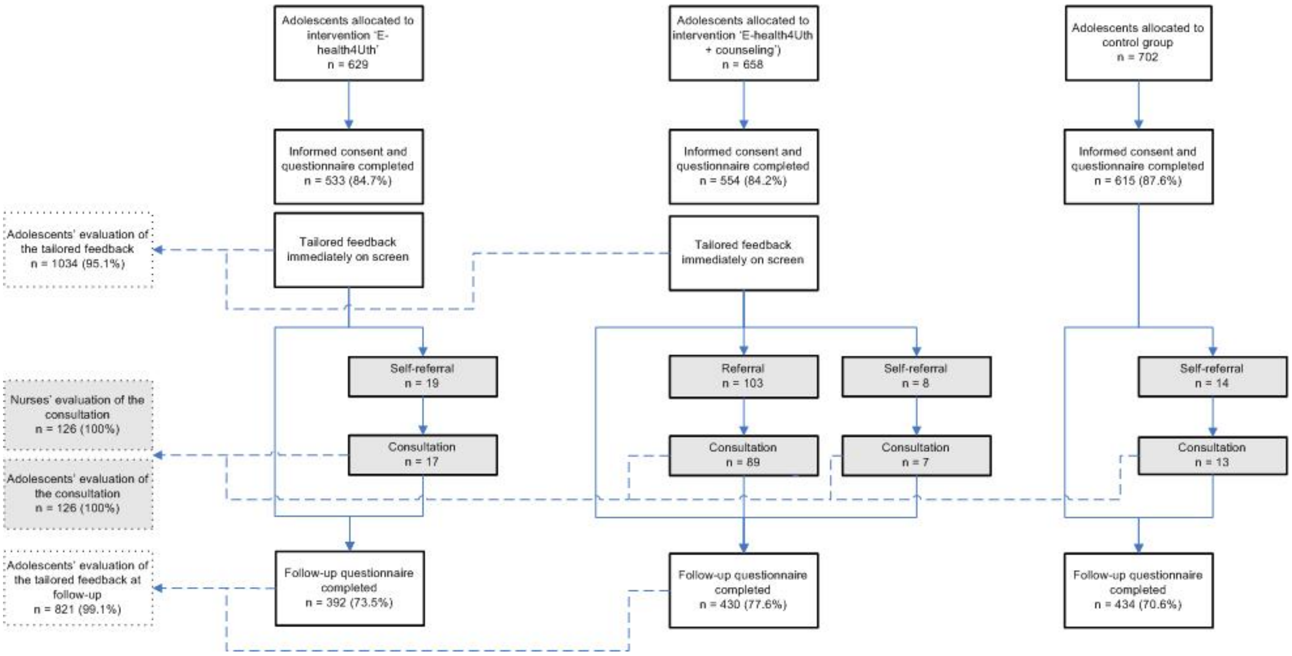
Two youth health care organizations in the Dutch cities of Dordrecht and Zwijndrecht participated in this study and conducted the interventions in secondary schools. The youth health care organizations invited all 14 secondary schools in these cities to participate, of which 12 agreed with a total of 11 classes with third-grade students (2 schools) and 75 classes with fourth-grade students (10 schools). In the Netherlands, adolescents in the third- and fourth-grades of secondary school are on average 15-16 years of age. In secondary schools, distinction is made in the level of education adolescents are following. Lower levels of education are called “vocational training” and higher levels of education are called “preuniversity education”. Adolescents following vocational training and adolescents following preuniversity education both participated in this study.

A few weeks prior to the start of the study, all adolescents and parents received information about the study. If parents did not want their child to participate, they could object to participation of their child. Adolescents were asked to provide written consent before they completed the baseline questionnaire. Of the 1989 eligible adolescents, 1702 (85.57%) adolescents participated; 533 in the E-health4Uth group, 554 in the E-health4Uth and counseling group, and 615 in the control group (Figure 1). The main registered reason for not participating was absence, mainly due to illness. Furthermore, 29 parents objected to their child’s participation, whereas 24 adolescents refused to participate. Of the 1087 adolescents who received the tailored messages (533 in the E-health4Uth group and 554 in the E-health4Uth and counseling group), 1034 (95.12%) completed the evaluation questionnaire at baseline.

At the 4-month follow-up, 3 schools did not succeed in scheduling the follow-up classroom assessments for all or several classes (missing data from 14 classes). At the remaining schools, 135 adolescents were absent at the follow-up. In total, 1256 adolescents participated at the 4-month follow-up (73.80%); 392 in the E-health4Uth group, 430 in the E-health4Uth and counseling group, and 434 in the control group. Of the 822 adolescents who participated at follow-up and received the tailored messages at baseline, 821 (99.9%) completed the evaluation questionnaire at follow-up.

All adolescents who attended the consultation with the nurse (n=126) completed the consultation evaluation questionnaire. Nurses also completed an evaluation questionnaire for every consultation (100%), but did not complete all questions.

Figure 1. Flow chart of the adolescent's participation.



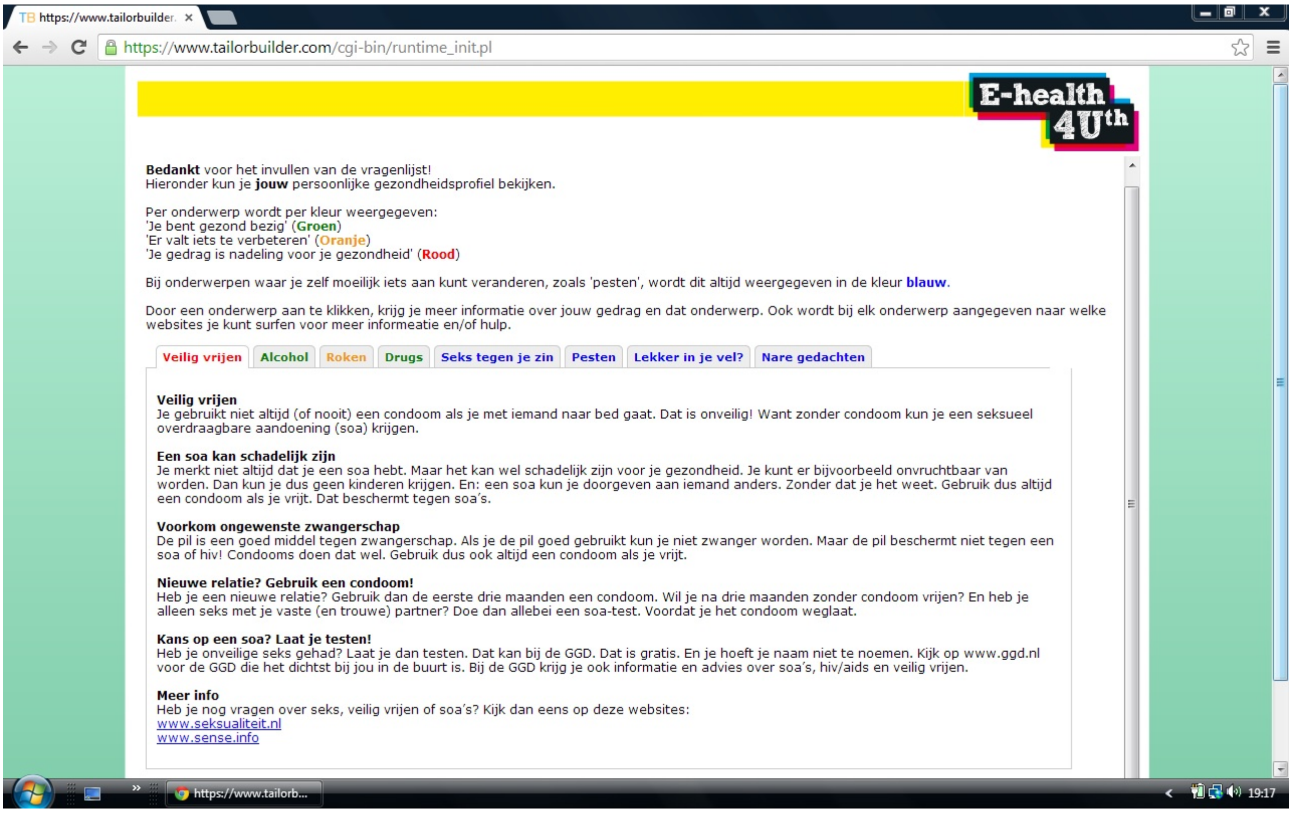
The E-health4Uth Intervention

During one classroom session (+/- 45 minutes), adolescents completed a self-report questionnaire via the Internet to assess health-risk behavior and well-being on the following topics: alcohol consumption, drug use, smoking, sexual behavior, bullying, mental health status, suicidal thoughts, suicide attempts, and unpleasant sexual experiences (Multimedia

Appendix 1). This questionnaire served as the basis to tailor the messages, but also as a baseline measure for the effect evaluation. For each topic, a score was computed that was compared with the Dutch health norms for adolescents [32,40]. Based on this score, a message was immediately presented on the screen, which reflected the person’s current behavior or well-being in relation to the Dutch health norm, and offered advice to change unhealthy behavior and/or to talk to a person the adolescent trusts (Figure 2). The messages were displayed in red, orange, or green, indicating unhealthy behavior, behavior just below the norm, or behavior according to the Dutch health norm, respectively. The topics on well-being were always displayed in blue. By providing links to relevant websites, adolescents were encouraged to read more information on the topics. These Web-based, tailored messages were specifically developed for adolescents (aged 12-18 years) in a previous study [32].

At the end of the program, adolescents were invited to follow the Facebook page of “E-health4Uth” to find additional information on the topics. Additionally, adolescents could check a box for a self-referral to the nurse or could send an email to the nurse. After 1 month, adolescents received a reminder of the tailored messages by email.

Figure 2. Screenshot of the computer-tailored messages. This is an example of a message (most left tab) that is presented to adolescents who have answered that they have had unsafe sex. The message is therefore displayed in red, indicating unhealthy behavior. By providing links to relevant websites, adolescents are encouraged to search for more information on the topic. The messages on the other topics are presented when clicking on the other (colored) tabs.



Bedankt voor het invullen van de vragenlijst!
Hieronder kun je **jouw** persoonlijke gezondheidsprofiel bekijken.

Per onderwerp wordt per kleur weergegeven:
'Je bent gezond bezig' (**Groen**)
'Er valt iets te verbeteren' (**Oranje**)
'Je gedrag is nadeling voor je gezondheid' (**Rood**)

Bij onderwerpen waar je zelf moeilijk iets aan kunt veranderen, zoals 'pesten', wordt dit altijd weergegeven in de kleur **blauw**.

Door een onderwerp aan te klikken, krijg je meer informatie over jouw gedrag en dat onderwerp. Ook wordt bij elk onderwerp aangegeven naar welke websites je kunt surfen voor meer informeatie en/of hulp.

Veilig vrijen
Je gebruikt niet altijd (of nooit) een condoom als je met iemand naar bed gaat. Dat is onveilig! Want zonder condoom kun je een seksueel overdraagbare aandoening (soa) krijgen.

Een soa kan schadelijk zijn
Je merkt niet altijd dat je een soa hebt. Maar het kan wel schadelijk zijn voor je gezondheid. Je kunt er bijvoorbeeld onvruchtbaar van worden. Dan kun je dus geen kinderen krijgen. En: een soa kun je doorgeven aan iemand anders. Zonder dat je het weet. Gebruik dus altijd een condoom als je vrijt. Dat beschermt tegen soa’s.

Voorkom ongewenste zwangerschap
De pil is een goed middel tegen zwangerschap. Als je de pil goed gebruikt kun je niet zwanger worden. Maar de pil beschermt niet tegen een soa of hiv! Condooms doen dat wel. Gebruik dus ook altijd een condoom als je vrijt.

Nieuwe relatie? Gebruik een condoom!
Heb je een nieuwe relatie? Gebruik dan de eerste drie maanden een condoom. Wil je na drie maanden zonder condoom vrijen? En heb je alleen seks met je vaste (en trouwe) partner? Doe dan allebei een soa-test. Voordat je het condoom weglaat.

Kans op een soa? Laat je testen!
Heb je onveilige seks gehad? Laat je dan testen. Dat kan bij de GGD. Dat is gratis. En je hoeft je naam niet te noemen. Kijk op www.ggd.nl voor de GGD die het dichtst bij jou in de buurt is. Bij de GGD krijg je ook informatie en advies over soa’s, hiv/aids en veilig vrijen.

Meer info
Heb je nog vragen over seks, veilig vrijen of soa’s? Kijk dan eens op deze websites:
www.seksualiteit.nl
www.sense.info

The E-health4Uth and Counseling Intervention

During a classroom session, adolescents in the E-health4Uth and counseling group completed the questionnaire assessing health-risk behaviors and well-being. This was the same questionnaire as the one that was applied in the E-health4Uth-only group. They also received the tailored messages, and were invited to follow the Facebook page (see “The E-health4Uth intervention”). Adolescents could also check a box for a self-referral to the nurse or could send an email to the nurse.

Additionally, in this group adolescents at risk of mental health problems were invited for a consultation with the nurse. Adolescents were classified as at risk of mental health problems when: their score on the total problem scale of the Strengths and Difficulties Questionnaire (SDQ) was higher than 16, and/or their score on the SDQ emotional problems was higher than 5, and/or they reported having suicidal thoughts occasionally, more frequently, or did not want to answer this question, and/or they reported a suicide attempt last year or did not want to answer this question [31]. The consultation took place at school. The nurses received the results of the assessment for each referred adolescent prior to the consultation. During the consultation the nurses focused on specific risk areas and referred adolescents to other professionals if considered necessary.

Control Group

Adolescents in the control group completed the same questionnaire assessing health-risk behaviors and well-being as adolescents in the intervention groups. The control group received care as usual (ie, adolescents could check a box for a self-referral with the nurse or could send an email to the nurse with any question or request for information or care). Due to the aim of this paper, this paper only uses this control group to assess the use and appreciation of the self-referred consultations (n=14).

Measures

Evaluation of the Web-Based, Tailored Messages

Immediately after receiving the tailored messages and after 4 months, the adolescents were invited to complete an online evaluation questionnaire on the appreciation and use of the tailored messages. Effect outcome measures were also included, but these measures are described elsewhere [31], as they were not included in this study.

The use of the tailored messages was assessed with seven items. Immediately after adolescents received the tailored messages two items assessed the use of the messages: (1) reading the tailored messages (having read the messages completely/partly, or not at all), and (2) viewing websites to which reference was made (yes or no/not yet). Five items assessed the use of the tailored messages at the 4-month follow-up: (1) viewing the Facebook page of E-health4Uth (yes or no), (2) discussing messages with parents (yes or no), (3) discussing messages with peers (yes or no), (4) adhering to the advice, and (5) changing own behavior in a positive way. The last two items were scored on 5-point Likert scales ranging from 1 (totally disagree, most negative evaluation) to 5 (totally agree, most positive evaluation).

Appreciation of the tailored messages was assessed with 11 items immediately after the adolescents received the tailored messages. Six items assessed if the content of the tailored messages was credible, easy to understand, personally relevant, gave the adolescents insight into their own behavior, contained new information, and was attractive to read. A further two items assessed whether the adolescent learned a lot and appreciated to get information in this manner. Finally, three items measured overall satisfaction with the program, the ease of use of the program, and if the program was interesting. These items on the appreciation of the tailored messages and the program were all scored on a 5-point Likert scale ranging from 1 (totally disagree, most negative evaluation) to 5 (totally agree, most positive evaluation) with exception of the overall satisfaction with the program, which was scored on a scale from 1 (most negative evaluation) to 10 (most positive evaluation).

Evaluation of the Consultation

The use and appreciation of the consultation with the nurse was evaluated by computer log data and a paper-and-pencil questionnaire. That is, the number of adolescents that was referred or referred themselves to a nurse was measured objectively, based on computer log data. When adolescents attended the consultation, they were invited to complete a paper-and-pencil questionnaire about their appreciation of the consultation. The nurses noted whether or not the adolescents attended the consultation, and if the adolescent attended the consultation, they were invited to complete a written evaluation form regarding the consultation as well.

Various dimension of appreciation of the consultation were assessed among adolescents and nurses. One item measured the overall satisfaction with the consultation among adolescents on a scale from 1 (most-negative evaluation) to 10 (most-positive evaluation). Another two items evaluated the appreciation of being invited for consultation and whether the consultation was a valuable addition to the tailored messages among adolescents. These items were measured on 5-point Likert scales ranging from 1 (totally disagree, most negative evaluation) to 5 (totally agree, most positive evaluation). Two items addressed the nurse’s evaluations of whether the referral was legitimate and whether the information on the referred adolescents was helpful. These two items were also measured on a 5-point Likert scale ranging from 1 (not legitimate at all/very unhelpful) to 5 (completely legitimate/very helpful).

Demographics

Age (assessed by date of birth), gender, country of birth of the adolescent and both parents, and the level of education that the adolescents attended (ie, vocational or preuniversity education) were assessed in the evaluation questionnaire. Ethnicity was classified as Dutch or non-Dutch, in accordance with the definitions of Statistics Netherlands [40]. Adolescents with at least one parent born outside the Netherlands were classified as non-Dutch.

Statistical Analysis

Overview

Descriptive statistics were used to describe both the study sample that received the tailored messages and the sample referred for consultation. Chi-square tests and independent samples *t* tests were conducted to test differences in demographic characteristics between both intervention groups. Descriptive statistics were also used to describe the use and appreciation of the tailored messages and the consultation. Chi-square tests (for dichotomous outcomes) and independent samples *t* tests or Mann-Whitney *U* tests (for ordinal outcomes) were conducted to test differences in use and appreciation according to: gender (boys versus girls), educational level (vocational versus preuniversity), and ethnicity (Dutch versus non-Dutch). Independent samples *t* tests were used for analysing data evaluating the tailored messages on 5- and 10-point scales. Because of the relative small sample size of the subsample receiving the consultation (n=126), data evaluating the consultation on 5- and 10-point scales were checked for normality. For ordinal variables that were nonnormally distributed, Mann-Whitney *U* tests were used.

Statistical analyses were performed using SPSS 20.0. Results were considered significant at $P<.05$.

Nonresponse Analysis

A comparison of adolescents participating at follow-up (n=822) with adolescents who were not participating at follow-up (*n*=265) did not indicate significant differences in terms of educational level ($\chi^2_1=1.92$; $P=.17$) or gender ($\chi^2_1=0.64$; $P=.42$). However, the group participating at follow-up was more often of Dutch ethnicity ($\chi^2_1=32.12$; $P<.001$).

Results

Adolescents' Characteristics

The average age of adolescents who received the tailored messages was 15.9 years (SD 0.72); 57.13% (621/1087) of the sample consisted of boys, 72.40% (787/1087) was of Dutch ethnicity, 52.53% (571/1087) attended vocational training, and 47.47% (516/1087) preuniversity education (Table 1). Although adolescents in the E-health4Uth group were significantly younger than adolescents in the E-health4Uth and counseling group, the actual mean age difference was very small (mean 15.9, SD 0.73 vs mean 16.0, SD 0.70, *P*=.02, respectively).

Table 1. General characteristics of the study population, and by intervention group (N=1087).

	Total N=1087	E-health4Uth n=533	E-health4Uth and counseling n=554	*P* value
Age in years, mean (SD)	15.9 (0.72)	15.9 (0.73)	16.0 (0.70)	.02[a]
Boys, n (%)	621 (57.13)	294 (55.16)	327 (59.03)	.20[b]
Ethnicity, Dutch, n (%)	787 (72.40)	395 (74.11)	392 (70.76)	.22[b]
Educational level, vocational training, n (%)	571 (52.53)	265 (49.72)	306 (55.23)	.07[b]

[a] Independent samples *t* tests

[b] χ^2 tests

Adolescents' Use of the Web-Based, Tailored Messages

The results regarding the use of the tailored messages (E-health4Uth) are shown in Tables 2 and 3. During the school session, 81.72% (845/1034) of the adolescents read the messages, whereas 4.5% (38/841) of these adolescents also viewed the websites to which reference was made in these messages. After 4 months, 3.6% (29/814) of the adolescents had viewed the Facebook page of E-health4Uth. Of the adolescents who reported at follow-up that they read the messages, 18.4% (105/572) had discussed these messages with their parents and 24.0% (137/572) with their peers, 41.1% (235/572) reported that they could adhere to advice, and 21.5% (123/572) indicated that the messages changed their behavior in a positive way.

Adolescents receiving preuniversity education read the tailored messages more often than adolescents in vocational training (*P*<.001), whereas adolescents in vocational training more often viewed the websites to which they were referred (*P*<.001), more often indicated that they could adhere to advice (*P*<.001), and had changed their behavior accordingly in a positive way (*P*<.001). Adolescents of Dutch ethnicity and girls discussed the messages more often with their peers than adolescents of non-Dutch ethnicity (*P*<.02) and boys (*P*<.04), whereas adolescents of non-Dutch ethnicity more often indicated that they could adhere to advice (*P*<.005).

Adolescents' Appreciation of the Web-Based, Tailored Messages

Of the adolescents who had read the messages, a large majority (703/843, 83.4%; mean 4.02, SD 0.83) was positive about the ease to understand the messages (Table 2). More than half of the adolescents found the messages credible (510/843, 60.5%; mean 3.59, SD 0.96) and the program easy to use (557/843, 66.1%; mean 3.68, SD 0.93). On six other items, the adolescents evaluated the messages and the program about neutral (score 3 reflects not negative/not positive): personal relevance (mean 3.21, SD 1.06), appreciated getting information in this manner (mean 3.15, SD 1.02), gave insight into own behavior (mean 2.83, SD 1.11), attractive to read (mean 2.89, SD 1.05), learned a lot (mean 2.80, SD 1.07), and program was interesting (mean 2.96, SD 1.06). In general, adolescents evaluated the messages on containing new information as slightly negative (mean 2.44, SD 1.14), indicating that at least a part of the information in the messages was not new to the adolescents. Furthermore, adolescent's mean rating of the E-health4Uth program was positive, namely a 6.70 (SD 1.60) on a scale from 1 (most-negative evaluation) to 10 (most-positive evaluation).

When considering subgroups, adolescents receiving preuniversity education considered the messages easier to understand (*P*=.03) and the program easier to use (*P*=.01) than adolescents in vocational training (Table 3). Adolescents in vocational training appreciated the messages better than adolescents receiving preuniversity education on three items; they rated the messages as containing more novel information (*P*<.001), providing them more insight into their own behavior (*P*<.001), and more instructive (*P*<.001). Adolescents of non-Dutch ethnicity also appreciated these three items better (ie, contained new information, *P*=.002; gained insight into own behavior, *P*=.02; and learned a lot, *P*=.002), and they rated the program as more interesting than adolescents of Dutch ethnicity (*P*=.004). Furthermore, girls appreciated the messages and the program better than boys; girls found the messages more credible (*P*=.03) and easier to understand (*P*=.002). Furthermore, they were more satisfied with the program (*P*=.005), found the program easier to use (*P*=.004), and more interesting (*P*=.006) than boys.

Table 2. Adolescents' use and appreciation of the tailored messages and the E-health4Uth program for the study.

	Total sample		Educational level		
			Vocational	Preuniversity	*P* value
	n (%)	Mean (SD)	n (%) or mean (SD)	n (%) or mean (SD)	
Use tailored messages					
Read during school session	845/1034 (81.72)		407/533 (76.36)	438/501 (87.43)	<.001[a]
Viewed websites to which reference was made (when read messages)	38/841 (4.52)		31/403 (7.69)	7/438 (1.60)	<.001[a]
Viewed Facebook page of E-health4Uth[b]	29/814 (3.56)		18/415 (4.34)	11/399 (2.76)	.22
Discussed with parents[b]	105/572 (18.36)		57/270 (21.11)	48/302 (15.89)	.11
Discussed with peers[b]	137/572 (23.95)		59/270 (21.85)	78/302 (25.83)	.27
Could adhere to advice[b,c]	235/572 (41.08)[e]	3.24 (1.14)	3.47 (1.13)	3.04 (1.11)	<.001[a]
Changed own behavior in a positive way[b,c]	123/572 (21.50)[e]	2.69 (1.19)	2.89 (1.23)	2.52 (1.12)	<.001[a]
Appreciation content-tailored messages [c]					
Credible	510/843 (60.50)[e]	3.59 (0.96)	3.60 (0.98)	3.58 (0.94)	.70
Easy to understand	703/843 (83.39)[e]	4.02 (0.83)	3.93 (0.92)	4.10 (0.74)	.003[a]
Personally relevant	356/843 (42.23)[e]	3.21 (1.06)	3.27 (1.03)	3.17 (1.08)	.17
Gave insight into own behavior	234/843 (28.83)[e]	2.83 (1.11)	3.00 (1.12)	2.67 (1.08)	<.001[a]
Contained new information	162/843 (19.22)[e]	2.44 (1.14)	2.71 (1.18)	2.20 (1.05)	<.001[a]
Attractive to read	243/843 (28.83)[e]	2.89 (1.05)	2.94 (1.09)	2.85 (1.01)	.26
Learned a lot	212/843 (25.15)[e]	2.80 (1.07)	2.95 (1.11)	2.66 (1.01)	<.001[a]
Appreciated getting information in this manner	332/843 (39.38)[e]	3.15 (1.02)	3.19 (1.05)	3.12 (0.99)	.36
Appreciation E-health4Uth program					
Overall satisfaction[d]		6.70 (1.60)	6.77 (1.81)	6.64 (1.39)	.26
Easy to use[c]	557/843 (66.07)[e]	3.68 (0.93)	3.60 (0.95)	3.76 (0.91)	.01[a]
Interesting[c]	261/843 (30.96)[e]	2.96 (1.06)	3.03 (1.09)	2.89 (1.03)	.06

[a] Indicate significant *P* values.

[b] Measured at follow-up.

[c] Scores on a 5-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree).

[d] Scores on a 10-point Likert scale ranging from 1 (most-negative evaluation) to 10 (most-positive evaluation).

[e] Percentages of adolescents who scored a 4 agree or 5 totally agree on the 5-point Likert scale.

Table 3. Adolescents' use and appreciation of the tailored messages and the E-health4Uth program by gender and ethnicity.

	Gender			Ethnicity		
	Boys	Girls	*P* value	Dutch	Non-Dutch	*P* value
	n (%) or mean (SD)	n (%) or mean (SD)		n (%) or mean (SD)	n (%) or mean (SD)	
Use tailored messages						
Read during school session	473/590 (80.17)	372/444 (83.78)	.14	624/755 (82.65)	221/279 (79.21)	.20
Viewed websites to which reference was made (when read messages)	25/467 (5.35)	13/374 (3.48)	.19	23/621 (3.70)	15/220 (6.82)	.06
Viewed Facebook page of E-health4Uth[a]	16/458 (3.49)	13/356 (3.65)	.90	22/625 (3.52)	7/189 (3.70)	.90
Discussed with parents[a]	45/290 (15.52)	60/282 (21.28)	.08	83/449 (18.49)	22/123 (17.89)	.88
Discussed with peers[a]	59/290 (20.34)	78/282 (27.66)	.04[d]	117/449 (26.06)	20/123 (16.26)	.02[d]
Could adhere to advice[a,b]	3.21 (1.19)	3.28 (1.09)	.46	3.17 (1.12)	3.50 (1.16)	.005[d]
Changed own behavior in a positive way[a,b]	2.69 (1.22)	2.70 (1.15)	.98	2.71 (1.16)	2.65 (1.28)	.65
Appreciated content-tailored messages [b], mean (SD)						
Credible	3.53 (1.00)	3.67 (0.89)	.03[d]	3.57 (0.92)	3.65 (1.05)	.30
Easy to understand	3.94 (0.91)	4.11 (0.71)	.002[d]	4.01 (0.80)	4.02 (0.93)	.91
Personally relevant	3.21 (1.08)	3.22 (1.03)	.96	3.19 (1.03)	3.28 (1.23)	.27
Gave insight into own behavior	2.79 (1.15)	2.88 (1.06)	.21	2.78 (1.09)	2.98 (1.16)	.02[d]
Contained new information	2.41 (1.16)	2.48 (1.11)	.42	2.37 (1.11)	2.64 (1.21)	.002[d]
Attractive to read	2.84 (1.08)	2.96 (1.02)	.10	2.87 (1.02)	2.96 (1.14)	.25
Learned a lot	2.76 (1.12)	2.85 (1.00)	.22	2.73 (1.02)	3.00 (1.18)	.002[d]
Appreciated getting information in this manner	3.12 (1.05)	3.20 (0.98)	.27	3.13 (1.01)	3.20 (1.05)	.42
Appreciation E-health4Uth program, mean (SD)						
Overall satisfaction[c]	6.57 (1.75)	6.87 (1.39)	.005[d]	6.72 (1.54)	6.65 (1.78)	.56
Easy to use[b]	3.60 (0.98)	3.79 (0.86)	.004[d]	3.72 (0.90)	3.58 (1.02)	.08
Interesting[b]	2.87 (1.07)	3.07 (1.04)	.006[d]	2.90 (1.04)	3.13 (1.11)	.004[d]

[a] Measured at follow-up.

[b] Scores on a 5-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree).

[c] Scores on a 10-point Likert scale ranging from 1 (most-negative evaluation) to 10 (most-positive evaluation).

[d] Indicate significant *P* values.

Adolescents' Use of the Consultation

The results regarding the use of the consultation with the nurse are shown in Tables 4 and 5. Of the 554 adolescents in the E-health4Uth and counseling group, 103 (18.6%) adolescents were referred to a nurse. Adolescents were most often referred based on a high score (>16) on the total problem scale of the SDQ (12.1% of the 18.6%, ie, 65.0%; Table 4). Adolescents in the two intervention groups and the control group could also check a box for a self-referral; 44 of the 1702 adolescents checked the box for a self-referral (2.6%). Three of these 44 adolescents were in the E-health4Uth and counselling group and at risk of mental health problems, and therefore already referred to a nurse.

One hundred twenty-six of 144 adolescents who were referred or self-referred attended the consultation (87.5%). The average age of adolescents who presented for the consultations was 16 years (SD 0.73); 50.7% of this sample consisted of boys, 61.4% was of Dutch ethnicity, and 66.4% attended vocational training.

Adolescents in vocational training were more often referred to a nurse because of a high total problem score on the SDQ than adolescents receiving preuniversity education (*P*=.035), whereas girls and adolescents of Dutch ethnicity were more often referred to a nurse because of a high score on the SDQ emotional problems subscale than boys (*P*<.001) and adolescents of non-Dutch ethnicity (*P*=.039). Adolescents of non-Dutch ethnicity were more often referred to a nurse because they did not want to answer the question about suicidal thoughts (*P*=.002) and/or suicide attempts (*P*=.001) than adolescents of Dutch ethnicity. Adolescents of non-Dutch ethnicity more often asked for a referral than adolescents of Dutch ethnicity (*P*<.001), whereas adolescents in vocational training attended the consultation more often than adolescents receiving preuniversity education (*P*=.047).

Table 4. Description of adolescents' use and appreciation of the consultation for the study sample and by educational level.

	Total sample		Educational level		
			Vocational	Preuniversity	*P* value
	n (%)	Mean (SD)	n (%), or mean (SD)	n (%), or mean (SD)	
Use of consultation					
Referred to a nurse	103/553 (18.62)		69/305 (22.62)	34/248 (13.71)	.007[f]
Total SDQ score>16	67/553 (12.11)		45/305 (14.75)	22/248 (8.87)	.035[f]
SDQ subscale emotional problems>5	40/553 (7.23)		24/305 (7.87)	16/248 (6.45)	.52
Suicidal thoughts 'occasionally' or more often	22/553 (3.98)		12/305 (3.93)	10/248 (4.03)	.95
Did not want to answer question about suicidal thoughts	26/553 (4.70)		19/305 (6.23)	7/248 (2.82)	.06
Suicide attempt last year	4/553 (0.72)		3/305 (0.98)	1/248 (0.40)	.42
Did not want to answer question about suicidal attempt last year	20/553 (3.61)		14/305 (4.59)	6/248 (2.42)	.17
Asked for a referral	44/1702 (2.59)[a]		27/914 (2.95)	17/788 (2.16)	.30
Attending consultation	126/144 (87.50)		86/94 (91.49)	40/50 (80.00)	.047[f]
Adolescent, Appreciation of consultation					
Overall satisfaction[b]		8.07 (1.21)	8.07 (1.00)	8.08 (1.58)	.42[e]
Appreciated to be invited[c]	83/126 (65.9)[d]	3.70 (1.10)	3.81 (1.05)	3.45 (1.18)	.09[e]
Valuable addition to the tailored messages[c]	81/126 (64.3)[d]	3.85 (1.04)	3.99 (0.98)	3.55 (1.11)	.03[e,f]
Nurse, Appreciation of consultation					
Referral was legitimate[c]	63/89 (70.8)[d]	3.53 (1.00)	3.60 (0.99)	3.35 (1.02)	.21[e]
Self-referral was legitimate[c]	21/37 (56.8)[d]	3.30 (1.15)	3.17 (1.19)	3.50 (1.09)	.45[e]
Information of the adolescent was helpful[c]	88/110 (80.0)[d]	3.83 (0.86)	3.75 (0.92)	3.97 (0.71)	.21[e]

[a] Three of the 44 adolescents who asked for a referral were in the E-health4Uth + counselling group and at risk of mental health problems, and therefore also referred to a nurse.

[b] Scores on a 10-point Likert scale ranging from 1 (most-negative evaluation) to 10 (most-positive evaluation).

[c] Scores on a 5-point Likert scale ranging from 1 (most-negative evaluation) to 5 (most-positive evaluation).

[d] Percentages of adolescents or nurses who scored a 4 agree/legitimate/helpful or 5 totally agree/completely legitimate/very helpful on the 5-point Likert scale.

[e] Mann-Whitney *U* test.

[f] Indicate significant *P* values.

Table 5. Description of adolescents' use and appreciation of the consultation by gender and ethnicity.

	Gender			Ethnicity		
	Boys	Girls	*P* value	Dutch	Non-Dutch	*P* value
	n (%), or mean SD	n (%), or mean SD		n (%), or mean SD	n (%), or mean SD	
Use of consultation, n (%)						
Referred to a nurse	51/326 (15.64)	52/227 (22.91)	.03[d]	69/391 (17.65)	34/162 (20.99)	.36
Total SDQ score>16	37/326 (11.35)	30/227 (13.22)	.51	45/391 (11.51)	22/162 (13.58)	.50
SDQ subscale emotional problems>5	11/326 (3.37)	29/227 (12.78)	<.001[d]	34/391 (8.70)	6/162 (3.70)	.039[d]
Suicidal thoughts 'occasionally' or more often	13/326 (3.99)	9/227 (3.96)	.99	17/391 (4.35)	5/162 (3.09)	.49
Did not want to answer question about suicidal thoughts	14/326 (4.29)	12/227 (5.29)	.59	11/391 (2.81)	15/162 (9.26)	.001[d]
Suicide attempt last year	2/326 (0.61)	2/227 (0.88)	.72	4/391 (1.00)	0/162 (0.00)	.20
Did not want to answer question about suicidal attempt last year	11/326 (3.37)	9/227 (3.96)	.71	8/391 (2.05)	12/162 (7.41)	.002[d]
Asked for a referral	24/906 (2.65)	20/796 (2.51)	.86	20/1207 (1.66)	24/495 (4.85)	<.001[d]
Attending consultation	62/73 (84.93)	64/71 (90.14)	.35	74/88 (84.09)	52/56 (92.86)	.12
Adolescent, appreciation of consultation, mean (SD)						
Overall satisfaction[a]	8.20 (0.98)	7.95 (1.39)	.47[c]	8.10 (0.97)	8.04 (1.50)	.85[c]
Appreciated to be invited[b]	3.69 (0.97)	3.70 (1.22)	.55[c]	3.59 (1.03)	3.85 (1.18)	.11[c]
Valuable addition to the tailored messages[b]	3.92 (1.00)	3.78 (1.08)	.50[c]	3.70 (1.14)	4.06 (0.83)	.13[c]
Nurse, appreciation of consultation, mean (SD)						
Referral was legitimate[b]	3.53 (0.98)	3.52 (1.03)	.90[c]	3.66 (0.88)	3.27 (1.17)	.16[c]
Self-referral was legitimate[b]	3.00 (1.20)	3.61 (1.04)	.13[c]	3.07 (1.16)	3.45 (1.14)	.33[c]
Information of the adolescent was helpful[b]	3.73 (1.01)	3.90 (0.72)	.47[c]	3.98 (0.62)	3.59 (1.09)	.06[c]

[a] Scores on a 10-point Likert scale ranging from 1 (most-negative evaluation) to 10 (most-positive evaluation).

[b] Scores on a 5-point Likert scale ranging from 1 (most-negative evaluation) to 5 (most-positive evaluation).

[c] Mann-Whitney *U* test.

[d] Indicate significant *P* values.

Adolescents' and Nurses' Appreciation of the Consultation

Adolescents appreciated being invited for the consultation (mean 3.70, SD 1.10), found the consultation a valuable addition to the tailored messages (mean 3.86, SD 1.03), and they gave the consultation a positive mean rating of 8.07 on a 10-point scale (SD 1.21). Adolescents in vocational training considered the consultation a more valuable addition to the Web-based, tailored messages than adolescents receiving preuniversity education (*P*=.034).

After the consultation, nurses evaluated most referrals for the adolescents at risk of mental health problems (63/89, 70.8%; mean 3.53, SD 1.00) and for adolescents that self-referred (21/37, 56.8%; mean 3.30, SD 1.15) as legitimate. In most cases (88/110, 80.0; mean 3.83, SD 0.86), the nurses also rated the information they received about the adolescents prior to the consultation as helpful.

Discussion

Principal Results

In the present study, we evaluated the use and appreciation of two interventions (E-health4Uth and E-health4Uth and counseling) applied by preventive youth health care in secondary schools. Results showed that most adolescents had read the tailored messages and evaluated the use and appreciation of the tailored messages and the E-health4Uth program overall as positive. In general, adolescents in vocational training, girls, and adolescents of non-Dutch ethnicity used the Web-based, tailored messages more and appreciated them better than adolescents receiving preuniversity education, boys, and adolescents of Dutch ethnicity, respectively. Adolescents in vocational training and girls were more often referred to a nurse than adolescents receiving preuniversity education and boys, respectively. Adolescents of Dutch and non-Dutch ethnicity were as often referred to a nurse, but for different reasons. Adolescents of Dutch ethnicity were more often referred because of a high score on the SDQ emotional problems subscale, whereas adolescents of non-Dutch ethnicity were more often referred because they did not want to answer questions about suicidal thoughts and suicide attempts. Adolescents of non-Dutch ethnicity asked for a referral more often than adolescents of Dutch ethnicity, whereas adolescents in vocational training attended the consultation more often than adolescents receiving preuniversity education. The adolescents who attended the consultation evaluated the consultation positively, just as the nurses did. Adolescents, especially those in vocational training, considered the consultation a valuable addition to the Web-based, tailored messages.

Interpretation

This study indicates that Web-based tailoring is useful in a preventive-care setting to provide adolescents with information about their lifestyle behaviors and well-being. Other studies in which tailored messages were used among adolescents have shown comparable ratings of use and appreciation of tailored messages about health and healthy behavior [22,41,42]. Adolescents in the E-MOVO (Electronic Monitor and Health Education) study, in which similar tailored messages were used, appreciated the messages slightly more than adolescents in our study with regard to credibility, personal relevance, giving insight into own behavior, and ease of understanding [43]. However, in the E-MOVO study the response rate of the evaluation questionnaire was very low (ie, only 3%). Therefore, perhaps only the highly-motivated adolescents completed the evaluation questionnaire, which could have resulted in a more positive rating.

Results of earlier studies [28,41] and this study show that a vast majority of the adolescents had read the messages. This indicates that adolescents are interested in receiving feedback on lifestyle behaviors and well-being when communicated through the Internet. Furthermore, Web-based tailoring seems an appropriate way to adjust messages to adolescents' needs of information on their lifestyle behaviors and well-being in a preventive-care setting. It must be noted though that the percentage of adolescents that clicked on a link or viewed the Facebook page to obtain additional information on the various topics in the intervention was relatively low. This could be due to the messages already containing enough information, the adolescents not wanting to obtain more information, or adolescents not wanting to be continually sent "off-site" from the intervention page to view information [44]. Beside these explanations, visiting Facebook is often not allowed at schools, and therefore maybe not preferable to use in this context. Furthermore, approximately 20% of the adolescents indicated they had discussed the messages with their parents or peers. In a study of Ezendam et al [41], which used Web-based, tailored messages on dietary and physical activity, 40% of the adolescents indicated that they discussed the messages with their parents or peers. Although in our study, fewer adolescents discussed the messages with their parents or peers, this still may be an indication that adolescents, to some extent, actively process the information, a prerequisite for behavior change [35,36]. Moreover, the rationale behind using tailored messages is that the information is personally relevant, new, giving insight into own behavior, and is interesting, which results in greater attention and more thoughtful consideration of the information [13,45]. In our study, these items regarding personal relevance, giving insight into own behavior, and finding it interesting were evaluated as neutral and at least part of the information in the messages was not new to the adolescents. Therefore, the tailored messages in this study possibly need further improvement, which may result in the messages becoming even more effective. The current messages could be further tailored using, for example, demographics, personal cognitive factors (eg, manner in which health risks are perceived by the individual), social factors (eg, susceptibility to social pressure from peers), or self-efficacy of the individual (eg, judgement of capability to change unhealthy behavior) [46,47].

The differences in use and appreciation of the tailored messages according to demographics of the adolescents found in our study also support the need to further tailor the messages to the individual adolescents' needs. That is, in line with the research of Ezendam et al [41], in our study, adolescents receiving preuniversity education perceived the messages as easier to understand than adolescents in vocational training. An explanation for this finding, which is supported by research of Ezendam et al [41] and our results on the novelty of the information, may be that the information was already familiar to adolescents receiving preuniversity education. Therefore, we suggest that messages should be tailored to educational level. This is important as lesser-educated adolescents tend to have a less healthy lifestyle and they rate their well-being as lower compared with higher-educated people [2,41,48]. However, effects for other demographics were also found. Additional analyses (data not shown) showed that the various demographics (ie, level of education, gender, and ethnicity) had an effect on the use and appreciation of the tailored messages independent of each other, indicating it is important to use multiple characteristics to best tailor these messages.

Although the tailored messages have the potential to reach large groups of adolescents in a very cost-effective manner [13], the consultation with the nurse was rated more positively. This was supported by additional analyses with the subsample of adolescents who evaluated the tailored messages and received and evaluated the consultation. These analyses showed similar results on the use and appreciation of the tailored messages for the subsample of adolescents compared with the whole group of adolescents (data not shown). The more positive evaluation of the consultation in comparison with the tailored messages could have been due to the interaction between the nurse and adolescent during the consultation, as previous research has shown that interaction in health communication could improve patient satisfaction [49,50]. Furthermore, the collected information on adolescents' health prior to the consultation could have supported the nurse during the consultation to better tailor the provided information to the adolescent's needs. Sciamanna et al [27] have shown that discussing previously collected information with a patient during a consultation could improve patient satisfaction as well. Therefore, the consultation seems a valuable addition to the Web-based, tailored messages for adolescents at risk of mental health problems and for adolescents wanting a referral to the nurse.

Finally, as expected, approximately one-fifth of the adolescents met the inclusion criteria for an appointment with the nurse [31]. In line with previous studies [2,51], adolescents in vocational training were more often at risk of mental health problems than adolescents receiving preuniversity education, whereas girls and adolescents of Dutch ethnicity were more often at risk of emotional problems than boys and adolescents of non-Dutch ethnicity. Adolescents of non-Dutch ethnicity more often did not want to answer the questions about suicidal thoughts and suicide attempt. It is possible that the stigma associated with suicidal thoughts and suicide attempts among some cultural groups may have contributed to not wanting to answer the questions regarding these issues [52,53]. Adolescents of non-Dutch ethnicity more often asked for a referral than adolescents of Dutch ethnicity, which is in line with, for example, the more frequent use of the general practitioner by ethnic minorities in the Netherlands [54].

In this study, as well as in another study in a similar setting [28], most adolescents attended the consultation, and in most cases nurses evaluated the referral as legitimate and the information they received on the adolescent prior to the consultation as helpful. This may indicate that the criteria we used to select adolescents at risk of mental health problems were suitable and selected adolescents were willing to attend the consultation with the nurse. Furthermore, the information regarding adolescents' health and health behavior from the E-health4Uth tool to facilitate communication during consultation seemed appropriate.

Strengths and Limitations

The response rate on the evaluation questionnaires was relatively high and our study population resembles the average Dutch adolescent population in secondary schools in gender, ethnicity, and educational level [55]. However, this study was only conducted among Dutch adolescents of ages 15-16 years in a preventive-care setting and therefore generalization to other countries, age groups, and settings should be done with caution. Because adolescents' response was not anonymous, but confidential due to the necessity to match the follow-up data and to provide the nurse with information about the adolescents who were invited for the consultation, this could have had an effect on the social desirability of the adolescent's responses. However, a previous study showed that anonymous and confidential collection of data revealed similar results on adolescents' self-report measures of various (psychological) health indicators [56].

A strength of this study is the focus on multiple behaviors, which is also becoming an increasingly popular strategy in research on the effectiveness of Web-based, tailored messages [57-60]. However, due to this focus on multiple behaviors, adolescents received a lot of information and it is conceivable that adolescents became overwhelmed due to the amount of information and may have read the information less carefully. Future studies might therefore consider reducing the number of topics or offering the multiple tailored messages consecutively at different points in time [60]. Moreover, the current messages could be further tailored by using demographics, personal cognitive factors, social factors, or self-efficacy of the individual to show healthy behavior.

A strength of the interventions is the adaptability to other settings. For example, the tailored messages could be embedded in the school's health promotion curriculum, and offered at relevant moments in the curriculum. But it is also possible that the assessment takes place at home and the subsequent consultation at the preventive health care organization. However, future research is required to investigate the application of the interventions in other settings. Finally, it is possible that some adolescents have mainly read the messages because they had to attend their class anyway. Nevertheless, our study showed that the adolescents rated the messages overall as positive, indicating that regardless of their motivation to participate they appreciated the content of the messages.

Conclusions

The Web-based, tailored messages and additional consultation were used and appreciated positively by adolescents and nurses. The consultation seems a valuable addition to the tailored messages for adolescents at risk of mental health problems and for adolescents wanting a referral to the nurse. However, the tailored messages may need further improvement, since adolescents did not rate all the evaluation items on the messages as positive. As these interventions were already interweaved with the existing practice of the preventive youth health care, they are especially promising for future implementation. Furthermore, algorithms generating tailored information can be easily extended using more characteristics of the adolescent to tailor the messages, and wide-scale distribution can be arranged at relatively low cost. Future research is necessary to investigate the possible effects of the Web-based, tailored messages and the consultation with the nurse on the well-being and health behaviors of adolescents.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Topics of the eHealth modules.

[PDF File (Adobe PDF File), 28KB - resprot_v3i1e61_app1.pdf]

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Abbreviations

E-MOVO: Electronic Monitor and Health Education
RCT: randomized controlled trial
SDQ: Strengths and Difficulties Questionnaire
WMO: Wet Medisch wetenschappelijk Onderzoek met mensen

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Original Paper

Examining Participant Engagement in an Information Technology-Based Physical Activity and Nutrition Intervention for Men: The Manup Randomized Controlled Trial

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Abstract

Background: Males experience a shorter life expectancy and higher rates of chronic diseases compared to their female counterparts. To improve health outcomes among males, interventions specifically developed for males that target their health behaviors are needed. Information technology (IT)-based interventions may be a promising intervention approach in this population group, however, little is known about how to maximize engagement and retention in Web-based programs.

Objective: The current study sought to explore attributes hypothesized to influence user engagement among a subsample of participants from the ManUp study, a randomized controlled trial testing the efficacy of an interactive Web-based intervention for promoting physical activity and nutrition among middle-aged males.

Methods: Semistructured interviews were conducted and audiotaped with 20 of the ManUp participants. Interview questions were based on a conceptual model of engagement and centered on why participants took part in the study, what they liked and did not like about the intervention they received, and how they think the intervention could be improved. Interview recordings were transcribed and coded into themes.

Results: There were five themes that were identified in the study. These themes were: (1) users' motives, (2) users' desired outcomes, (3) users' positive experiences, (4) users' negative emotions, and (5) attributes desired by user.

Conclusions: There is little research in the field that has explored user experiences in human-computer interactions and how such experiences may relate to engagement, especially among males. Although not conclusive, the current study provides some insight into what personal attributes of middle-aged males (such as their key motives and goals for participating) and attributes of the intervention materials (such as usability, control, and interactivity) may impact on user engagement in this group. These findings will be helpful for informing the design and implementation of future health behavior interventions for males.

Trial Registration: Australian New Zealand Clinical Trials Registry: ACTRN12611000081910; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12611000081910 (Archived by WebCite at http://www.webcitation.org/6M4lBlvCA).

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KEYWORDS

qualitative; intervention; physical activity; retention; technology; website; engagement

Introduction

Engaging Men in Healthy Lifestyles

Despite strong evidence that physical inactivity and poor nutrition are associated with an increased risk of chronic diseases and mortality [1,2], the majority of the adult population in western societies continues to live an unhealthy lifestyle [3-7]. Interventions that promote healthy lifestyles at a population level are needed to address this public health issue [1,8]. Of particular concern is how to engage males in such interventions. Compared to their female counterparts, males are less likely to engage in lifestyle modification programs, utilize health services, and participate in intervention research [9,10]. This may be a contributing factor to the shorter life expectancy and higher age-specific rates of chronic diseases, such as heart disease, Type 2 diabetes, obesity, and mental health issues experienced by males compared to females [11-13]. To effectively reach males and have them engage in health promotion initiatives, interventions that appeal to males and meet their specific needs are required.

There is a clear gap in the research literature addressing the physical activity and nutritional behaviors of males. Little male-specific research has been undertaken, and best practice approaches have not been identified [12,14,15]. Overall, males receive less educational advice than women from health professionals about modifiable lifestyle behaviors associated with disease risk [16], and there are a lack of resources available that are targeted specially at males [17,18]. There is strong evidence that behavior change interventions that address characteristics and behavior change determinants unique to particular subgroups are more effective than generic “one-size-fits all” approaches [19]. Given the difference in social norms regarding masculine and feminine gender roles and the influence of these norms on behavior [16], the development of resources targeted specially at men is required.

Purpose of the ManUp Study

The purpose of the ManUp study [20] was to address this issue by developing and testing innovative physical activity and nutrition modification strategies that would be appealing and effective for middle-aged males. As part of this study, comprehensive reviews of the literature were undertaken to identify strategies that have worked in previous interventions targeting males [21,22]. Original research exploring male’s intervention preferences [23] and factors influencing physical activity and nutrition behavior among males were also conducted [24]. From this, Web- and mobile phone-based interventions that include the delivery of quantitative information and feedback and encourage goal setting and self-monitoring were identified as a promising intervention approach for targeting and engaging males. This was due to Web-based interventions with these features successfully improving physical activity and nutrition behaviors in previous studies [21,22], and the potential for Web-based interventions to be accessed by large numbers of individuals without time of day or geographic restrictions, which was considered necessary for overcoming key barriers to participating in healthy lifestyle behaviors reported by males (such as work and family commitments) [24]. On this basis, a Web-based social cognitive [25,26] and self-regulation theory-based [27] intervention, designed to increase knowledge and self-efficacy via information provision, goal setting, and self-monitoring, was developed and evaluated in a two-arm randomized controlled trial [20].

Issues With Participant Engagement and Retention

Despite the comprehensive and systematic approach to intervention development, issues with engagement and retention of participants were experienced. Few participants logged on to the website regularly (median number of log-ins over the 9 month intervention period was 2 per participant) (interquartile range-IQR=6), and engagement in key behavior change components was low overall (median number of self-monitoring entries was 1 per participant) (IQR=20); median number of challenges initiated was 1 per participant (IQR=3). The dropout was high across both intervention groups, but was significantly higher in the Web-based intervention arm (52/96, 54%, had dropped out at the 9 month follow-up) compared to the print-based positive intervention control arm (96/205, 46.8%, had dropped out at the 9 month follow-up). This is in line with findings from other Web-based-delivered health behavior intervention studies [14,28]. If such interventions are to be effective public health tools, a greater research focus on user engagement is needed [28,29]. This should include research examining the underlying theoretical mechanisms of engagement.

Prior research examining user experiences in human-computer interactions suggests that engagement consists of four distinct stages: (1) the point of engagement, (2) a period of sustained engagement, (3) disengagement, and (4) (possibly) reengagement [30]. According to O’Brien and Toms’ [30] conceptual framework of engagment with technology, the *point of engagement* is initiated by the aesthetic appeal and/or novel presentation of the interface, the users' motivations and interests, the users' ability and desire to be situated in the interaction, and to perceive that there is sufficient time to use the application. At this phase, users typically have a goal in mind for what they would like to gain from the interaction. Engagement is sustained when users are able to maintain their attention and interest in the application and is characterized by positive emotions.

Attention and interest are perpetuated by the interactivity of the computer environment (physical, social, and cognitive), the usability of the interface, and how well these features match the users' attention, motivation, interest, and need for aesthetic and sensory appeal, novelty, control, and challenge. Users must be made to feel a part of the interaction through an awareness of what the system is doing (via feedback), by feeling connected to the technology (via interactivity) or to other people, and by feeling in control over what is happening. *Disengagement* can occur for many reasons, such as the usability of the technology (ie, challenge and interactivity) and distractions in the user’s environment. This stage, depending on the outcome, will result in either positive (user’s needs and motivations are satisfied and they feel successful) or negative emotions (user feels frustration, overwhelmed by challenges or information, loss of interest or motivation). Users may cycle through the stages of engagement several times during a single session or over several sessions, thus demonstratating reingagement. Reingagement shares the same attributes as the point of engagement [30].

The aim of the current study was to explore participant engagement in the ManUp intervention using this framework and to generate directions for future research in the field. The behavioral outcomes of the ManUp randomized trial, relating to changes in diet and physical activity behavior, are forthcoming and will be published in a separate manuscript.

Methods

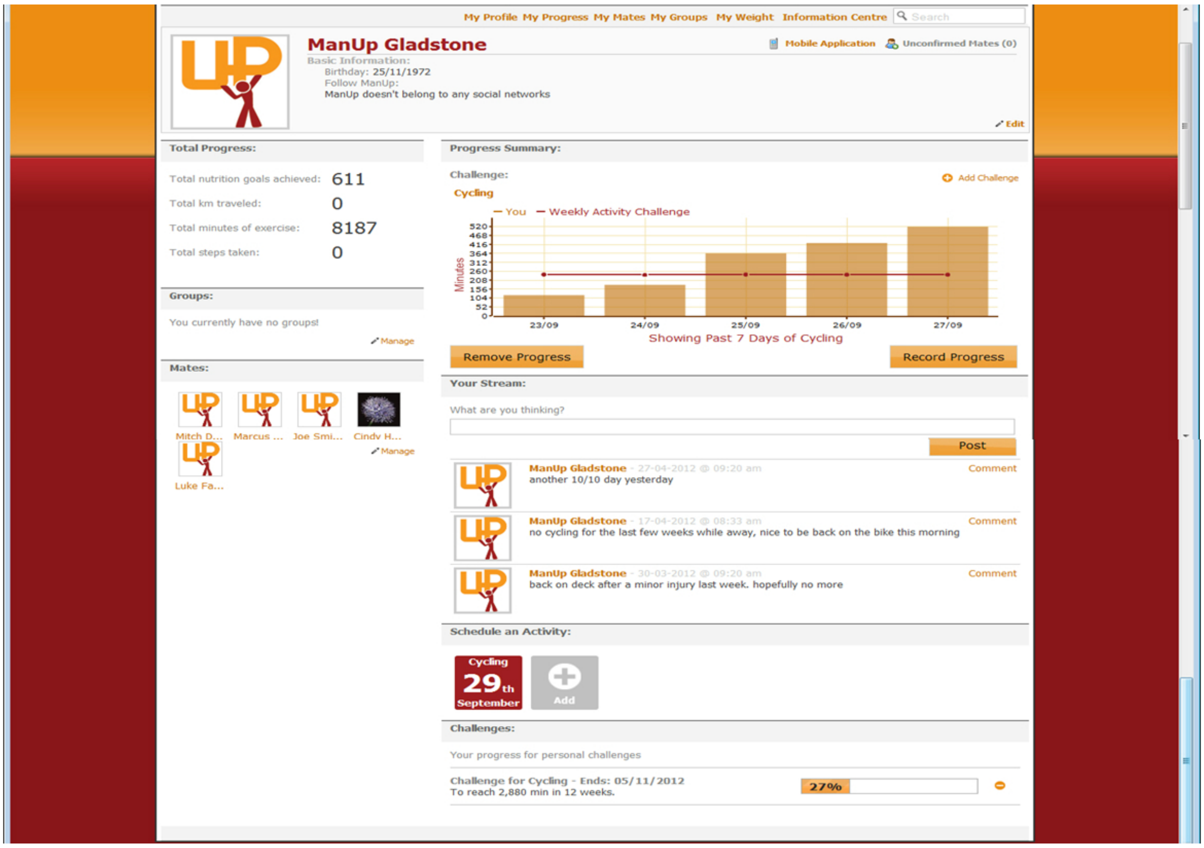
The ManUp Trial

A detailed description of the ManUp randomized controlled trials (RCT) protocol and study sample has been published previously [20]. Briefly, 317 middle-aged men (35-54 years old) recruited from two areas in Central Queensland, Australia were randomly allocated to one of two intervention arms: (1) an Information Technology (IT)-based intervention arm (Web- and mobile phone-based), or (2) a print-based positive-intervention control arm. A print-based intervention was selected as the positive control due to evidence that print-based interventions can be effective among adults, and because they are low-cost and wide-reaching and therefore may be of equal public health potential to IT-based approaches [31,32]. A positive intervention control was employed rather than a standard or true control (eg, wait list), as this approach has been recommended in order to more readily inform public health policy and practice [32,33]. Allocation was conducted on a 2:1 ratio in favor of the IT-based intervention. This was to control for attrition and ensure adequate power [20]. An overview of the interventions is provided below and a screenshot of the ManUp intervention can be found in Figure 1. This study was registered retrospectively (ACTRN12611000081910).

Both interventions comprised three main components: (1) educational materials that were designed to enhance health literacy by clearly communicating the health benefits associated with physical activity and a healthy diet, show the risks associated with inactivity and an unhealthy diet, and show the amount or type of physical activity and nutrition behaviors required to achieve health benefit; (2) ManUp physical activity, nutrition personal, and group “challenges” constructed to provide participants with specific, measureable, and time-based goals and to encourage self-monitoring behaviors, and; (3) self-monitoring resources, providing participants with the ability to record progress and keep themselves informed of progress towards completing these challenges.

Participants in the print-delivered intervention arm received these components via a hard copy booklet that contained a series of log sheets that could be used to monitor their progress and/or successful completion of any of the ManUp physical activity or nutrition challenges. Participants in the IT-delivered intervention arm were given access to a password protected website containing these components across six separate sections which participants could navigate (ie, My Profile, My Progress, My Mates, My Groups, My Weight, and Information Center). The website contained additional components that reflected the ability of the IT-based intervention to deliver automated feedback on challenge progress. Participants were also able to record and receive feedback on their body weight (kg), Body Mass Index (BMI) (kg/m2), and waist circumference (cm), as well as view summaries of all data recorded, schedule activities, search for “mates,” write on “mates” profile pages, and take part in group challenges. Additionally, participants with Internet access on their mobile phones were given access to a mobile phone application, facilitating self-monitoring behaviors by allowing them to quickly and conveniently start a new ManUp physical activity or healthy eating challenge, record progress, and view progress towards completing challenges.

Figure 1. Screenshot of ManUP intervention website (participant profile).



ManUp Gladstone

Basic Information:
Birthday: 25/11/1972
Follow ManUp:
ManUp doesn't belong to any social networks

Total Progress:

Total nutrition goals achieved:	611
Total km traveled:	0
Total minutes of exercise:	8187
Total steps taken:	0

Groups:

You currently have no groups!

Mates:

Progress Summary:

Challenge:

Your Stream:

What are you thinking?

ManUp Gladstone - 27-04-2012 @ 09:20 am
another 10/10 day yesterday

ManUp Gladstone - 17-04-2012 @ 08:33 am
no cycling for the last few weeks while away, nice to be back on the bike this morning

ManUp Gladstone - 30-03-2012 @ 09:20 am
back on deck after a minor injury last week. hopefully no more

Schedule an Activity:

Challenges:

Your progress for personal challenges

Challenge for Cycling - Ends: 05/11/2012
To reach 2,880 min in 12 weeks.

Recruitment

Before approaching ManUp participants an estimate of the required sample size to reach saturation was conducted [34]. As the study was relatively narrow in scope and based on participants' direct experiences, we expected that the sample size needed to reach saturation would be small and aimed to recruit 30 ManUp participants (15 from each intervention arm) [34-36]. ManUp participants were contacted by telephone (in alphabetical order) and invited to take part in the study. Up to three call attempts were made to participants before labeling them as a nonresponder. It was intended that calls would continue to be made until 30 interviews had been conducted. However, after contacting 60 ManUp participants, with 20 participants consenting (a response rate of 33%), a decision was made to delay inviting additional men to participate until a judgment about theoretical saturation could be made on the already recruited sample. Theoretical saturation arises when no new data occurs after continuing sampling and analyzing data [36]. After conducting interviews with this sample, it was agreed that further interviews were unlikely to result in new information, and as such, no further attempts to recruit participants were made.

Procedure

Semistructured telephone interviews were conducted and audiotaped by research assistants working on the ManUp project. During each interview, written notes were taken in as much detail as possible to aid in the interpretation of the recordings. Each interview ran for approximately 10 minutes. Telephone interviews were chosen over other interview methods due to the geographical dispersion of participants and evidence that this method can provide rich data [37].

Prior to conducting interviews with participants, training interviews were conducted on a convenience sample (n=5) to provide the interviewers with an opportunity to practice interview skills and refine the interview materials if necessary. Feedback was provided to the interviewers by the lead investigator (MJD) and necessary changes were made to the interview protocol prior to data collection.

Discussion Guide

Interview questions were designed to explore attributes associated with participant engagement and disengagement in the intervention materials. The development of the open-ended questions was guided by O'Brien and Toms' [30] conceptual model of engagement and centered on why participants took part in the study, what they liked and did not like about the intervention they received, and how they think the intervention could be improved. Leading questions about specific intervention attributes were avoided, and, instead, questions were designed to allow participants to voice their own views, values, and experiences. Participants were prompted to expand on their answers and give as many details as possible using standard prompting techniques (eg, requesting more information, paraphrasing, and using affirmative noises). The interview questions in the context of the conceptual model are presented in Table 1.

Table 1. Hypothesized attributes influencing engagement and related interview questions.

Phase	Hypothesised attributes influencing engagement	Interview questions
Point of engagement	Aesthetic appeal	What was the reason you participated in the study?
	Novel presentation	What did you expect to get out of the program?
	Users' motivations	What did you like about the program?
	Users' desired outcome/goal for interacting with the application	
	Users' ability	
	Users' perception that there is sufficient time to use the application	
Engagement	Usability of the interface	Did the program meet your expectations?
	Feeling of connectedness to the technology (influenced by physical, social and cognitive interactivity)	What did you like about the program?
	Feeling of control	
	Positive/negative emotions associated with how well the application features match the users' motivation/goal, and need for sensory appeal, novelty and challenge	
Disengagement	Usability	What didn't you like about the program?
	Distractions in the user's environment	What would you suggest to improve the materials?
	Positive emotions (user's needs are satisfied)	
	Negative emotions (frustration, overwhelmed by challenges or information, boredom, loss of motivation or interest).	

Data Analysis

Data collection was conducted from April 2012 to June 2012. Data extraction was conducted between January and February 2013. Interview recordings were transcribed verbatim by a research assistant and analyzed thematically using a theory-driven code [38] into a tabular format (based on O'Brien and Toms' [30] preexisiting description of attributes influencing engagement; see Table 1). During the coding process frequencies of each issue raised were noted. Data were analysed in this way to enable the investigators to identify patterns and facilitate discovery of the most prevalent themes. However, in accordance with qualitative research methodology, where the focus is on richness and not representativeness, frequencies are not reported in the text [35,36]. There were two researchers (CS, MWD) that conducted the coding process independently to ensure the trustworthiness of the themes. Results of the independent analyses were compared and discussed until agreement was reached.

Results

Participants

Twenty out of the 60 individuals contacted took part in the study. A summary of participant characteristics is presented in Table 2 (data obtained using Web-based surveys as part of baseline assessment in the ManUp study) [20]. Overall, the majority of participants were professional or white collar workers, with moderate health literacy for physical activity and nutrition topics, were classified as overweight or obese (based on BMI), and were partaking in some physical activity, but not at a level sufficient to meet the national guidelines (ie, 150 minutes/week of moderate-vigorous physical activity spread across at least five days) [39]. There were no significant differences between ManUp participants who participated in the RCT and those who participated in the current study in terms of age, income, health literacy, physical activity, and diet behavior (*P*>.05). However, a higher proportion of interviewed participants were employed in professional and white collar occupations than those who were not interviewed (*P*=.03), and of those that received the IT-based intervention, interview participants of the current study had higher median log-in rates as compared to those who did not participate (*P*=.01).

Themes from the theory-driven analysis are summarized here. Representative quotes relating to each theme are provided in Tables 3 and 4.

Table 2. Participant characteristics.

		Print (N=7)	IT-based (N=13)
Demographics			
	Age (years; x, SD)	43.42 (6.02)	42.08 (4.25)
	University education (N)	6	4
Employment type (N)			
	Professional	4	9
	White collar	2	4
	Blue collar	1	0
BMI		27.69 (2.81)	31.33 (7.56)
Knowledge			
	Nutrition literacy scale (x, SD)	25.85 (1.46)	25.58 (1.67)
	Physical activity literacy scale (x, SD)	2.57 (1.81)	3.66 (1.30)
Behavior			
	Meeting the physical activity guideline (N)	3	7
	Moderate/vigorous physical activity (mins/wk; x, SD)	42.86 (57.07)	123.33 (278.25)
	Serves of vegetables/day (x, SD)	3 (1.91)	2 (1.34)
	Serves of fruit/day (x, SD)	2.71 (2.62)	2.41 (2.27)
	Frequency of eating red meat last week (x, SD)	6 (0.81)	5.41 (1.62)
Usage data			
	Median log-ins (1-36 weeks) and interquartile range	N/A	13.5 (interquartile range=26)

Users' Motivations

The most common motivating factors among participants were weight loss and gaining the necessary tools and incentives to self-manage one's health. In particular, participants expressed a desire to "gauge" their health and fitness levels and to be provided with feedback and advice on how to control their weight and maintain healthy lifestyle habits. For a few participants, participation was driven by external factors, such as pressure to participate from their partner.

Users' Desired Outcomes

Overall, the outcomes people anticipated from engaging in the program largely reflected their motives for participating. Most were expecting to receive guidance and counseling from the project team to help them enhance their diet and participation in physical activity. For some, this guidance and advice were expected to be specific, such as a prescriptive diet plan to follow or support for their particular sport and activities. For others, the type of advice and support expected were described more generally, such as "tips and suggestions" to live a healthier life. Strategies to help participants stay disciplined and to take action were also expected, such as the provision of materials to record diet and physical activity behaviors. A few participants also expressed that they expected to improve their lifestyle behaviors and/or weight status as a result of participating in the study.

Users' Positive Emotions

Participants from both intervention groups liked that the information they were provided with was easy to read, use, and had an appropriate tone (ie, not derogatory). Participants from both groups liked that the materials could be used as a benchmark and reference tool when thinking about their own health. Participants who received the IT-based intervention liked the ability to record and view a visual summary of their progress.

Users' Negative Emotions

Some participants who received the printed information found that the booklet was too long and that some of the text was long-winded. Furthermore, there were a few participants who expressed disappointment with the level of interaction and feedback provided and felt they would have done better with the "Web-based stuff." Among those who received the IT-based intervention, some participants expressed that they would have liked functional aspects of the website to be improved, such as the ability to enter and keep track of different types of activities, the ability to enlarge text, and the progress calendar. Furthermore, a few participants raised sustaining self-monitoring as an issue, especially when personal physical activity routines did not change (ie, self-monitoring via the website was considered less useful) or when in out-of-service areas (ie, when self-monitoring could not be done immediately and conveniently due to a lack of Internet connection). A few participants also expressed disappointment with the intervention content, with some participants reporting that the physical activity and nutrition content was not prescriptive enough, and others reporting that they would have liked to have received more personalized information and feedback about how their changes in health behavior were likely to impact on their health.

Attributes Desired by Users

Suggestions on how to improve the print-based intervention included providing more tips and helpful hints that are based on the experiences of their peers, and transferring the intervention onto a Web or mobile phone platform to make it more interesting and accessible. Suggestions on how to improve the IT-based intervention were more varied and included both suggestions on how to improve the website usability and for improving intervention content. Specific functional components requested by participants included a facility to report IT-based issues, reminder emails offering direct links to participant profiles (without logging in), the capacity to use the mobile app when there is no Internet connection, and to sync the data with the website at a later date. Suggestions on how to improve intervention content included providing links to nutrition and physical activity information on a separate page of the website, allowing participants to set their own challenge metrics, providing more detailed and iterative feedback, and providing access to other useful tools, such as a calorie conversion calculator. Some of these suggestions, namely a facility to report IT-based issues and links providing further lifestyle information, were actually included on the website.

Table 3. Representative quotes from participants relating to each theme.

Theme	All participants
Users’ motivations	I was looking to lose a bit of weight
	I was hoping you could give me some sort of insight into how to control my weight
	My wife told me I had to
	Just to gauge my fitness
	To keep track that I’m doing the right thing and a bit more of an incentive
Users’ desired outcomes	To gain a bit more knowledge on my body and how I can better manage my health
	Guidance to make sure that I was doing the right thing as far as exercising a bit more and eating properly
	To record what I was doing and then talk to your consultant and actually see ways of improving either fitness or health
	A solution to weight loss
	Documenting what I was doing/motivation to continue

Table 4. Representative quotes from participants relating to each theme.

	Print	IT-based (Web + mobile)
Users' positive emotions	I didn't know too much about what I was doing each day so that helped me out	The program made me focus more on my physical activity and diet after actually seeing the data
	I went in with an open mind and it was pretty much what I thought it would be	Overall I think it's great
	It was easy to read	I got a little bit out of it. It actually encouraged me to start walking a lot more. In my particular job I'm out of town a lot so there are not a lot of regular exercise programs I can actually sign up for. Whereas, I ended up buying myself a pedometer and I have been walking
	Gives you a good benchmark on how to lose weight	It was easy to read
	I used print material as a reference tool	I really liked seeing the visual record of my progress
	They were well written and It wasn't too derogatory or you didn't feel like you were being taught a kindergarten lesson but by the same token, it was quite readable and achievable for anybody with limited literacy skills	I like the idea of being able to use the calendar to record progress
	It was all pretty good relevant information	I'm not high tech minded but I could still use it
Users' negative emotions	I was expecting more feedback and interaction	I wanted to be told what the outcome would be if I did specific amounts of activity
	I think I would have done better with the Web-based stuff, more motivation that way	I wanted to count cross training exercise but didn't think that it was really designed for this
	I was never going to be able to fill the whole book in and I suppose you've written the book with that in mind, so I suppose the expectation might have been a little bit high for me to fill something in every week	I didn't like that you couldn't enlarge the calendar
	They were a little bit long winded	It wasn't prescriptive enough
		It didn't give me the outcome I was looking for
		I think I may have let the system down by not following through as much as I should. Initially I was recording my activity weekly but it was a routine that didn't change much so I sort of fell off on the updating sort of sense
Attributes desired by users	Tips, helpful hints	I would have liked reminder emails with link to direct entry without log-in
	Encouragement, people to give you ideas	Capacity to enter data when no reception is available and then sync when phone has reception
	I think one method to address some of my habitual failings, is if it was on either a mobile phone app or an Internet version. Cause I'm more of a technology orientated person than I am paper orientated. I probably would have addressed and achieved more of the challenges purely because, you know, if it's on the phone or on my computer it's more ah, it's more interesting and more accessible for me	Post challenge-report that detailed progress over time period of the entire challenge
		I would have liked to have been able to measure total physical activity across different types of activity
		I'd have liked a calorie conversion option on my progress chart
		I would have liked to have been able to set my own challenge metrics and timeframes
		I'd like to be able to pause my challenge or reset for when I am sick or away

Discussion

Aim of the Study

Poor user engagement in Web-based health behavior interventions is consistently reported in the literature [14,28]. Despite this, very little research in the field has explored user experiences in human-computer interactions and how such experiences may relate to engagement, especially among males who are in general harder to engage than women in behavior change interventions [9,10]. The aim of the current study was to explore participant engagement in the ManUp intervention using a conceptual framework [30] and to inform future research in the field. Although not conclusive, the current study provides some insight into what personal attributes of middle-aged males (such as their key motives and goals for participating) and attributes of the intervention materials (such as usability, control, and interactivity) may impact on user engagement in this group. When considered in the context of previous research, these findings will be helpful for informing the design and implementation of future health behavior interventions for males and assist researchers and practitioners to engage males in health behaviors.

Comparison to Previous Research

The desirable intervention components reported in this study are similar to those reported in previous (atheoretical) qualitative studies exploring participant's experiences with Web-based interventions [40,41]. Participants in Morgan et al's [40] Australian self-help, exercise, diet, and information technology (SHED-IT) intervention, an Internet-based weight loss program designed specifically for men [41], found the use of a calorie converter website that provided instant and visual feedback an invaluable part of the program, especially for education about foods and for self-monitoring. Participants also reported that email feedback was helpful, but felt they would have benefited more if the information provided was more specific to them personally. SHED-IT participants were not interested in the forum facility of the website, which was designed to provide them with an opportunity to engage in discussions with other men about weight loss. Participants in Ferney and Marshall's [42] study (including both males and females) reported that the overall usability of the website was extremely important to them and that engagement in the website would be better sustained if there were more interactive features such as self-reported progress charts allowing users to set goals and monitor their progress, and if they received regular newsletters via email. They also suggested that a forum would help encourage engagement by offering a social support network along with other helpful advice and suggestions. Interestingly, in randomized trials associated with both of these previous qualitative studies, participants did not use forum features of the website [41,43]. The current study did not include a forum feature, rather the ability to post comments on their own or another user's profile page was included, and this was not widely used by participants. It may be that utilization of the forum is dependent on social environmental factors such as the presence of a forum moderator for participants to interact with. In the current study, the low usage of the comments feature may be due to participants not knowing each other and being reluctant to comment or interact with unknown people. Future research is needed to explore this further. One website component that was not discussed by participants in the current study, but did emerge as an important factor in both of the aforementioned studies, was the speed of the website. In both of these previous studies, participants reported dissatisfaction and reduced use of the website if the loading time was slow [27,28].

Implications for Practice

The findings of this study provide some insight into how we may improve engagement among males in Web-based behavior change interventions targeting physical activity and nutrition. First, as weight management appears to be a key motivator for many males participating in Web-based programs, participant engagement (in terms of recruitment and content) may be higher if weight loss is also highlighted as an intervention outcome. Findings from the SHED-IT trial showed that how the weight loss intervention is framed is important and suggest that programs that are framed as nonintrusive and flexible are most appealing [27]. Second, as participant's experience of the intervention (positive and negative) seemed to be guided by their initial expectations, managing outcome expectations from the outset and avoiding violations of these expectations may help to improve engagement, retention, and maintenance [30,31]. This could be achieved in the following ways: (1) by ensuring recruitment information adequately explains the aim, content, and structure of the intervention program; (2) by educating participants about the health outcomes associated with adhering to the intervention protocol; (3) by allowing participants to set their own goals; and (4) by ensuring participants set goals that are both achievable and in line with their desired outcomes. The use of positive reinforcement (internal or external) may also be helpful, especially in cases where outcomes may not be immediate (eg, disease prevention) [30,31]. Finally, participants provided several suggestions regarding how to improve website usability and intervention content which may improve efficacy, engagement, and maintenance in future interventions. As some of these suggestions (namely a facility to report IT-based issues and links providing further lifestyle information) were actually included on the website, this may suggest potential user navigation issues, communication issues (eg, use of the word “bug” for computer issue), lack of use of the IT-based platform, and/or that the website did not sufficiently “grab” the attention of some participants to encourage more elaborate use of the site. These issues highlight that researchers and practitioners need to consider the attributes of user disengagement (as well as engagement) when designing websites. This is particularly so for disengagement that occurs due to negative emotions, such as feeling frustrated due to usability issues with the website or feeling bored due to lack of interactivity and/or novelty of the content.

Strengths and Limitations

A major strength of this study is that it provides a greater understanding of what males want in terms of Web-based health behavior interventions. Males are a hard-to-reach population [9,10]. As such, little male specific research has been undertaken and best practice intervention approaches targeting males have not been identified. This research directs some insight into what recruitment and intervention strategies may enhance a male's engagement, retention, and maintenance in these interventions. This is useful information, considering the paucity of research in this area, a male's preference for IT-based strategies compared to face-to-face strategies, and the potential public health impact of such interventions if engagement and maintenance can be achieved. However, there are some limitations that should be acknowledged when interpreting these findings. As not all participants agreed to be contacted to take part in follow-up interviews, the results presented in this manuscript may not be representative of the whole ManUp sample. In addition, the ManUp Trial participants were primarily employed in white-collar and professional occupations, as were the participants of the current study. As such, the findings may not be representative of those in lower socioeconomic positions. While interesting outcomes have been reported, due to the exploratory and qualitative nature of the study (where the focus is on information richness rather than representativeness) [21,22], more comprehensive methodologies, such as intervention research, are now needed to confirm the outcomes revealed by the present study.

Compared to their female counterparts, males have higher age-specific rates of chronic disease (such as heart disease, Type 2 diabetes, obesity, and mental health issues) [11-13] and are less likely to engage in lifestyle modification programs and utilize health services [9,10]. Given this, interventions that appeal to males, which meet their specific needs and that are not resource intensive are required. The development and evaluation of lifestyle modification programs that have a strong theoretical and evidence base, grounded in sound behavioural and communication-based research, and that are tailored to specific at risk subgroups are an important public health response to the growing prevalence of chronic disease and the survival deficit experienced by males. Our study highlights intervention and participant attributes that impacted on the engagement of males participating in a lifestyle modification program. These findings will help inform the design and implementation of future health behavior interventions for males and assist researchers and practitioners to engage males in health behaviors.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
IQR: interquartile range
IT: information technology
RCT: randomized controlled trials
SHED-IT: self-help, exercise, diet, and information technology

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Original Paper

A Smartphone-Based Pain Management App for Adolescents With Cancer: Establishing System Requirements and a Pain Care Algorithm Based on Literature Review, Interviews, and Consensus

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Abstract

Background: Pain that occurs both within and outside of the hospital setting is a common and distressing problem for adolescents with cancer. The use of smartphone technology may facilitate rapid, in-the-moment pain support for this population. To ensure the best possible pain management advice is given, evidence-based and expert-vetted care algorithms and system design features, which are designed using user-centered methods, are required.

Objective: To develop the decision algorithm and system requirements that will inform the pain management advice provided by a real-time smartphone-based pain management app for adolescents with cancer.

Methods: A systematic approach to algorithm development and system design was utilized. Initially, a comprehensive literature review was undertaken to understand the current body of knowledge pertaining to pediatric cancer pain management. A user-centered approach to development was used as the results of the review were disseminated to 15 international experts (clinicians, scientists, and a consumer) in pediatric pain, pediatric oncology and mHealth design, who participated in a 2-day consensus conference. This conference used nominal group technique to develop consensus on important pain inputs, pain management advice, and system design requirements. Using data generated at the conference, a prototype algorithm was developed. Iterative qualitative testing was conducted with adolescents with cancer, as well as pediatric oncology and pain health care providers to vet and refine the developed algorithm and system requirements for the real-time smartphone app.

Results: The systematic literature review established the current state of research related to nonpharmacological pediatric cancer pain management. The 2-day consensus conference established which clinically important pain inputs by adolescents would require action (pain management advice) from the app, the appropriate advice the app should provide to adolescents in pain, and the functional requirements of the app. These results were used to build a detailed prototype algorithm capable of providing adolescents with pain management support based on their individual pain. Analysis of qualitative interviews with 9 multidisciplinary health care professionals and 10 adolescents resulted in 4 themes that helped to adapt the algorithm and requirements to the needs of adolescents. Specifically, themes were overall endorsement of the system, the need for a clinical expert, the need to individualize the system, and changes to the algorithm to improve potential clinical effectiveness.

Conclusions: This study used a phased and user-centered approach to develop a pain management algorithm for adolescents with cancer and the system requirements of an associated app. The smartphone software is currently being created and subsequent work will focus on the usability, feasibility, and effectiveness testing of the app for adolescents with cancer pain.

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KEYWORDS
adolescent; pain; neoplasms; cellular phone; algorithms

Introduction

The Burden of Pain in Adolescents With Cancer

Pain is one of the most distressing symptoms in adolescents with cancer. It is estimated that 49%-62% of adolescents with cancer will experience pain related to the disease and/or associated invasive procedures and treatments [1-3]. Pain negatively affects an adolescent's quality of life [3-5], impedes cancer recovery [6], results in adolescent and family distress [7-10], and is associated with long-term morbidity [11,12]. Pain related to cancer also represents a significant cost burden to the health care system and families [13], with pain being the most common reason for cancer patients to utilize emergency health services [14-16].

Treatment advancements and health care system changes have allowed adolescents with cancer to spend increasing amounts of time in the outpatient setting over the course of their cancer care [17,18]. While this is a welcome change for many adolescents and families, it means that a significant amount of cancer symptoms (including pain) are experienced in an environment where management options may be limited (eg, at home). Despite the impact of cancer on adolescent health quality and cost, very limited research has been conducted on how to best manage outpatient pain in adolescents with cancer.

mHealth Care Solutions for Adolescents

In response to this need, our team aimed to develop a smartphone-based pain app capable of providing adolescents with real-time pain management support. It is intended that this app will enable adolescents to better manage their cancer pain in real-time and in their natural settings. This app will use the PainSquad app our group previously developed [19] as an assessment platform. Specifically, we intend to build upon the PainSquad app by providing adolescents with cancer real-time pain management advice based on their PainSquad pain assessments.

At present, smartphone apps have been designed for and tested in a variety of health conditions and with a variety of patient populations. Conditions that have been targeted by apps include diabetes, alcoholism, cancer, and post-traumatic stress disorder [19-24]. A consistent focus of researchers to date has been on the development of apps to aid in patient self-management of chronic diseases or symptoms. In this capacity, apps may support patient self-monitoring, provide self-care advice, or facilitate interaction with health care providers and peers. Because mHealth is a relatively burgeoning field, few rigorous examinations of the impact of smartphone app interventions on patient, provider, and system outcomes have been conducted, especially in the area of pain [25]. Still, the application of patient-centered e-interventions to health problems has been evaluated in both adults and children in the form of computer-based Internet programs. Developed programs have been created for patients with conditions including arthritis, depression, anxiety, alcoholism, diabetes, and migraine [26-33]. These programs have positive effects across a range of health outcomes related to health status, health-related quality of life, symptom management, and disease knowledge. Further highlighting the potential for positive outcomes related to e-based programs, high rates of adherence with the interventions, low rates of study dropout, and high ratings of intervention acceptability have been observed [27,28,32,34,35].

To maximize the clinical utility and effectiveness of the new pain management app, our group intended to develop evidence-based and clinically appropriate care tools [36]. Specifically, as a pain care tool, an algorithm to guide pain care advice given by the app in response to particular pain inputs was considered to be especially advantageous. Algorithms are readily adaptable for use as part of computerized systems because they include explicit decision points [37] and help to ensure quality care by standardizing clinical decision making [38-40], while also allowing for individualization if guided by a patient's data. The effectiveness of algorithm-informed and e-based cancer symptom monitoring and management has also been demonstrated. Research in the area in adults with cancer has demonstrated >30% decreases in symptom occurrence when care is compared to usual medical regimens [41]. A set of system requirements (eg, key functionalities and features) needed to improve the clinical effectiveness of the app was also considered to be important. These requirements may aid in improving the acceptability of the app to end users, or improve the ability of the app to fit with an institution's policies and workflow [36].

Approaches to the Development of mHealth Interventions

There are inherent challenges (ie, time and resource utilization, need for safe and effective interventions) to the design and eventual evaluation of complex health care interventions. To address these challenges, a phased approach to intervention design and testing has been encouraged [42]. The United Kingdom Medical Research Council (UK MRC), specifically, has proposed a framework to guide the development of well-utilized and effective complex interventions for health care [42,43]. The UK MRC approach can be used by mHealth developers throughout the app design and evaluation phases to minimize resource utilization and maximize potential effectiveness.

In addition, user-centered methods to the design of complex interventions, such as apps, have been repeatedly advocated for in the literature. User-centered design is an approach that grounds the process of product design in the needs and understandings of end users [44-46]. Incorporating stakeholders in all stages of the design of complex interventions means that the resultant products are more likely to be used by end users as intended, which will affect intervention effectiveness [44,45,47]. Critiques of user-centered design, including issues navigating the complex dynamics of multidisciplinary teams, time and financial costs associated with development, have been made [45,47]. However, to date, several studies that have incorporated user-centered design in the development of mHealth interventions have shown the resultant interventions to be well used and/or effective when tested [19,20,36].

Direct quantitative comparisons of products designed using a user-centered approach and those designed using more traditional developer-centered approaches on product usability are now beginning to be conducted. Results of these comparisons will be important in providing further evidence for the usefulness of user-centered design methods. For instance, the efficiency, usability, and safety of a computerized physician order set developed using user-centered design methods has been compared to that developed by the hospital informational technology team [48]. Results indicated that the order set designed with physician input from the onset was significantly less time consuming to complete compared to that designed by computer specialists. When using the order set designed with user-centered principles, physicians also requested significantly less assistance from the research team than when trialing the system designed by computer specialists.

In this paper, the development of clinical tools that will inform pain management advice given by a smartphone app is described. The specific objective of this research was to use a phased-approach (2-day consensus conference and iterative interviewing with system end users) to build, vet, and refine a pain care algorithm and catalogue of system requirements for the adolescent cancer pain management app.

Methods

Phase 1: Multidisciplinary Consensus Conference

Overview and Planning

A 2-day multidisciplinary conference in Toronto, Canada was held to develop consensus regarding the important pain inputs, pain management advice, and feature requirements of the mobile phone-based pain management system for adolescents with cancer. The content and structure of the conference was decided upon using modifications to the methods of a previous and successful health care consensus conference [49]. A facilitator for the meeting with research and clinical expertise in pediatric pain and pediatric oncology, as well as expertise in consensus conference methods and facilitation, was selected to lead the proceedings. Research Ethics Board approval was obtained at the host institution.

A systematic review of the published pediatric oncology pain management literature was conducted prior to the meeting to understand the current body of knowledge pertaining to pediatric cancer pain management. Results of this review, along with the meeting agenda, were disseminated to conference participants in advance of the meeting for their review and consideration.

Participants

Fifteen participants were selected based on their professional and research expertise in pediatric pain, pediatric oncology, or mHealth technology development and testing. Health care experts provided input on the needed clinical aspects of the system, and technology experts provided input on the technical practicality and feasibility of the system suggestions made by clinicians. A consumer (ie, a university educated adult living with chronic pain) was also included. The pain consumer did not have cancer but was asked to participate because of their extensive experience with pain and participation in scientific research and clinical projects. Table 1 outlines the demographic characteristics of conference participants.

Process

This conference used nominal group technique to develop consensus on the necessary features of the smartphone-based pain management system. Nominal group technique is a method used to pool judgment from a group of subject matter experts through quantitative and qualitative data collection methods [50-52]. Briefly, nominal group technique involves the use of a highly structured face-to-face meeting consisting of 2 facilitated rounds of voting on solutions to a problem posed to the group [51,53]. In the consensus conference conducted for the present study, an introductory presentation to conference participants on Day 1 highlighted (1) results of the systematic literature review, (2) overall goals of the 2-day meeting, and (3) reviewed the nominal group method. When the proceedings began, a question was posed to the group (eg, “What are the ‘patient-driven’ pain treatment techniques adolescents may use to manage their pain?”). A list of all questions posed to the group is shown in Multimedia Appendix 1. Each participant then had 2 uninterrupted minutes to address the group with 1 particular answer to the question and their rationale for selecting this answer. Answers were recorded and participants voted on the validity of each answer. Results of the vote were presented to the conference participants by the facilitator and each participant had an additional opportunity to address the group regarding the selected answers. A second round of voting followed. Consensus was considered achieved when 75% of the participants endorsed a given answer. All answers that did not reach 75% endorsement were discarded or reformulated through discussion. Conference proceedings were audio-recorded and field notes were made during both days.

Following the consensus conference, participant answers to the posed questions were used to develop a catalog of system requirements and a standardized pain treatment algorithm. When clarification on the data generated during the conference was required, consensus conference participants were queried by email and provided feedback. Audio-recordings and field notes were also referred to as necessary.

Table 1. Consensus conference participant characteristics (N=15).

Characteristic		n (%)
Expertise		
	Pediatric oncology clinician	7 (57)
	Pediatric pain clinician	4 (27)
	mHealth software design	3 (20)
	Pain consumer	1 (7)
Country of residence		
	Canada	9 (60)
	United States	4 (27)
	Australia	1 (7)
	Sweden	1 (7)
Highest degree/licensure obtained		
	MD PhD	3 (20)
	RN-EC PhD	3 (20)
	MD	2 (13)
	PEng PhD	2 (13)
	PhD Psych	2 (13)
	BA	1 (7)
	BASc MBA	1 (7)
	MN RN-EC	1 (7)

Phase 2: Algorithm Vetting and Refinement

Overview

Prior to commencement of Phase 2 of this study, Research Ethics Board approval was obtained from the participating institution. A catalogue of system requirements and a prototype algorithm were developed based on Phase 1 results and iterative cycles of individual qualitative interviews were conducted with pediatric oncology and pain health care providers and adolescents with cancer to vet and refine the algorithm and requirements. A computer-based functional mock-up of the app was also developed to test with participants to improve their understanding of the intervention under development and focus their recommendations.

Participants

Participants were recruited from 1 large pediatric academic health care institution (Toronto, Canada) over a 3-month period in 2013. Health care professionals were included in the study if they specialized in either pediatric pain or oncology, were English speaking, were from any clinical profession, and had worked for at least 1 year. Health care professionals were excluded if they were in training and had not achieved full licensure. Adolescents who were English speaking, 12-18 years of age, diagnosed with cancer at least 3 months before testing, actively undergoing cancer treatment, and having experienced pain of any intensity in the week preceding testing were eligible to participate. The adolescent exclusion criterion was severe cognitive impairment as identified by a member of their health care team. A convenience sampling strategy, augmented with purposive sampling, was used to attempt to achieve maximum sample variation in age, sex, and diagnosis for adolescents. Maximum variation in profession was sought from health care professionals. This sampling strategy provided information-rich cases and ensured insight from a heterogeneous sample. Characteristics of both groups are shown in Table 2.

Table 2. Qualitative interviewing participant characteristics.

Characteristic		n (%)
Health care professional participants (N=9)		
Expertise		
	Oncology	7 (78)
	Pain	2 (22)
Profession		
	Physician	5 (56)
	Nurse	1 (11)
	Nurse practitioner	1 (11)
	Physical therapist	1 (11)
	Psychologist	1 (11)
Highest degree/licensure obtained		
	MD	3 (33)
	MD MSc	2 (22)
	MScN RN-EC	1 (11)
	PhD Psych	1 (11)
	PT MSc	1 (11)
	RN BScN	1 (11)
Adolescent participants (N=10)		
Age in years, mean (SD, range)		14.9 (2.0, 12.0-17.8)
Years since diagnosis, mean (SD, range)		1.2 (1.6, 0.3-5.0)
Sex		
	Female	3 (30)
	Male	7 (70)
Diagnosis		
	Lymphoma	4 (40)
	Acute myeloid leukemia	3 (30)
	Ewing’s sarcoma	1 (10)
	Osteosarcoma	1 (10)
	Wilm’s tumor	1 (10)
Smartphone ownership		
	No	1 (10)
	Yes	9 (90)
Comfort with smartphones		
	Not at all comfortable	0 (0)
	A little comfortable	0 (0)
	Comfortable	1 (10)
	Very comfortable	9 (90)
Smartphone use per day [a]		
	Less than 7 times	1 (11)
	7-10 times	3 (33)
	Greater than 10 times	5 (56)

[a]Data are for adolescents who own smartphones only (N=9).

Process

Audio-recorded individual interviews were conducted with adolescents with cancer and health care professionals. Interviews were conducted with each participant group until data redundancy or the point when no new data were gathered that had not previously been categorized [54]. Each adolescent participant completed brief demographic and disease-related questionnaires, as well as a survey related to smartphone use. Additional information was obtained from medical charts as needed. Each interview lasted between 20 and 45 minutes. Semistructured interview guides were used to lead the discussion. Participants were given a brief description of the app and its intended function. Adolescent participants were additionally shown a semifunctional mock-up of the app using laptop-based smartphone emulator software. Very early in the interview process, it became clear that adolescents were not comfortable commenting on and critiquing the developed algorithm. As such, the process of algorithm vetting was conducted only with health care professionals because they are accustomed to algorithm use in the clinical setting and could provide valuable clinical insight.

Interview questions moved from general to specific and focused on eliciting adolescent and health care professional perceptions and suggestions on the system and algorithm [55,56]. The interview guides used with both adolescent and health care professional participants are shown in Multimedia Appendix 2. The interviewer recorded field notes on participant comfort with the interview process and other nonverbal communication. All audio-recorded interviews were transcribed and entered into NVivo 10.0 software [57] for coding. Field notes were also transcribed and coded alongside transcripts using NVivo 10.0.

Analysis

The qualitative data analysis process began as soon as the first interview was conducted. Two people independently conducted data analyses and discussed themes that emerged from the interviews with reference to field note data. Discrepancies in opinion were resolved using group discussion with a third party. A conventional qualitative content analysis approach was used to code data [58]. Specifically, each analyst independently made notes on impressions and thoughts (codes) related to the interview, according to the study objectives [55]. Codes were then grouped into meaningful categories or themes that reflected perceptions and suggestions for the smartphone-based pain management system and its clinical algorithm. Changes to the catalogue of system requirements and the algorithm were made following individual interviews. Further interviews were conducted until neither the adolescents nor health care professionals had further suggestions for changes. All descriptive quantitative data (for both study phases) were analyzed using SAS 9.1 software [59].

Results

Phase 1: Multidisciplinary Consensus Conference

Overview

The 2-day consensus conference established the key elements of the smartphone pain management system, which could be used to build the catalogue of system requirements and design the preliminary pain care algorithm.

Clinically Important Pain Inputs by Adolescents

Clinically important pain inputs defined the clinical characteristics of an adolescent's pain experience that should result in pain management support from the app. Specifically, a clinically important pain input represented a threshold of adolescent-reported pain that facilitates the generation of automated help. Using the nominal group technique, 11 pain inputs were originally suggested by clinical experts. Following voting and a second round of discussion, 4 inputs were retained as thresholds for system-delivered pain management advice. These adolescent inputs were (1) pain of any severity now, (2) pain of any severity in the previous 12 hours, (3) pain interference with activities of daily living, and (4) a sense of not being able to control pain. Below, a clinical psychologist discussed the rationale for including multidimensional pain assessment responses as important inputs:

"We've talked a lot about assessing the intensity of pain…but from the psychology side one of the missing ingredients is the interpretation of pain in some way…So, it becomes important to understand how someone is coping with pain and the emotional climate when pain is occurring…because pain interpretation is an important part of self-management techniques."

Appropriate Pain Management Advice From the System

The appropriate pain management advice, which the smartphone system could provide to adolescents, was also established. Pain management advice was grouped as being pharmacological, physical, or psychological in nature. Endorsement for this grouping is illustrated in a quote from a pediatric pain management expert:

"I agree that you need the broad categories up front. And then, you know, you may…click on a selection and you have everything within it and you can delve in a bit deeper for some suggestions about things you might use."

Clinical experts concentrated their suggestions on pain management advice that was considered appropriate for an adolescent to undertake on their own. Therefore, complex pain management strategies, or strategies requiring advanced clinical training and licensure (eg, medication adjustments), were not suggested as potential advice for adolescents.

Consensus conference participants suggested 2 pharmacological options, which were retained throughout voting. Pharmacological options were reminders to take prescribed medications. Six physical strategies were suggested and 4 were retained after both rounds of voting, including suggestions such as the use of hot/cold therapies. Eighteen psychological pain management therapies were originally suggested, with 9 being retained after voting. Psychological recommendations included using distraction and seeking social support, among others.

System Requirements of the Smartphone-Based Pain Management System

Finally, nominal group technique established the needed system functionalities to maximize the effectiveness of the app. Following 2 rounds of voting, 5 requirements were retained and included in the smartphone system design. Table 3 details the system requirements and the rationale for including each in the pain management system.

Table 3. Requirements of the smartphone-based pain management app based on expert consensus

Design feature	Feature details	Rationale for feature	Representative health care professional quote
Truncated ad hoc pain assessment	In addition to scheduled long-form morning and evening pain assessments, adolescents will have the ability to complete a truncated (short-form) pain assessment on an ad hoc basis.	The ad hoc assessment will provide the ability to complete a pain assessment and receive timely, 'in-the-moment' pain management advice during pain episodes. A truncated assessment for ad hoc reports will minimize response burden for adolescents.	*If [kids] miss that morning window to complete a report, what happens? They should be able to log pain when they have pain.*
Delivery of multiple different pain management recommendations	Adolescent-logged pain data will drive the app's provision of a list of several user-selectable pain management recommendations. The pain management algorithm will determine the generated list.	The provision of several different pain management recommendations will minimize the chance that an adolescent is provided with undesirable or inconvenient advice. Note: The system will recognize "pain emergencies" (eg, sustained severe pain based on historically saved survey records) and recommend emergency action.	*And I think we should take into consideration your point…and make sure that we give [a variety of therapies] that work over a variety of training and developmental stages.*
Access to a selected pain management recommendation	Upon selection of a pain management recommendation, adolescents will be able to access this pain management strategy via the app (eg, if 'listen to music' is selected, the app will link available music on the phone).	Direct access to the pain management strategy will minimize time-to-intervention and will maximize automation of tasks to improve the user-experience. Note: Direct access will not be available for all recommendations (eg, talk to your parent).	*We could also think about, you know, 'are there videos or something that you could embed in the app?' Because that app could be really good at providing [access to] those types of things.*
Pain re-assessment	Pain will be re-assessed 1 hour following a pain management recommendation.	A follow-up assessment should be conducted to assess pain after the management recommendation. If an adolescent remains in pain, another recommendation should be made.	*Is there some capacity for a reminder alarm for a re-assessment. So that you learn in real-time how effective each of these things are.*
Capacity to prevent or mitigate procedural pain	Adolescents will have the ability to inform the system of upcoming painful procedures (eg, venipuncture) and receive advice on pain prevention or mitigation strategies (eg, 'remember to listen to a favorite song').	To be as comprehensive as possible in managing adolescent cancer-related pain, the app should endeavor to prevent and mitigate procedural pain.	*A kid's going in for a procedure sometime in the future…we're going to have a toolbox that's ready for procedures. And the question is what's in that toolbox for something like a finger-stick all the way up to something more invasive.*

Phase 2: System Refinement and Algorithm Vetting

Overall Endorsement of the System

All participants endorsed the smartphone system and thought that it would be beneficial to adolescents with cancer pain. Specific beneficial aspects of the system from the point of health care professionals included the ability to manage pain the moment it occurs and to intervene when adolescents experience cancer pain in their home environments. The benefits of the system as cited by adolescents included having a record of pain and pain care to discuss with their health care team at subsequent clinic visits, the ability to connect through the system with other adolescents with cancer, and the ability to manage pain the moment it occurs, including through the use of several psychological and physical management strategies. Adolescent endorsement of the ability to receive several diverse pain management strategies is highlighted in the quote below.

"[I like] that there's different options available. It's not like, 'Ok, take this medication or something'. Yeah, I think I like that about the app…Like, you can learn more about pain and…you know, you could like write a journal too."

Addition of a Clinical Expert

Overwhelmingly, both oncology health care professionals and adolescents endorsed the inclusion of a clinical expert in the smartphone system design. The app was originally designed as a stand-alone system that would provide pain management advice to adolescents without the active input of a health care professional. However, following the interview process it was decided that the active input of a clinical expert (eg, an oncology-trained registered nurse) would improve both the effectiveness and safety of the system. The system design was then changed so that adolescent pain reports considered clinically important (eg, 3 consecutive reports of moderate-to-severe pain [pain ≥ 4/10]) will trigger an email alert to a registered nurse. The nurse will then contact the adolescent to assist in clinical decision making. A representative quote from an adolescent about the addition of a health care professional is below:

"Um, if [a health care professional] contacts you, I think that also makes sense. But, um, like I'm not sure if you need them to contact for every single pain. But, I think if it falls under certain categories then that'll be good."

Individualization of the System

Both health care professionals and adolescents recognized that individualization of pain management advice is important. Both groups highlighted that individuals may respond to pain management advice uniquely based on their personal characteristics and preferences. One adolescent stated:

"I don't know, I think it depends on the person, I think. Like, I wouldn't mind it talking to my parents, but that's just me I guess."

As such, a mechanism that allows adolescents to rate the likability and effectiveness of the pain management advice the system offers was added to the design. Through this mechanism, when future pain management advice is given to adolescents, the advice adolescents liked and used most often will be offered first. A capacity for the system to individualize pain management advice to a specific adolescent was endorsed by health care professionals as highlighted in the below quote:

"You can kind of think about this as an N of 1 trial each time somebody is doing it. So if there is a way to build in that learning, then ultimately [the app] becomes evidence-based for that particular person."

Vetting of the Algorithm With Health Care Professionals

Vetting of the algorithm occurred with health care professionals who recommended changes to the algorithm based on their clinical and research expertise. Required major changes included revision of the threshold for a change in pain management, suggestion that the wording used in app be changed to improve an adolescent's ability to understand questions and management advice, and the recommendation that adolescents be informed regarding time to contact from the registered nurse monitoring the system. For instance, a health care professional said this regarding the wording used in this app:

"This could be clearer in terms of the language here. It's almost like in needs to be black and white, 'take your narcotic'."

In response to these required changes: (1) the threshold for the system to offer additional advice was lowered so that if pain was not improved 1 hour after initial management advice was made, new advice may be delivered; (2) adolescent-appropriate wording of system questions and management instructions was used; and (3) an alert was added to the system to tell adolescents that a health care provider was being informed about their pain. The alert further stated that if the adolescent did not hear from the health care professional within a given amount of time, they should talk to their caregivers and/or seek medical help. Following these revisions, clinicians suggested no further changes and the algorithm was considered finalized.

Discussion

Principal Findings

The pain decision algorithm and catalogue of pain management system requirements were successfully developed using a 2-day consensus conference with clinical and technology experts, and an iterative interview process with system end users (ie, health care professionals and adolescents with cancer). Through the methods presented here, we were able to establish core pain inputs from adolescents, appropriate pain management advice, and necessary system requirements for a remote real-time pain management system.

The stepwise approach endorsed by the UK MRC has provided an important framework for the development of the smartphone-based system and its algorithm. The systematic review conducted before the consensus conference enabled understanding of the current scientific evidence regarding pain management in adolescents with cancer. The review was required to provide the necessary data for the development of a system that delivers cancer-specific evidence-based pain management support to adolescents. The 2-day consensus conference provided data that were synthesized to develop the pain management algorithm that is fundamental to effective system performance. The use of nominal group technique at this conference successfully enabled the pooling of thought and opinion from a highly diverse group of experts. Qualitative interviewing with both adolescents and health care professionals then provided critical feedback regarding their perceptions of system and algorithm utility and safety, as well as suggestions for improving overall design and function. Interview data can now be used to inform the user-centered design principles for the development of the app software [46].

Internet- and mobile-based interventions to manage symptoms of diseases such as cancer have the potential capacity to provide patients with cost-effective, accessible, and high-quality treatments [29,60-62]. Because of these perceived benefits, using e-based health interventions as the initial step in a stepped-care approach to patient care has been suggested [29]. A stepped-care approach as a model for care describes the initial provision of a form of care to all patients that is typically cost-effective and low intensity. Care is then escalated for patients who do not sufficiently benefit clinically from the initial intervention. On the other hand, a stratified model to the delivery of care, including e-based care, may be used. In this case, the selection of an initial intervention is based on an a priori assessment of a given patient.

Lipton et al [31] conducted a randomized trial to assess the effect of each of the stepped-care and stratified models on headache pain intensity and disability in a group of adults. Results showed that patients stratified to care based on headache disability at study onset had a significantly better response to treatment than those treated using a stepped care approach. With respect to the adolescent pain management app in question, the effectiveness of the intervention is likely to vary depending on an adolescent's pain and their social, psychological, and demographic characteristics. A stratified approach to delivering the app as a health care intervention may therefore be warranted. However, the criteria by which to allocate adolescents to a given strata remains to be established.

Comparison With Prior Work

The methodology used in this study has been used previously to develop care algorithms and assessment tools. For instance, using qualitative interviewing with clinical experts and iterative refinement, a rule-set for the remote telemonitoring of patients with heart failure was developed [36]. The monitoring system based on the rule-set was tested in a randomized control trial, which showed the preliminary effectiveness of rule-set-based e-systems [63]. Nominal group technique has also recently been used to develop consensus on the needed elements of an electronic symptom assessment questionnaire for children with cancer [64]. The authors of this study were able to develop a preliminary version of a new assessment tool and attributed a part of the success to the use of nominal group technique. Finally, similar consensus conference methodology has been used to develop an e-based pain assessment questionnaire for use in routine pediatric rheumatology [49], which is currently undergoing validity and reliability testing.

The finding that the inclusion of a clinical expert in the system design was recommended as an important means to improve system effectiveness is consistent with previously published research. For instance, the importance of clinician involvement has been shown in a 2012 systematic review of the content, structure, and efficacy of pain self-management programs for adults with cancer [65]. In this review, those studies with the largest effect sizes in terms of pain reduction included the interaction between clinicians and study participants. Second, in a meta-analysis of Internet-based cognitive behavioral therapy for depression and anxiety, interventions that included therapist support were more effective than those without. Specifically, interventions with support had a large pooled mean effect size (1.0; 95%CI, 0.75-1.24), while those without support had a small pooled mean effect size (0.26; 95%CI, 0.08-0.44) [26]. Together, these results suggest that interventions across a variety of symptoms and diseases may benefit from the inclusion of a clinical expert. Furthermore, although the optimal of dose of clinician contact in Internet- and mobile-based interventions has not been established [61], these results also provide support for the inclusion of such an expert in the pain management app discussed presently.

Limitations

The results presented in this study are tempered by limitations that should be addressed. For instance, although we used qualitative interviewing with adolescents to vet and refine the algorithm, we did not include patients or families in the consensus conference. The inclusion of adolescents with cancer and their parents would have provided valuable insight into end-user perceptions of system and algorithm utility that could have streamlined the interviewing process. An additional limitation is that the developed algorithm and list of system features were developed through qualitative interviewing at 1 hematology/oncology center. The smartphone-based app with health care provider support described here is therefore optimized to the clinical practices and workflow of this center. Adolescents with cancer who are from multiple centers will be enrolled in feasibility testing of the pain management app, which will afford the opportunity to examine the practicality of our system across diverse care environments.

Conclusions

The use of a phased user-centered approach used in the present study allowed for the efficient and successful development of the decision algorithm and smartphone system design. The methodology presented here may represent a viable roadmap for the creation of e-based health systems and care algorithms for a variety of health conditions and populations. Next steps will involve development of the real-time pain management app interface as well as usability and feasibility testing of the system with adolescents. Successful development of this smartphone-based pain management app has the potential to improve pain management for adolescents with cancer, minimize barriers to optimal symptom treatment, and enhance interaction with health care providers to improve quality of life. Moreover, the model of technology-assisted care represented by this app has the potential to usher in a paradigm shift in the care of patients with a variety of chronic and life-threatening illnesses. If ultimately effective, this app as a care model represents an excellent opportunity to improve patient care through remotely monitoring and efficiently managing a range of physical and psychological health conditions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Voting questions for consensus conference.

[PDF File (Adobe PDF File), 138KB - resprot_v3i1e15_app1.pdf]

Multimedia Appendix 2

Guide for individual algorithm vetting and refinement interviews.

[PDF File (Adobe PDF File), 49KB - resprot_v3i1e15_app2.pdf]

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Abbreviations

UK MRC: United Kingdom medical research council

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Original Paper

Combining Users’ Needs With Health Behavior Models in Designing an Internet- and Mobile-Based Intervention for Physical Activity in Cardiac Rehabilitation

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Abstract

Background: Internet-based physical activity interventions have great potential in supporting patients in cardiac rehabilitation. Health behavior change theories and user input are identified as important contributors in the effectiveness of the interventions, but they are rarely combined in a systematic way in the design of the interventions.

Objective: The aim of this study is to identify the appropriate theoretical framework, along with the needs of the users of a physical activity intervention for cardiac rehabilitation, and to combine them into an effective Internet- and mobile-based intervention.

Methods: We explain the theoretical framework of the intervention in a narrative overview of the existing health behavior change literature as it applies to physical activity. We also conducted a focus group with 11 participants of a cardiac rehabilitation program and used thematic analysis to identify and analyze patterns of meaning in the transcribed data.

Results: We chose stage-based approaches, specifically the transtheoretical model and the health action process approach as our main framework for tailoring, supplemented with other theoretical concepts such as regulatory focus within the appropriate stages. From the thematic analysis of the focus group data, we identified seven themes: (1) social, (2) motivation, (3) integration into everyday life, (4) information, (5) planning, (6) monitoring and feedback, and (7) concerns and potential problems. The final design of the intervention was based on both the theoretical review and the user input, and it is explained in detail.

Conclusions: We applied a combination of health behavioral theory and user input in designing our intervention. We think this is a promising design approach with the potential to combine the high efficacy of theory-based interventions with the higher perceived usefulness of interventions designed according to user input.

Trial Registration: Clinicaltrials.gov NCT01223170; http://clinicaltrials.gov/show/NCT01223170 (Archived by WebCite at http://www.webcitation.org/6M5FqT9Q2).

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KEYWORDS

focus group; design methodology; user involvement; user needs; health behavior models; tailoring; SMS; Internet; cardiac rehabilitation; smoking cessation; physical activity

Introduction

Burden of Cardiovascular Diseases

The contribution of noncommunicable diseases to the burden of disease has increased over the last decades, especially in Western Europe. Cardiovascular diseases clearly have an important impact in this, ranked at the top of the causes of death with an increasing share in the burden of disease from 1990 to 2010 [1].

Internet-Based Interventions to Support Physical Activity

In the same period the world experienced the explosive development of the Internet. Nowadays, use of the Internet is so widespread in many countries that it has become a popular means of delivering interventions to assist in diagnosis, treatment, prevention of illness, and the promotion of health. The number of health-related websites was estimated in the year 2000 to be more than 100,000, while today there are so many that it is not even possible to find an accurate estimate [2]. It would also be risky to estimate the general impact of Internet use on the burden of disease, but research shows that under certain conditions it can be a very useful tool in supporting self-management [3-9]. More specifically, there is the potential to influence physical activity that is very important for the prevention and the rehabilitation of cardiovascular diseases [7,10].

The effectiveness of Internet-based health interventions is connected with the adoption of the appropriate theoretical framework [11-14], while the viability of these interventions is associated with strong user involvement in their design [15]. For that reason, we are using a methodological approach that is combining the user-input and health behavioral theory to develop an Internet- and mobile-based physical activity intervention for cardiac rehabilitation.

Following our suggested process, we first review relevant models of health behavior and discuss our choice of the theoretical background for the intervention. We next present results from a user needs focus group, and finally, we describe the resulting design of the intervention.

Methods

Construction of Theoretical Framework

The choice of a theoretical framework is explained through a narrative overview and discussion of models of health behaviors in light of applicability to longitudinal tailoring. Then, theoretical concepts fitting well within different stages of behavioral change are reviewed.

User Needs Focus Group

The user needs focus group took place in February 2010 at the Skibotn Rehabilitation Center in Norway. There were 3 women with mean age 64.3 years and 8 men with mean age 59.4 years, all attending the center's cardiac rehabilitation program that month. The focus group was conducted at the center during the fourth and last week of the program's duration and lasted one hour.

The discussion was based on an interview guide, but it was stressed that the goal would be an open discussion. The first part of the focus group was about needs, thoughts, and ideas of the users regarding support to increase physical activity and the corresponding role of technology. During this first part, the interviewers didn't present any of the ideas for the intervention. The second part started with a very short presentation of some of the researchers' ideas regarding the proposed intervention. The discussion that started in parallel with the presentation, and continued afterwards, focused on the opinions and reflections of the participants on the proposed concepts and intervention features. There were two interviewers that led the discussion.

The focus group discussion was audio recorded, verbatim transcribed, and analyzed with thematic analysis. Of the two researchers that analyzed the data, the first is a nurse with work experience in cardiovascular diseases. By the time of the focus group, the cardiovascular nurse had already developed some ideas regarding the intervention based on discussions with personnel at the rehabilitation center and on previous experiences with heart patients. The second researcher is a health psychologist with previous experience in developing Internet-based as well as tailored, health behavior change interventions, thus interpreting the data through glasses tinted by health behavior theories.

Results

Narrative Overview of Background for Theoretical Framework

Tailoring and Models of Health Behavioral Change

In this section, we present the rationale behind the choice of the theoretical framework for the Internet- and mobile-based intervention for physical activity. At first we explain why we use tailoring, an effective element of persuasive technology [15]. Then we present the different models of health behaviors, and how we combined them to comprise the core of the tailoring algorithm.

Tailoring

Bibliographic evidence is pointing toward the effectiveness and usefulness of tailoring. For example, perceived program relevance and amount of the materials read are found to be mediators of the effect of an Internet-based smoking cessation program [16]. A tailored intervention is one that is adapted to the characteristics of the individual, typically based on responses to a questionnaire [17]. Tailoring relies on three main methods: (1) personalization, (2) adaptation, and (3) feedback [18]. Personalization involves referring to the recipient in the text on the basis of details such as first name, age, gender, or hometown. Adaptation concerns the content of the text itself, which can be tailored according to a variety of theories. Feedback is a widely used feature in which the recipient is informed about scores on a scale, and how to interpret the results. In newer, more complex tailoring, these features are often combined, and the components of the Internet-based intervention may also be tailored.

Tailored health messages are in general perceived as more interesting and personally relevant, liked better, read more thoroughly, discussed more, and remembered better compared to nontailored educational material [19-22]. Personalization shows the most consistent effects of being tailored to [23,24] and involves referring to the recipient in the text on the basis of details such as first name, age, gender, or hometown. This is consistent with self-referent encoding, that all information that we associate with ourselves, is more easily noticed, stored, and retrieved [25].

Models of Health Behavioral Change

Continuum Versus Stage-Based Models of Behavioral Change

Models for health behavior can be roughly divided into two categories: (1) continuum models, and (2) stage-based models [26]. Velicer and Prochaska [27] argue that Schwarzer's [26] division between continuum versus stage-based models can be conceptualized as theories of behavior versus theories of behavior change. The continuum models, to a great extent, are based on correlational studies of predictors of an on-going behavior, whereas the latter, to a greater extent, have studied predictors of transitional processes into a greater readiness for change. For the purpose of clarifying different implications for tailoring, we will continue our discussion with Schwarzer's dichotomy.

Continuum models describe antecedents of behavioral change with the implicit assumptions that the sum of these antecedents needs to be above a certain threshold for a behavior to occur. Models vary as to whether and which variables are necessary and sufficient for behavioral change to happen. For instance, several models agree that having an intention to perform a behavior is necessary (but not sufficient) for the actual behavior to occur. Stage-based models, on the other hand, assume that there are distinct stages characterized by specific cognitive processes and motivational needs that the individual should pass through in sequence to get to behavioral change.

The Intention-Behavior Gap

Researchers within both kinds of models agree that there is a "gap" between intention and behavior [28], but a discussion with important implications for interventions is whether (for instance) intention is a static (indicator) or a dynamic (and changeable) variable [27]. Before and after forming an intention is a common chasm across several stage-based models [26], and is also seen as an important distinction demanding different strategies in nontheoretical methods such as motivational interviewing [29], which has been successful in supporting people in changing a host of health behaviors [30,31], including those relevant to cardiovascular disease risk [32-35]. Tailoring based on the continuum kind of models would imply that one determines which variables are "low" and then aims the intervention at increasing these, while tailoring based on stage-based models will identify the stages and deliver an intervention directed at the described processes within the particular stage.

Noar et al [36] found in their meta-analysis of tailored interventions that those based on the Transtheoretical model (TTM) [37] had the greatest effect. They further found that the number and type of theoretical concepts tailored on, including stage of change and processes of change, were associated with behavior change [36]. In general, physical activity interventions based on the TTM have not been very effective. Adams and White [38] point out potential reasons why this may be-that physical activity is complex, and that several of the reviewed interventions might not have optimally operationalized the TTM concepts. In other words, how we tailor to the relevant needs and processes within each stage is at least as important as the overarching framework (ie, the stages).

Starting From Stage of Change

As the first step in our tailoring, the participants' stage of change is assessed using the University of Rhode Island Change Assessment - Exercise 2 (URICA-E2) [39]. In the next step, they follow different paths depending on the stage, starting with feedback on the current stage. As can be seen in Table 1, in addition to the variables described in the TTM [37], we have added some specific constructs from other theories according to what we see to be a good fit to the relevant processes in each stage. These are described in more detail below, along with our operationalization of these constructs in the tailoring of our physical activity intervention.

Table 1. The five TTM stages enriched with well fitting constructs from several theories.

	Stages from the TTM				
	Precontemplation	Contemplation	Preparation	Action	Maintenance
Relevant psychological constructs in different stages	Consciousness raising [37], Regulatory focus [40,41], Values [29], Environmental reevaluation [37], Outcome expectancies [42], and Supporting autonomy [29]	Decisional balance [37] and Self-reevaluation [37]	Action planning [26], Coping planning [26], Implementation intentions [43], and Self-efficacy for action [26]	Contingency monitoring [37], Countercondi-tioning [37], Stimulus control [37], Helping relationships (TTM) [37], Social support, Self-monitoring rewards, and Self-efficacy for maintenance [26]	Self-efficacy for recovery [26] and Relapse prevention

Regulatory Focus

A variable that we tailor on when we deliver health information to those who are concerned with the pros and cons of behavior change (ie, those in the first two stages) is the individuals' promotion- or prevention-goal orientation (regulatory focus). Regulatory focus theory [40,41] separates those who are primarily motivated by achievement and gaining rewards (promotion) from those who are more concerned about avoiding loss and risk of such (prevention). This has implications for the kind of health information the individual is most affected by, and consequently, how we frame health information. Latimer et al showed that tailoring to regulatory focus (ie, matching it to the individuals' regulatory focus) could increase both physical activity [44] as well as fruit and vegetable intake [45]. Our participants are presented with a regulatory focus assessment (Regulatory Focus Questionnaire-RFQ)[41]. Depending on classification, the participants are sent either prevention- or promotion-framed SMS text messaging (short message service, SMS) messages concerning physical activity over the next two weeks.

Decisional Balance

The balance between the pros and cons of behavior change has been shown to predict readiness to change across a host of health behaviors [46]. Our contemplators are presented with a decisional balance questionnaire [47]. The participant is then presented with immediate feedback according to whether they perceive more pros or cons with regard to regular physical activity. Next, the participant is presented with a list of potential reasons for becoming more physically active, and asked to tick off the relevant ones, before being asked to add some more in free text. This list is displayed on "My Page." "My Page" is the profile page of the intervention where the most important information, the activities and the interaction of the user, and of their friends, are presented as a feed. A more detailed description of the functionality, as developed in combination with the user input, can be found in the section "Functionality" of the website.

Planning

In the planning phase of another stage-based model, the Health Action Process Approach (HAPA) [26,48], one separates action planning from coping planning [49,50]. Action planning refers to the planning of where, when, and how to perform the target behavior, and is thus similar to Gollwitzer's concept implementation intentions [43]. Coping planning, on the other hand, concerns strategies for dealing with anticipated barriers, and is thus strongly connected to self-efficacy. From the preparation stage and onwards, the participant is asked to plan their physical activity in the "Exercise Agenda." There, they can add several entries by planning what kind of activity, when, and where for each entry, thus forming an implementation intention. After completing planning, they are assessed for self-efficacy for this action plan. If it is very low, the user is asked to revise the action plan to make it more realistic.

Self-Efficacy

The concept self-efficacy refers to the degree to which an individual perceives that he or she can perform a particular behavior. The concept of self-efficacy stems from the social cognitive theory [42], but since self-efficacy is so closely related to behavior change, several researchers have assimilated it into other theories [26,29,51,52]. In the context of the two-stage HAPA [26], self-efficacy is important throughout behavior initiation, action, and maintenance, but HAPA distinguishes three kinds of self-efficacies: (1) action self-efficacy, you can perform the target behavior; (2) maintenance self-efficacy, you can maintain the target behavior despite barriers; and (3) recovery self-efficacy, you believe that you can succeed after a setback. While action self-efficacy in the HAPA model is directly related to intention, it is only indirectly related to behavior mediated via intention. Maintenance and recovery self-efficacy are on the other hand not related to intention, but directly related to behavior [26]. All these self-efficacies are assessed in the preceding stage. If the self-efficacy is low or moderate, the participant receives SMS messages concerning self-efficacy for the relevant stage over the next two weeks and also is asked to identify potential barriers (selecting from a list and in free text), and to generate strategies to address them. Strategies are then listed on "My Page."

Social Support

Social support is important both directly for health status and via its influence on health behaviors [53]. In the TTM, social support is referred to as helping relationships and is seen as relevant to the action stage [37]. Social support is also found to increase throughout the stages [54]. We assess and give immediate feedback on social support in the preparation stage.

Relapse Prevention

Relapse prevention is trying to identify, prevent, or prepare to deal with high-risk situations. The most important goal is to make a plan for getting back to the plan; to prepare for continuing with the new health behavior in the event of a lapse, rather than giving in, perceiving the situation as all gains are lost, and all effort wasted, thus turning the lapse into a full-blown relapse [55]. Relapse prevention is mostly considered in relation to giving up substance use (eg, smoking cessation) [56], but we consider it relevant for other health behaviors too, and send SMS messages about relapse prevention to those of our participants in the maintenance stage that have indicated low to moderate self-efficacy for maintenance.

The Focus Group

The Seven Themes

There are seven main themes that were identified in the focus group: (1) *social*, (2) *motivation*, (3) *integration to everyday life*, (4) *information*, (5) *planning*, (6) *monitoring and feedback*, and (7) *concerns/potential problems*. The themes are presented in the thematic map (Figure 1 shows these themes, also see Multimedia Appendix 1 for these themes). The results and the thematic map presented in this paper are a slightly more revised version than the one used for the development of the intervention, in the direction of improved synthesis of the data.

Figure 1. Thematic map of the focus group themes.

Social

The largest pattern of meaning that appeared in the focus group was the *social* theme. In addition to its high level of frequency, this theme is the one that included the most subthemes and codes. Under this theme we have included ideas, thoughts, and needs, expressed by the users referring to companionship, belonging to a group, or communication with others.

One of the dimensions of this theme repeatedly expressed by the participants was the importance of not being alone in the behavior change endeavour. This was an important factor that helped them during their stay in the rehabilitation center, and it was something that they wished to maintain after they were discharged. In some cases, they were referring to the importance of staying connected with the very same people with whom they shared the rehabilitation program.

> *I am like this, that I need a bit of this motivation from the others also, to try alone, this is…This is the problem…so...this here with the local team, this can be a reasonable angle of this also, or approach eeh…attach yourself to the local team, also continue this you have started with them now…for example.* [Male]

The importance and the benefits of belonging to a group were further explained. Peer support is the main benefit the participants seemed to enjoy at the rehabilitation center, and is one of the mechanisms through which they can help each other.

> *A forum of course is also something to talk about, a brilliant thing…talk with each other in a forum and ask things…put out eeh…* [Male 1]
>
> *you should have a forum only between… peers…* [Male 2]

As expected, the peer support appears to be connected with the functionality of the forum. In the next extract, we also see the concept of the social obligation that the participants recognize as a possible mechanism to maintain or increase physical activity. The participants feel the obligation to do something that their peers are doing or ask them to do.

> *I am saying that if we have it fixed, one time per week, that we send a message to each other and then, then you feel committed to say yes, for as long as you like…Yes, then you must have something else that really, you have something else that you have to do, or else…you just do it.* [Female]

In another instance, the social obligation is connected with a request for a training diary combined with the forum.

> *Training diary on the Internet…And also have a group where someone can subscribe to a forum, or have a…to brag…yesterday I walked for an hour and today I have been to the training…and tomorrow I have thought, yes…So, it is like this that someone gets to, a bit, a bit like a competition, internally between each of us. We will train, as much as possible we will commit to ourselves a bit more also.* [Male]

Commitment is also related to a healthy competition with each other. Through the forum, the participants suggested that they would succeed simply to encourage each other, an important mechanism related to the *social* theme.

> *Yes, yes I think that for many…if you take as basis the situation we are in now and you want to prolong it as long as possible, all of us want to stay here four weeks more, isn't it? And four weeks after that, life is great here…But to stay in touch with the "gang," so, so I think that the most of us would think that, yes, the Internet, the approach that is best, I don't have any faith in SMS, but eeh, Internet, a forum yes. To keep up, keep the spirit of the team up, the mood, the good flow.* [Male]

The participants also had specific suggestions regarding the functionality of the forum. For example, they were positive about having two levels of access, one reserved only for the members of the same monthly group. In this level, they would like to share photos with the other members, maintaining their bonds after the rehabilitation stay. The social dimension of the forum was not only mentioned in relation to the other participants, but also included the personnel of the center. The participants mentioned that they would like to know that at the forum there are health professionals they can trust to answer their questions.

> *Yes, there should be someone that can answer, that has a clue and that can answer.* [Male]
>
> *There should be professionals too…yes.* [Female]

The fact that Facebook is the largest and most popular social network, and one of the most popular websites in Norway, can explain that users were often inspired by Facebook functionality, and sometimes even explained a desired functionality as "like Facebook." In the same context, the concept of a training buddy was also popular. That is a person that would be paired with that participant, and they would support each other possibly with their physical presence, but mainly through the interaction the Internet tool would provide.

> *Almost like Facebook that…A forum is a living thing, like you come here and just are…new things pop up all the time and…between users…it's alive. (…) Do you want to be my workout friend? (Laughter from the rest of the group)* [Male]

Regarding the choice of technology that would support the social functions of the intervention, participants mentioned the Internet and SMS in both parts of the focus group (in the general discussion and the discussion after the initial ideas were presented). One participant was sceptical to the usefulness of the SMS, but this didn't reflect the opinion of the rest of the group.

Motivation

The theme *motivation* includes ideas and methods believed to influence or capable of influencing the participants' behavior. The theme includes the strong belief that the responsibility for change of behavior is personal. The participants mentioned it mainly in relation to what is going to happen after they leave the rehabilitation center.

> *I believe actually, I believe that someone gets used to it, if we make a system, habits. That it doesn't get too much, that we know that…we go online…and we get our own responsibility of our own training.* [Male 1]
>
> *It is not, it is not that anyone says that you have to cycle. Also, it is made that each does what himself/herself feels.* [Male 2]
>
> *So, so, it requires self-discipline.* [Male 3]

Making a decision to prioritize themselves and the behavioral change was also very central. Prioritization was discussed in several instances as a method to maintain physical activity and generally continue the changes in behavior after the discharge.

> *That we chose to prioritize the demands others have of us.* [Female]
>
> *Down-prioritize ourselves all the time.* [Male 1]
>
> *Got to be better at saying–"No thanks, today I can't." But on Tuesday it doesn't work either, for I'm exercising"* [Male 2]

Integration to Everyday Life

Another theme that emerged from the focus group was *integration to everyday life*. The participants often referred to thoughts and things to do that are helping them to integrate a desirable behavior into their everyday life. In the same way, the participants wanted technology that would assist them in maintaining the desired behavior in a way that also integrates it into their everyday life. Special emphasis was placed on simple changes in the activities of their everyday life that can increase physical activity.

> *I think that someone should not have high expectations of himself, that would make him strive to get there. I believe that you get tired of it, I think you should have only simple changes in your life.* [Male]

The participants also discussed that creating new habits is helpful in changing behavior by integrating the desired behavior into everyday life, mainly by replacing old bad habits. The reverse order also seemed to be possible. By integrating an activity or even a technology into everyday life, an old habit could be replaced with a new good one that would assist in changing behavior.

> *I believe in small simple things like in everyday life, that if someone manages to walk to the store or walk to work maybe…things like that can also be important, instead of taking the elevator, if you are working in a building that you can take the stairs instead of the elevator, if you do it often, it is not bad either…instead of sit in the car and drive a few meters, to walk to the shop instead, so can someone ride a bicycle when it is becomes summer, or go with the chair-sledge…that someone can do things like that, it gets possible. Someone becomes so lazy that doesn't bother, sits in the car, the old habit, instead of just walking.* [Male]

A technology that would help to integrate the desired behavior into everyday life should also be integrated into everyday life. Ubiquitous technology can support behavior change in the challenging situations of everyday life, or remind users of their own commitments.

> *If you could get a message every day, there and then?* [Male 1]
>
> *Have you been good today? No, now you have to go out, time for exercise.* [Male 2]
>
> *Get out you lazy bastard!* [Male 1]
>
> *And it should come on a specific time you have decided to walk today, or go out…* [Male 2]
>
> *Or even better, a couple of hours before…so you won't change your mind.* [Male 1]

Information

Despite being in a rehabilitation program where they could have access to all the information they needed, or maybe because they were there and were experiencing good access to information, the participants of the focus group expressed their need for tools that would help them access the right information for a long time after their discharge. They referred repeatedly to the need to find the right answers, either through a forum or a kind of knowledge bank. They also wanted the health professionals to take an active part in the forum, and specifically for physical activity, provide suggestions for training plans.

> *It should be a forum where you have the opportunity to get…eeh…get the right answers, […] access to a resource, this is what I believe it becomes. It has an effect.* [Male 1]
>
> *What is good with a forum is that everything that is asked and discussed and answered…it stays there, you don't even have to ask, if…if it [the forum] is used a lot, you can just with a simple search find what you need…The hope is that it will become a kind of knowledge bank. And the problems you have experienced like pain and things that you can go in and have a look and talks to others about them.* [Male 2]

Planning

This theme covers a very effective part of the behavior change process. The participants expressed the necessity to plan in advance their physical activity in order to actually do it. First of all, the plans have to be realistic in order to make it possible to achieve them.

> *[…] if we were sportsmen, we would have to climb extremely high. As you say, leave the car, to walk a bit, we have made a lot.* [Male]
>
> *Maybe it is a bit of [your] responsibility, a time schedule with realistic goals.* [Female]

The technical dimension of this theme was expressed with a clear request for a training diary that would help the users plan activity, preferably on a weekly basis so they would avoid being drawn to their old way of behaving, where physical activity was constantly neglected.

> *[…] I believe that what is important with the schedule is that you set it off, you prioritize a bit, you see that okay, that and that day it passes better maybe. So you say at those two days or three days a week, they are mine, then I should train. If you don't make it to a system, it gets difficult, easy to neglect, if you don't put aside time for it, because then it is so many other things that comes in front all the time. Then it becomes neglected, this is anyway my experience. But if you, like what I did before Christmas, before I came here, then I decided that in the evenings I should be going on walking tours. When the children go to lie down, I am going for a tour. And I did it. […] It should come first…or we die, this is how I am thinking…* [Male]

Monitoring and Feedback

The theme of *monitoring and feedback* appears in the second part of the focus group, during the discussion and after the presentation of some specific ideas for the intervention. It refers to the necessity and the requirements related to keeping a record of the physical activity of the users, and how to present it in a meaningful way to them. The discussion was dominated by the previous experiences of some of the participants with monitoring sensors, feedback statistics, and graphs, mainly from commercial products and services. The rest of the group was also interested even if they had no personal experience with the sensors, and generally were positive to the idea.

> *After what I have seen, there is a whole program, and shows graphically also how the climb has been, also the mountains, everything is there. There is also the pulse there. I have been many times in on the Internet and seen how the whole training of the day has been. […] And there you can see them, there is graphic representation, how it has been, up the hill, down the hill and…* [Male]

Concerns and Potential Problems

Despite the positive reception to the idea of an intervention, several concerns and fears for potential problems were expressed during the focus group. Regarding the process of changing behavior, the participants of the focus group were concerned about the obstacles they have to overcome in their effort to maintain or increase physical activity. Lack of training facilities, lack of time, or just going back to their everyday life are possible obstacles that make them question their ability to maintain the desired behavior.

> *We have developed some habits while here. This, this I believe we cannot manage outside. And then we maybe cannot maintain, keep enough habits. We haven't…[…] I live far from people and fatherland, to say it like this. […] Yes, my place is far [from a city]…we have no swimming pool or any big activities. We should just organize our own activities…when we live far, far in a village.* [Male 1]
>
> *For example, 52 weeks that I can use them as I want, but I should try to use them right. [Me] and someone else that has to go to work, we cannot do it equally.* [Male 2]

Along with the concerns about the obstacles in changing behavior were the concerns about relapsing from the desired behavior. For various reasons individuals might stop being physically active for short or long periods of time, and for that case, the participants expressed a need for support to get them back on track.

> *And when you come home and you get back pain, you don't manage to keep up, so you become disappointed and sad, and you feel that, no, I am a loser.* [Male]

The major concerns though, were expressed for the technology. When it came to the usability of the website, the participants suggested that we should consider e-literacy issues and offer training to the users. They also recommended that the website be maintained in such a way that it is constantly updated, with the content remaining politically and religiously neutral and independent. A few participants were sceptical of the SMS technology, believing it was not answering the needs for behavior change. This view was balanced by the request of many other participants to send them reminders and motivational messages to trigger behavior change. The potential risk of high dropout rate from the forum was also discussed.

As in many Internet-based interventions, participants shared another important concern—privacy. They asked to have the choice on what to share with whom.

> *You can choose, if you want it…to make it public…Make it accessible for the others, so…it should be a keystroke or a choice you do […] In periods it might be like that, that you don't want to show it…* [Male]

A female participant also expressed a concern regarding the ability of an intervention to cover the needs of women too. This shows the need for a gender- sensitive approach, mainly by offering additional training where it is needed. Finally, tailoring, a concept very central to the suggested intervention caused scepticism in a few participants. They questioned the ability of technology to provide a satisfying degree of personalization.

> *But it is not possible that you [have] many different [categories], because someone is not so individual that cannot fit in maybe four different…I am thinking like this…I want to believe that to make conclusions from the questionnaire there, that has maybe four different categories…do you know what I mean?…I answer in this way, I belong to category four, Ola*

> *answered that, he belongs in category three, in this way, a bit slack it is,…If it is tailored to 12 different [categories], then it becomes, it becomes very ambitious, I think…* [Male]

The Design of the Intervention

The researchers translated the combination of the theoretical framework and the user input into the technical requirements documentation that was later used by an external collaborator to develop the actual intervention. In Table 2, we list the contribution of the theoretical constructs and the relevant focus group themes in each functionality element of the intervention. The intervention is based on the popular open source content management framework Drupal. The main phase development that produced a functional prototype lasted one year. It was followed by a second phase of six months that included bug fixing by the external collaborator, the implementation of the tailoring algorithm into Drupal, testing, and content development by personnel of the Norwegian Center of Integrated Care and Telemedicine and the Skibotn Rehabilitation Center.

Table 2. Contribution of theory and user input in the functionality included in each element of the intervention.

Elements of the intervention	Relevant theoretical constructs	Relevant focus group themes
Levels of access	-	*Social* and *concerns/potential problems*
Microblog functionality of “My Page”	Social support, Consciousness raising, and Helping relationships (TTM)	*Social* and *motivation*
Activity calendar	Preparation (TTM), Action planning, Contingency monitoring, and Self-monitoring	*Planning, monitoring and feedback, social, information, motivation,* and *integration to everyday life*
Discussion forum	Social support and Helping relationships (TTM)	*Social* and *information*
General information	Consciousness raising and Self-efficacy for action	*Information*
Contact with physiotherapist and technical support	Social support	*Social, information,* and *concerns/potential problems*
Weekly activity goal on “My Page”	Outcome expectancies, Self-efficacy for action, Action planning, Implementation intentions, and Supporting autonomy	*Motivation, planning,* and *monitoring and feedback*
Simple feedback graph on “My Page”	Outcome expectancies, Self-reevaluation, and Consciousness raising	*Monitoring and feedback, information,* and *planning*
My reasons for physical activity, my strategies to increase physical activity, and overcome barriers on “My Page”	Self-efficacy for maintenance and recovery, Values, Coping planning, Relapse prevention, and Decisional balance	*Motivation, integration to everyday life, information,* and *concerns/potential problems*
Tailoring algorithm	Mainly based on theoretical constructs (see detailed explanation under Theoretical framework and Table 1)	*Motivation, planning, social, information, integration to everyday life,* and *concerns/potential problems*

Functionality of the Website

The Graphic Design

The graphical design of the website was based on the graphic profile of the patient organization that owns the collaborating rehabilitation center. Since the offer of the intervention is an extension of the services offered by the face-to-face rehabilitation, it is important to use the visual elements and a palette familiar to the users and identical to the website of the rehabilitation center, to the website of the patient organization that owns the center, and to all the printed materials that are used by the organization and all its services. Since the patient organization is one of the biggest and most active in Norway, we expect that the level of trust toward our intervention will be positively affected. The main colors of the website are blue and light blue, which, according to the graphic profile of the organization, have been chosen because they symbolize clean air and breath. For the typography, modern, but simple fonts have been selected to make the information easy to read.

Three Levels of Access

There are three levels of access for most of the components of the website. The first one is information accessible by all the registered users of the website. The second level is accessible only by a specific group of users that are called friends. Friends are by default the participants of the same rehabilitation monthly group, for example, participants that have been to the rehabilitation center in January 2012. A user can add or delete friends from her profile page. A third level of access is reserved for the user and the information that is private. Users with administrative roles can have access to information of all levels.

My Page

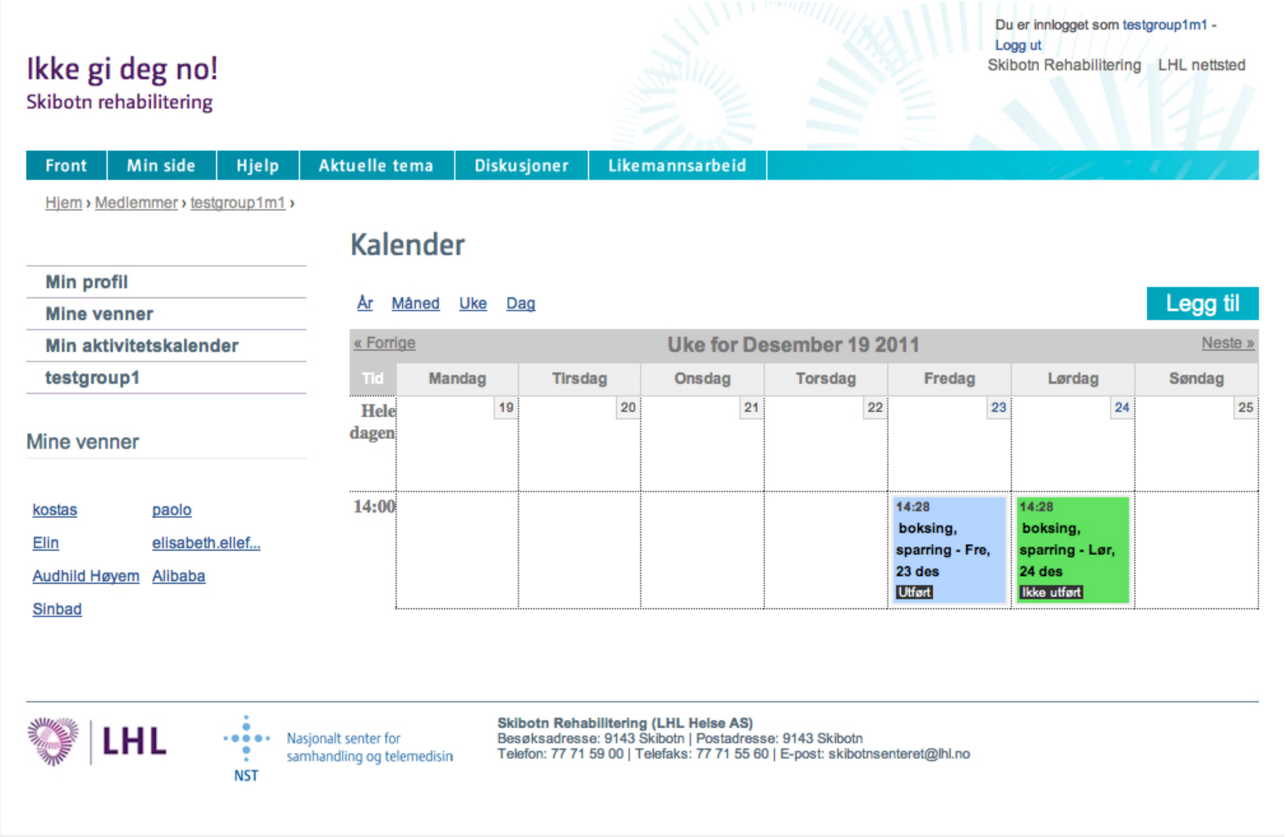
For the user, the starting point is the profile page, called “My Page” (Figure 2 shows this page). The profile page includes a wall functionality that could also be described as a microblog functionality, where the planned and completed activities from the calendar appear. The user can write how they feel in general or about the activities they have planned, and can see other users’ posts. To avoid lengthy posts, a limit of 340 characters is applied. For each post on the profile, there is the possibility for the friends of the user or the center's personnel to comment. From the profile page, the user can access the friends' list and the personal information page. The most recently planned physical activities appear also on the side of the profile page. There is also a link to the group page. The group page is similar to the profile page, but only shows the latest activities of the members of the monthly group to which the user belongs.

Figure 2. The profile page (My Page).

Activity Calendar

The activity calendar is a planning and reminder tool. The main view is the weekly calendar (Figure 3 shows this weekly view), since the users are encouraged to plan activities on a weekly basis, but daily, monthly, and yearly views are also available. The completed activities appear on the calendar with a different color, and the user can edit both the completed and planned activities. To plan an activity, the user can choose from a preselected list with common activities (Figure 4 shows this page). The user has to set the start date and time, duration in hours and minutes, and planned intensity according to Borg's scale [57]. In addition, the user can choose to make the activity public or private, to write the place of the activity, and to provide an additional description. An important functionality is that there is the possibility to challenge some or all of their friends to take part in the activity by inviting them through the same page. The invited friends will see an invitation on their profile page and will also get an email and an SMS invitation. For each planned activity, the user will receive an SMS reminder 15 minutes before the planned beginning of the activity, and an SMS at the planned end asking about the completion of the activity (Figure 5 shows this reminder). The last SMS contains a URL link that users with smartphones can use to confirm their activity as completed and state the actual duration of the activity, the actual intensity, and write a comment if they want (Figure 6 show this page). Users without a smartphone can update the information the next time they log in on the website. The information about the completed activity is published on the profile of the user and can also be seen by their friends on their page.

Figure 3. Weekly overview of the planned activities of the activity calendar.



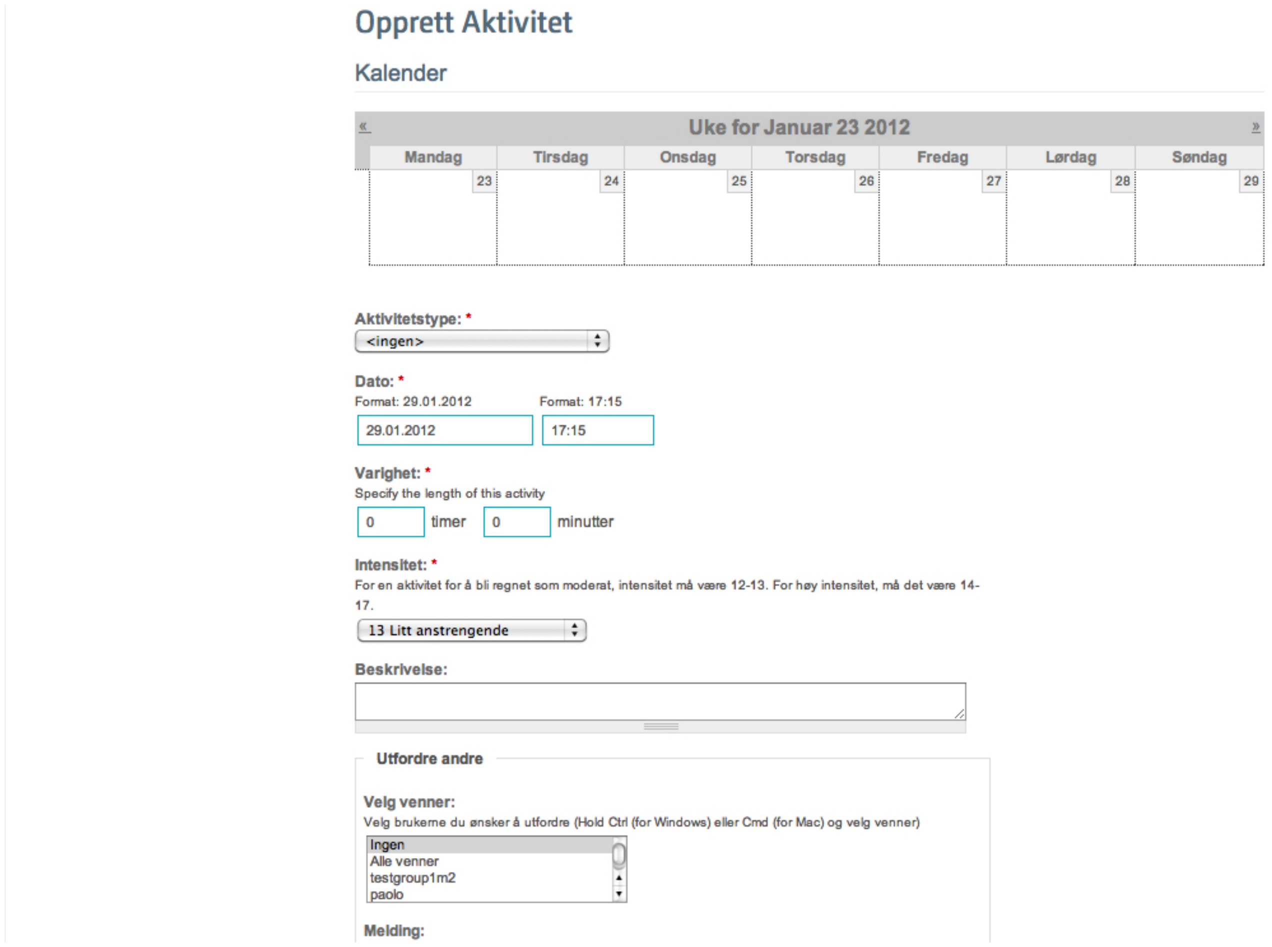
Kalender

Uke for Desember 19 2011

Tid	Mandag	Tirsdag	Onsdag	Torsdag	Fredag	Lørdag	Søndag
Hele dagen	19	20	21	22	23	24	25
14:00					14:28 boksing, sparring - Fre, 23 des Utført	14:28 boksing, sparring - Lør, 24 des Ikke utført	

Skibotn Rehabilitering (LHL Helse AS)
Besøksadresse: 9143 Skibotn | Postadresse: 9143 Skibotn
Telefon: 77 71 59 00 | Telefaks: 77 71 55 60 | E-post: skibotnsenteret@lhl.no

Figure 4. Planning of an activity in the activity calendar.



Opprett Aktivitet

Kalender

« Uke for Januar 23 2012 »

Mandag	Tirsdag	Onsdag	Torsdag	Fredag	Lørdag	Søndag
23	24	25	26	27	28	29

Aktivitetstype: *
<ingen>

Dato: *
Format: 29.01.2012 Format: 17:15
29.01.2012 17:15

Varighet: *
Specify the length of this activity
0 timer 0 minutter

Intensitet: *
For en aktivitet for å bli regnet som moderat, intensitet må være 12-13. For høy intensitet, må det være 14-17.
13 Litt anstrengende

Beskrivelse:

Utfordre andre

Velg venner:
Velg brukerne du ønsker å utfordre (Hold Ctrl (for Windows) eller Cmd (for Mac) og velg venner)
Ingen
Alle venner
testgroup1m2
paolo

Melding:

Figure 5. SMS before and after planned activity: "Remember Ball game, football/handball at 17:50 (second SMS from below)," "Did you do the activity Ball game, football/handball?" "If so, you can confirm it by following the link [unique URL]" (first SMS from below).

Ikke gi deg! Både unge og eldre har effekt av fysisk aktivitet. Det er derfor aldri for seint å begynne.

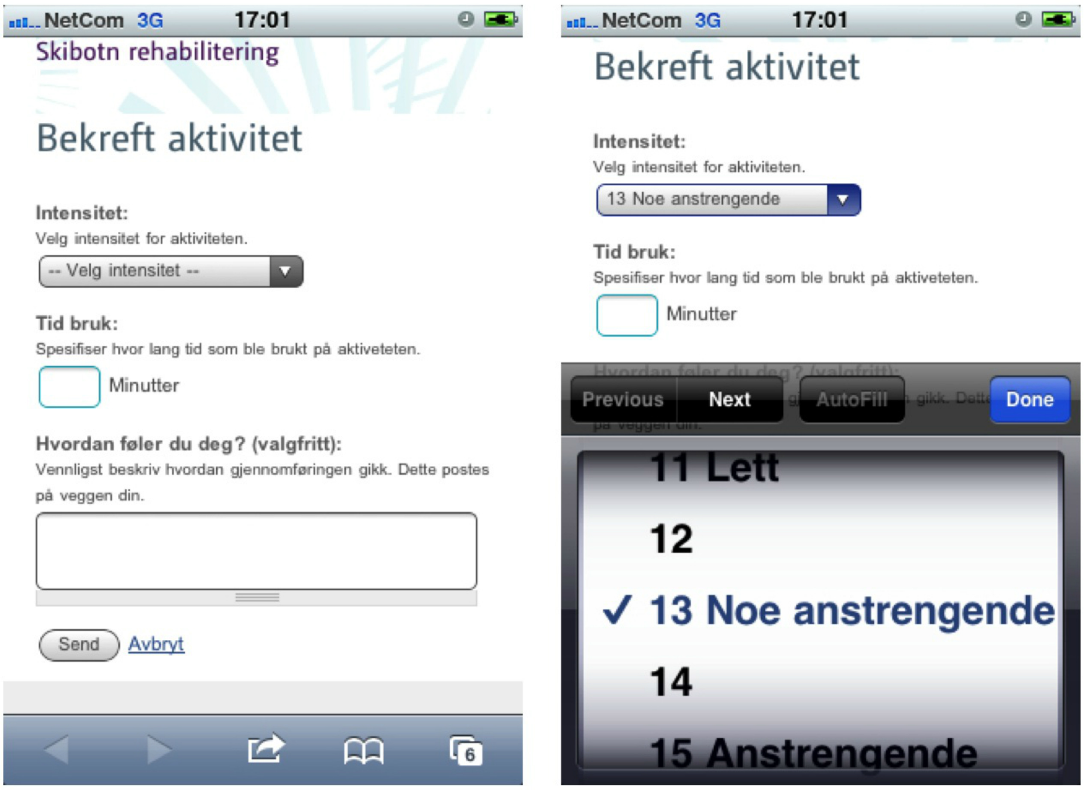
16. jan. 2012 17:34

Husk på Ballspill, fotball/håndball klokken 17:50.

16. jan. 2012 17:54

Har du gjort aktiviteten Ballspill, fotball/håndball? I så fall kan du bekrefte ved å følge lenka: https://ikkegideg.no/activity/confirm/3/750/c9127dc86c4fe92ccb9a44636becdaf9

Figure 6. Mobile page for confirming the completed activity. Questions about the intensity of the activity, actual duration of the activity, and free text comment field (left image). The intensity of the activity according to Borg's scale (right image).



Bekreft aktivitet

Intensitet:
Velg intensitet for aktiviteten.
-- Velg intensitet --

Tid bruk:
Spesifiser hvor lang tid som ble brukt på aktiveteten.
Minutter

Hvordan føler du deg? (valgfritt):
Vennligst beskriv hvordan gjennomføringen gikk. Dette postes på veggen din.

Bekreft aktivitet

Intensitet:
Velg intensitet for aktiviteten.
13 Noe anstrengende

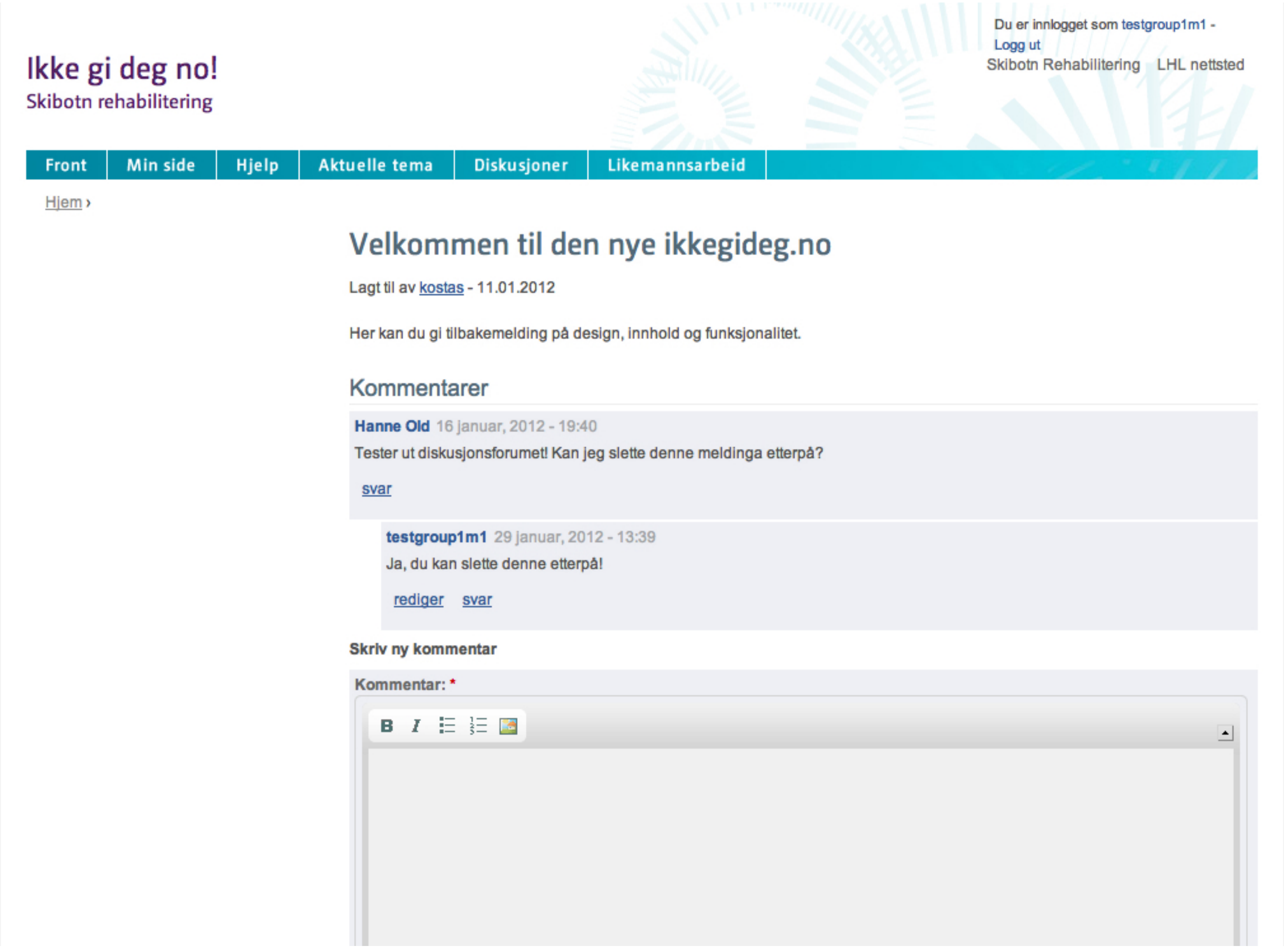
Tid bruk:
Spesifiser hvor lang tid som ble brukt på aktiveteten.
Minutter

11 Lett
12
✓ 13 Noe anstrengende
14
15 Anstrengende

Discussion Forum

The discussion forum is a standard discussion forum with three levels of access (Figure 7 shows the forum). The first one is only accessible to all the registered users of the website. The second level is for discussions that are only accessible by users that belong to the same monthly group. The third level of access is reserved for the administrators and the health professionals that can access all the discussions to moderate and give professional advice and motivation.

Figure 7. The discussion forum.



Velkommen til den nye ikkegideg.no

Lagt til av kostas - 11.01.2012

Her kan du gi tilbakemelding på design, innhold og funksjonalitet.

Kommentarer

Hanne Old 16 januar, 2012 - 19:40
Tester ut diskusjonsforumet! Kan jeg slette denne meldinga etterpå?

testgroup1m1 29 januar, 2012 - 13:39
Ja, du kan slette denne etterpå!

Skriv ny kommentar

Kommentar: *

General Information

The health professionals involved in the project have developed and posted on the site general information regarding physical activity and training, cardiovascular disease, diabetes, lung problems, cholesterol, smoking cessation, and other topics that are relevant for the users. There is also information regarding motivation, self-management, and lifestyle change that are closely related to the concepts the intervention is built upon. The information is accessible to all the visitors of the website, reflecting requests from participants of the rehabilitation program. It is a reliable and verified resource.

The users can seek assistance in navigating the website by calling a physiotherapist responsible for it, during working hours. For technical issues, they can complete an Internet-based form and submit their comment or problem. When possible, they receive a response within three working days.

Additional Functionality for Intervention Group

Some additional functionality is available only for the members of the intervention group of the randomized controlled trial [58]. On the profile page, those users can see their weekly activity goals. The users set the weekly goals on a new page as minutes of activity in two categories: (1) high intensity, and (2) moderate intensity. The users receive feedback regarding the level of activity in comparison to the suggestions by the American College of Sports Medicine that are much in line with the suggestions from the Norwegian Directorate of Health [59]. The feedback is offered as advice and the user can proceed even without complying with the suggestions, this is to reflect the individual needs and exercise capacity of the user and the focus on self-management. The goals appear on the side of the profile page and are accompanied by feedback related to the planned activity and how it compares to the set weekly goals. Related to the achievement of the goals, is the graph that appears on the profile page. In a simple feedback graph, the user appears as a figure on a ladder with 5 steps and, according to completed activities, the figure is on one of the 5 steps (Figure 2). The figure on the top of the ladder represents the successful completion of the weekly goals, and it appears to be in a more cheerful position than when on the base of the ladder. The figure is different for male and female users. On the side of the profile the user can find certain strategies to increase physical activity or overcome barriers (depending on the stage of change of the user), and their most important reasons to be more physically active, again chosen by the user. The strategies and the reasons appear only for users in specific stages and the users have either chosen them from a list of suggestions or written them by themselves.

Tailoring Algorithm

Stages of Change

As the first step in tailoring, the participants' stage of change is assessed using the URICA-E2 [39]. In the next step, they follow different paths depending on stage.

Precontemplation

The participant is given immediate feedback on the current stage, and is then asked whether they would like to test their knowledge about physical activity. If yes, a quiz on benefits of physical activity is given, followed by the results. Then the participant is presented with a RFQ [41]. Depending on classification, the participant will be sent either prevention- or promotion-framed SMS messages concerning physical activity over the next two weeks (see Multimedia Appendix 2). After two weeks the participant is reassessed for stage of change.

Contemplation

The participant is given immediate feedback on the current stage, and is then presented with a decisional balance questionnaire [47]. Afterwards, the participant is presented with immediate feedback according to whether they perceive more pros or cons regarding regular physical activity. Next, the participant is presented with a list of potential reasons for becoming more physically active, and asked to tick off the relevant ones, before being asked to add some more in free text. This list is displayed on “My Page.” The participant is then asked if they want to plan their physical activity. If yes, they are presented with the “Exercise Agenda.” There, they can add several entries by planning what kind of activity, when, and where for each entry, thus forming an implementation intention. After completing planning, they will be assessed for self-efficacy for this action plan. If it is very low, the user will be asked to revise the action plan to make it more realistic, while if it is moderately low, they will receive SMS messages concerning self-efficacy for action over the next two weeks. If the participant declines planning, they will be led to “My Page.” All participants will be reassessed for stage again in two weeks.

Preparation

The participant is given immediate feedback on the current stage, and then self-efficacy for their action is assessed. The participant is asked to identify potential barriers and to generate strategies to address them. These strategies are then listed on “My Page.” Next, social support is assessed and immediate feedback is given. Then, the participant is asked to plan physical activity in the activity calendar. Over the next two weeks the participant will receive SMS messages about self-efficacy and/or social support, depending on the above assessment, before stage is reassessed (see Multimedia Appendix 2).

Action

The participant is given immediate feedback on the current stage, and then self-efficacy for maintenance is assessed. The participant is asked to identify potential barriers and to generate strategies to meet them. The strategies are then listed on “My Page.” The participant is also asked if they want to update their activity calendar. After planning activities, they are asked about self-efficacy for this plan. Over the next two weeks SMS messages about maintenance are sent to those who were low on self-efficacy for this, and then stage is reassessed.

Maintenance

The participant is given immediate feedback on the current stage, and then self-efficacy for relapse is assessed. The participant is asked to identify potential barriers and to generate strategies to meet them. The strategies are then listed on “My Page.” The participant is then asked if they want to update their activity calendar. After planning activities, they are asked about self-efficacy for this plan. Over the next month SMS messages about relapse prevention are sent to those who were low on self-efficacy for this, and then stage is reassessed.

Discussion

Communication Design

The communication design of a website is an essential component of the intervention. There are several factors that have to be considered in relation to the target group and the communication channel that is going to be used, such as font style and size, balanced use of graphics and text, and intuitive structure and navigation menus [60,61]. Building credibility also has great potential; since it seems that it affects the confidence in one’s thoughts, health behavior, and cognition [62]. This can be effectively done with visual and design cues [63], and for our intervention this was applied with the right choice of communication design elements like template, colors, fonts, and of course the logos of the organizations.

Theoretical Implications

In this paper, we describe how we developed an intervention in which the existence of each of its functionality elements is grounded on both user input and theoretical constructs. Of course, the health behavior models that we used to create the theoretical framework were developed based on research of human behavior, which to a certain extent qualifies for user input. It was expected that those concepts about human behavior would be reproducible and would reappear in our focus group.

An example of the reflection of theory in the focus group appears in the themes of *planning* and *motivation*. According to the HAPA, there is a distinction between action planning and coping planning [49,50]. The participants of the focus group were clearly concerned in a different way about planning an activity, compared to preparing to cope with the barriers of physical activity once they completed their rehabilitation stay. It seemed that both are necessary, but prioritization and motivation are needed to make sure each participant will be ready to overcome any difficulties.

Another example of integration is concerning relapse prevention [64,65]. The focus group confirmed its relevance for the case of physical activity. The participants mentioned that after a health problem, like back pain, they might backslide and find it difficult to start physical activity again. For that reason, they would like to get support in dealing with such feelings as disappointment, sadness, and being a loser, in order to recover. Also, the relationship of the social support with the relapse prevention, as seen in the focus group, is coherent to the previous findings that indicated that social support is related to the resistance of relapse into physical inactivity in men [65].

Whereas the stage-based models that we applied may carry some merit for creating tailoring algorithms, they are not sufficient in accounting for all the determinants of physical activity [38]. Within health promotion, more ecological models

[66] are used, including factors from within the individual, via the closest network, community to societal regulations, and resources. Although more inclusive, these kinds of models raise a number of methodological and logistical challenges [66]. Some, such as the purely Internet-based, might be even more difficult to tackle, while others might benefit from the improved trackability of an Internet-based intervention. A somewhat more limited ecological model that would fit well to our existing variables, while including more of the social ones, is the social cognitive theory [67]. Whereas self-efficacy is the most important variable in the social cognitive theory, social variables play several important roles-they influence our expectations about outcomes, self-efficacy, and they constitute direct facilitators as well as impediments for behavior. Thus, in a temporal perspective, social variables are important throughout the stages of behavioral change.

Nevertheless, as we add more variables to our models, we should be careful to measure our proposed mediators to make sure that we are actually intervening according to our proposed theoretical framework [68]. By gathering data on the relevant processes hypothesized to take place, not only can we further develop our interventions, but our theories as well [69]. We therefore aimed to design the randomized controlled trial of the current intervention [58] so that in addition to being able to conclude whether the intervention was effective or not, we will know something about what works and why. Ideally, we believe, the design of the intervention and the design of the trial should go hand in hand.

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Authors' Contributions

KA and SCW participated in the design of the intervention as well as the study, analysis of data, and drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

The authors have participated in the design of the interventions mentioned in the manuscript.

Multimedia Appendix 1

Interactive thematic map of the focus group themes and subthemes.

[ZIP File (Zip Archive), 139KB - resprot_v3i1e4_app1.zip]

Multimedia Appendix 2

Video presenting an example of the tailoring algorithm.

[MOV File, 12MB - resprot_v3i1e4_app2.mov]

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Abbreviations

HAPA: Health Action Process Approach
RFQ: Regulatory Focus Questionnaire
SMS: short message service
TTM: Transtheoretical model
URICA-E2: University of Rhode Island Change Assessment – Exercise 2

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Original Paper

A Web-Based Supportive Intervention for Families Living With Depression: Content Analysis and Formative Evaluation

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Abstract

Background: Relatives of people with a mental illness who live together can experience additional burdens that may require support. A Web-based tool including a psychoeducation module, a diary, and a password-protected forum was developed to support relatives of a person with depression.

Objective: The objective of our study was to explore participants' use of the Web-based tool, with focus on the forum, and to assess its potential health and psychosocial benefits.

Methods: Twenty-five people participated in this explorative open trial. Self-rating instruments assessing caregiver burden, stigma, and the tool's usability were analyzed with Carer QoL7-D, DISC-12, and a system usability scale. A summary measure of subjective burden was assessed with CarerQoL-VAS. The forum posts were studied using content analysis.

Results: The majority reported fulfillment from their caregiving tasks (84%, 21/25), and had relational problems (76%, 19/25), their own mental health problems (72%, 18/25), support (72%, 18/25), and difficulties coordinating daily activities with caregiving (56%, 14/25). Most (72%, 18/25) reported having been able to use their inner strength to cope with stigma and discrimination, 64% (16/25) had concealed or hidden the person's condition, and 40% (10/25) reported having been avoided or shunned by people who knew about the illness. Forty-eight percent (12/25) reported unfair treatment from family; 40% (10/25) in marriage or divorce and 36% (9/25) from mental health staff. Almost one-third (28%, 7/25) reported having stopped themselves from having a close personal relationship. Participants' subjective assessment of the tool's usability resulted in a mean of 61.5 (range, 22.5-90; possible total value 0-100; >70=good). Ten people participated in the forum; content analysis resulted in five categories describing relatives' situations: balancing the caregiver's role and relationship to the patient; their own lives and need for support; resources and patient advocacy; a looming shadow on leisure, social, and professional life; and interaction and social support.

Conclusions: Further studies are needed to explore optimal ways of using Web-based tools to address support for relatives of a person with mental illness. Professional feedback may enhance the use and value of online communities.

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KEYWORDS

family caregivers; depression; online social networks; social support

Introduction

Living with a person with mental illness can produce additional burdens for families [1]. Depression will rank as the second leading cause of disability worldwide by 2020 for men and women aged 15-44 years, affecting 121 million individuals worldwide [2]. The lifetime prevalence for major depression in men is estimated at 10%-13% and in women at 21%-24% [3,4]. Increasing frequencies are found among young people [5], for whom suicide is a prominent cause of death at ages 10-24 years [6], and the elderly [5].

In 40% of families living with mental illness, psychological suffering requires therapeutic interventions [7]. The family's emotional climate can improve through family interventions [8], with lower relapse rates and better outcomes, reduced expressed emotion, and better problem-solving capacities [9,10]. Family interventions are highly prioritized in national and international guidelines, but studies show that implementation in practice has been scattered and slow. Lack of resources and stigma are barriers to the treatment of depression [2]. To optimize support for afflicted families, alternative support modalities should be explored, such as Web-based solutions.

Transportation issues, fatigue, and limited readiness to absorb information can be barriers to accessing psychoeducational programs [11]. Web-based services offer convenient access [12] and 24-hour availability of information and support, partly explaining the growth of online communities (OCs). OCs offer a space for the exchange of medical information, and provide social support and health education, entailing the benefits of major coping strategies [13]. Studies of health-related forums show an exchange of informational, emotional, esteem, and network support [14], as defined by Cutrona and Suhr [15]. Similar others can become a supporting network with important social contacts, reducing isolation and providing new perspectives [11]. Social support can be a buffering and mediating factor influencing physical and mental health [16,17]. While social isolation can be a stressor, social support can be a buffer against stress and influence health and disease processes in different directions depending on its availability and adequacy [18]. Clinical depression can be predicted by the lack of social support and depressive tendencies may reduce an otherwise healthy person's potential for social support [18]. Families living with a person with mental illness are vulnerable and relevant support may help alleviate caregiver burden, preventing further ill health.

Research shows that expressive writing has beneficial physical and mental health effects in different user groups in several cultural settings [19,20]. Making sense of traumatic events can reduce ruminative thoughts associated with illness [21]. In a previous study [22], a Web-based tool aimed at families living with a person with depression was developed in an iterative design process that included potential users. The tool was based on a theoretical framework entailing the potential health benefits of expressive writing and social support when experiencing stressful events and showed promising results. The tool was password-protected and entailed a Web-based diary (private) and forum (users-only access). The tool promoted communication with the self and others, leading to a sense of perspective and empowerment. It promoted reflection and offered a space to ventilate feelings and share experiences, and obtain support and advice from similar others, contributing to reduced feelings of alienation and social isolation [23].

The aim of our open study was to investigate participants' use of a Web-based tool and its potential beneficial health and psychosocial effects. Besides the diary and forum, the updated tool entailed a psychoeducation module. The tool was also targeted at an additional user group consisting of families living close to a person with schizophrenia, but these results are presented elsewhere [24]. We focused on the forum and the following research questions: What phenomena relating to the relatives' situations stand out in the forum? What kind of social support is exchanged and with what potential effects?

Methods

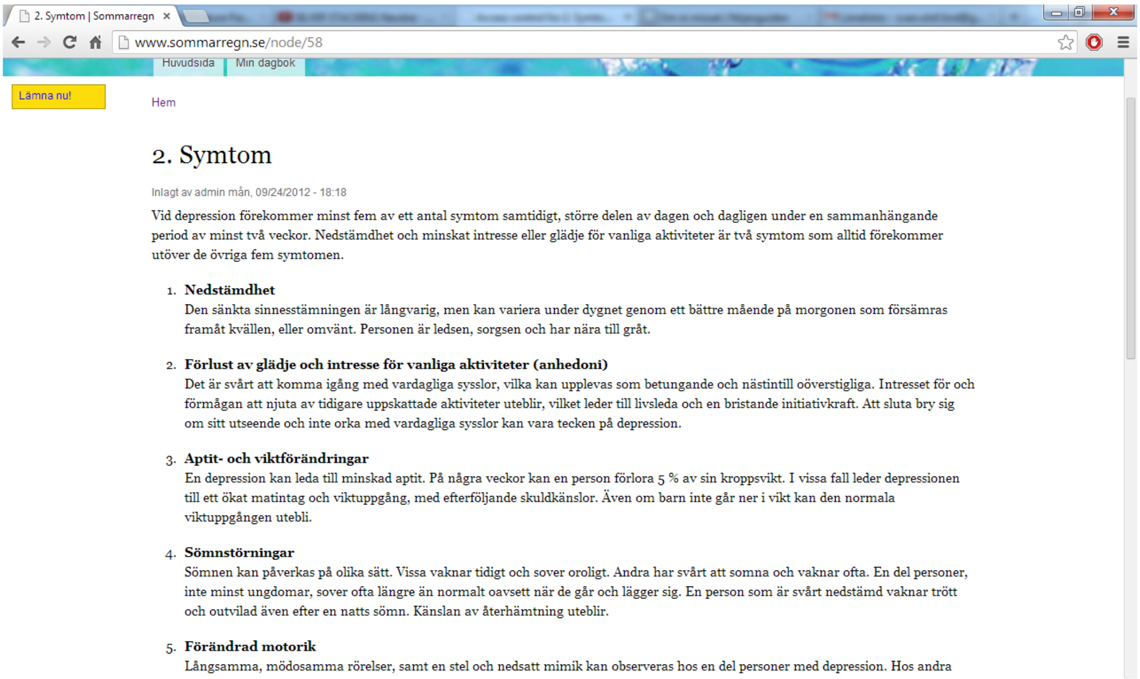
Design

The present open study was an explorative study, including a qualitative approach to assess the forum's value and a quantitative approach with self-rating instruments to assess caregiver burden, experiences of stigma and discrimination, and the tool's usability.

Intervention

The intervention consisted of a Web-based tool with three modules aimed at relatives/significant others of a person with depression: a psychoeducation module with information on mental illness, treatment, and the role of the family; a private diary, facilitating expressive writing; and a moderated and members-only forum, facilitating social support. A user peer group with patients and relatives reviewed the psychoeducation module's contents, a novelty compared to the initial project. Access to the full website required registration, and the use of an alias and a password to protect anonymity and users' integrity. The moderator (first author) occasionally submitted posts to spur discussions, for instance about personal needs for support and potential experiences of stigma. The test period was between February and May 2013 (16 weeks). Participants were asked to use the diary and forum weekly to ensure a certain level of activity. It was decided that participants writing posts that revealed alarming facts about, for example, signs of destructive behavior such as self-harm (in participants or patients) were recommended by the research team to seek professional help on their own behalf or on behalf of the patient (see screenshots in Figures 1-3).

Figure 1. Screenshot of the psychoeducation module.



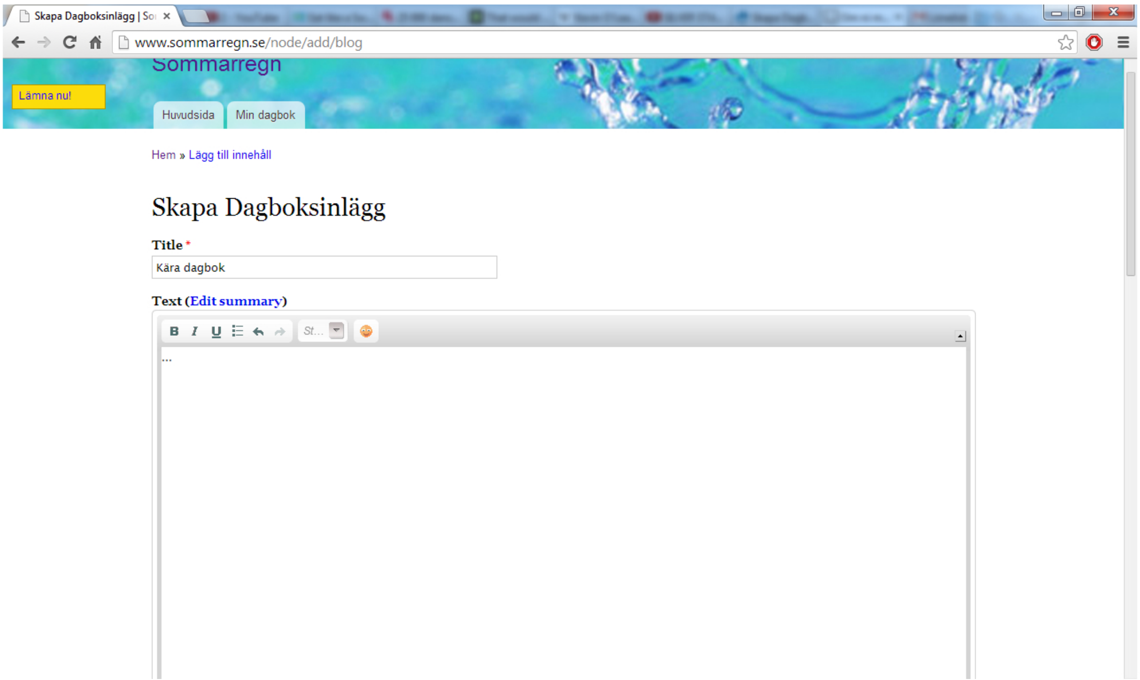
2. Symtom

Inlagt av admin mån, 09/24/2012 - 18:18

Vid depression förekommer minst fem av ett antal symtom samtidigt, större delen av dagen och dagligen under en sammanhängande period av minst två veckor. Nedstämdhet och minskat intresse eller glädje för vanliga aktiviteter är två symtom som alltid förekommer utöver de övriga fem symtomen.

1. **Nedstämdhet**
   Den sänkta sinnesstämningen är långvarig, men kan variera under dygnet genom ett bättre mående på morgonen som försämras framåt kvällen, eller omvänt. Personen är ledsen, sorgsen och har nära till gråt.
2. **Förlust av glädje och intresse för vanliga aktiviteter (anhedoni)**
   Det är svårt att komma igång med vardagliga sysslor, vilka kan upplevas som betungande och nästintill oöverstigliga. Intresset för och förmågan att njuta av tidigare uppskattade aktiviteter uteblir, vilket leder till livsleda och en bristande initiativkraft. Att sluta bry sig om sitt utseende och inte orka med vardagliga sysslor kan vara tecken på depression.
3. **Aptit- och viktförändringar**
   En depression kan leda till minskad aptit. På några veckor kan en person förlora 5 % av sin kroppsvikt. I vissa fall leder depressionen till ett ökat matintag och viktuppgång, med efterföljande skuldkänslor. Även om barn inte går ner i vikt kan den normala viktuppgången utebli.
4. **Sömnstörningar**
   Sömnen kan påverkas på olika sätt. Vissa vaknar tidigt och sover oroligt. Andra har svårt att somna och vaknar ofta. En del personer, inte minst ungdomar, sover ofta längre än normalt oavsett när de går och lägger sig. En person som är svårt nedstämd vaknar trött och outvilad även efter en natts sömn. Känslan av återhämtning uteblir.
5. **Förändrad motorik**
   Långsamma, mödosamma rörelser, samt en stel och nedsatt mimik kan observeras hos en del personer med depression. Hos andra

Figure 2. Screenshot of the diary.

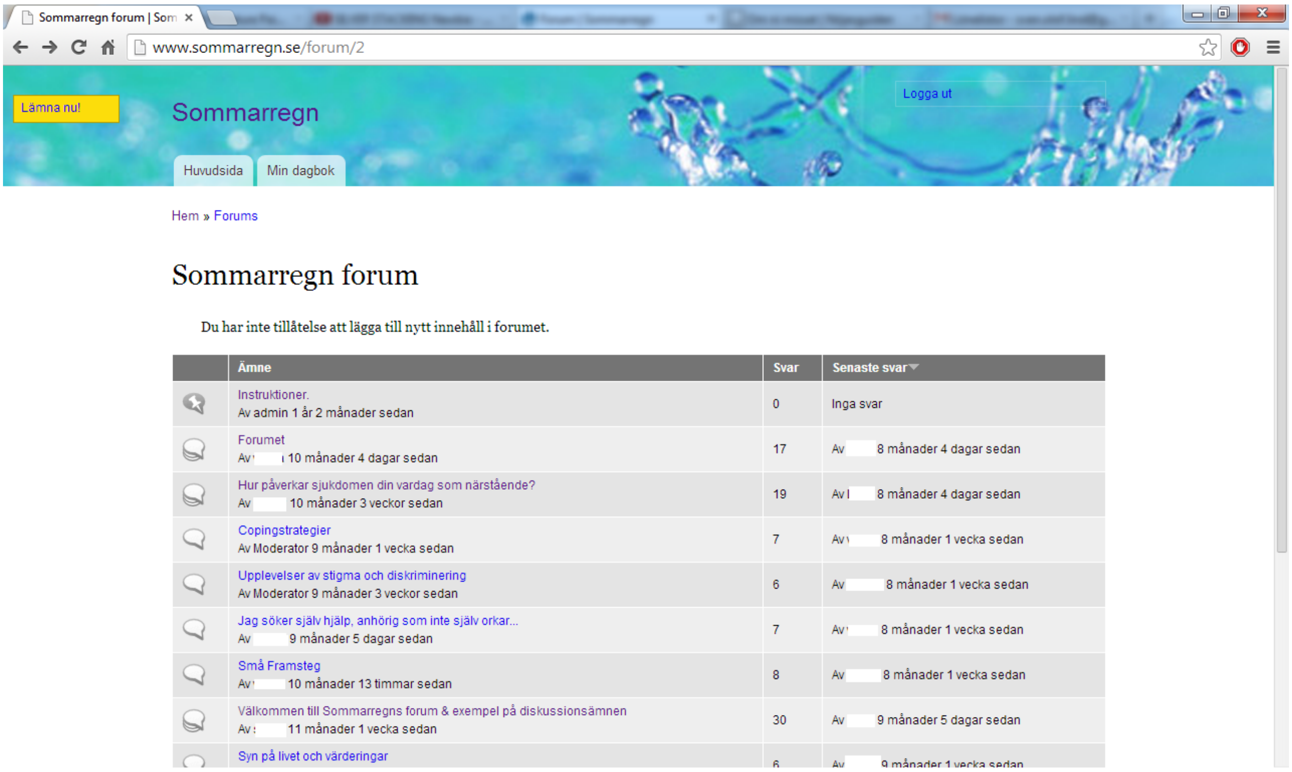


Skapa Dagboksinlägg

Title *
Kära dagbok

Text (Edit summary)
...

Figure 3. Screenshot of the forum.



Sommarregn forum

Du har inte tillåtelse att lägga till nytt innehåll i forumet.

Ämne	Svar	Senaste svar
Instruktioner. Av admin 1 år 2 månader sedan	0	Inga svar
Forumet Av [redacted] 10 månader 4 dagar sedan	17	Av [redacted] 8 månader 4 dagar sedan
Hur påverkar sjukdomen din vardag som närstående? Av [redacted] 10 månader 3 veckor sedan	19	Av [redacted] 8 månader 4 dagar sedan
Copingstrategier Av Moderator 9 månader 1 vecka sedan	7	Av [redacted] 8 månader 1 vecka sedan
Upplevelser av stigma och diskriminering Av Moderator 9 månader 3 veckor sedan	6	Av [redacted] 8 månader 1 vecka sedan
Jag söker själv hjälp, anhörig som inte själv orkar... Av [redacted] 9 månader 5 dagar sedan	7	Av [redacted] 8 månader 1 vecka sedan
Små Framsteg Av [redacted] 10 månader 13 timmar sedan	8	Av [redacted] 8 månader 1 vecka sedan
Välkommen till Sommarregns forum & exempel på diskussionsämnen Av [redacted] 11 månader 1 vecka sedan	30	Av [redacted] 9 månader 5 dagar sedan
Syn på livet och värderingar	6	Av [redacted] 9 månader 1 vecka sedan

Participant Sample

Participants were recruited through advertisement in regional newspapers and on support organizations' websites, social media, and advertisement on bulletin boards in public places (eg, libraries and hospital wards in 3 cities in southern Sweden). Inclusion criteria were being a relative/significant other of a person with depression, aged 18-80 years, having access to a computer and Internet connection, and understanding and writing Swedish. Information about the study was made available online and through email on request. Twenty-five persons enrolled by sending an informed consent form to the research team (Table 1). The sample included 6 men and 19 women, aged 18-68 years (mean, 51.80 years). No information about potential comorbidity in patients was collected.

Only 10 people wrote in the forum. Their sociodemographic characteristics appear to be representative of the total group, except for a higher mean age. For these 10 participants (9 women, 1 man), the mean age was 60.5 years (range, 48-68 years). Nine (90%) were in a relationship and 1 (10%) was single. Five (50%) shared their household with the patient, 4 (40%) did not, and 1 (10%) sometimes did. Participants' relationship to the patient was a child (n=3, 30%), parent (n=3, 30%), partner (n=3, 30%), and other relationship (n=1, 10%). Seven (70%) had attended postsecondary school, 1 (10%) had attended high school, and 2 (20%) participants had other educational backgrounds. The majority lived in a city and half of the participants worked. Most (n=9, 90%) had previously used the Internet to search for information about depression and 7 (70%) found the information useful (n=3, 30%) or partially useful (n=4, 40%), while 3 (30%) did not find it useful. Four (40%) felt as though they received support (1 [10%] fully, 3 [30%] partially) thanks to their Internet searches. Only 2 (20%) participants had searched for/visited support groups/chats online.

Table 1. Background information (N=25).

Criteria		n (%)
Marital status		
	In a relationship	22 (88)
	Single	3 (12)
Relationship		
	Parent	6 (24)
	Child	8 (32)
	Sibling	1 (4)
	Partner or ex-partner	6 (24)
	Other	4 (16)
Lives with the patient		
	Yes	11 (44)
	No	13 (52)
	Sometimes	1 (4)
Housing area		
	City/township	24 (96)
	Countryside	1 (4%)
Education		
	Elementary school	1 (4)
	High school	3 (12)
	Post-secondary school	18 (72)
	Other	3 (12)
Employed		
	Yes	18 (72)
	No	7 (28)

Data Collection and Analysis

When registering on the website, participants answered a demographic questionnaire and self-rating instruments online. The 7-item care-related quality of life for depression questionnaire (CarerQoL7-D) [25] measures 7 dimensions (fulfillment, relational dimension, mental health dimension, social dimension, financial dimension, perceived support, and physical dimension) of caregiver burden. It also includes the care-related quality of life visual analogue scale (CarerQoL-VAS), summarizing the level of happiness with caregiver's experiences and ranging from 0 to 10 (completely unhappy to completely happy).

The 12-item discrimination and stigma scale (DISC-12) [26] measures different aspects of stigma and discrimination related to mental illness. Nine items of relevance for caregivers were chosen from 3 of the 4 original subscales: (1) unfair treatment (6 items), (2) stopping self (2 items), and (3) overcoming stigma (1 item). Items were scored on a 5-point Likert scale ranging from 0 (not at all) to 3 (a lot) and 4 (not applicable).

After the test period, all 25 participants were provided a Swedish version [27] of the system usability scale [28], but only 13 participants (52%) replied. The scale's 10 questions have possible values ranging from 0 to 4; the total value can be 0 to 100. Values over 70 can be estimated as good (>85, excellent), although acceptability in the field cannot be guaranteed [29]. Quantitative data were analyzed with descriptive statistics in IBM-SPSS version 21**.**

Further data consisted of forum posts, amounting to approximately 45 printed pages, including 105 forum posts/comments, and were studied using content analysis [30]. Ten (40%) participants wrote in the forum, with a range of 1 to 30 posts/comments per participant (mean, 10.5). The printouts were read several times to reach an understanding of the whole. Contents relating to the research questions were marked and coded, then grouped and abstracted into categories and subcategories. Comparisons across categories were made to identify similarities and differences. The transcripts were re-read to assess the emerging coding scheme's fit with the material. Frequencies of diverse types of social support based on Cutrona and Suhr's definition [15] were noted. An additional researcher (second author) analyzed data to assess the reliability of the coding schemes and results.

Results

Scale Summary

Experiences of caregiver burden and stigma were reported through CarerQoL7-D (Figure 4) and DISC-12 items (Table 2). CarerQoL-VAS, a summary measure of the subjective burden, had a mean score of 6.16 (range, 3-10).

Results of CarerQoL showed that 84% (21/25) reported fulfillment from their caregiving tasks, 76% (19/25) reported relational problems, and 72% (18/25) reported their own mental health problems. Most (72%, 18/25) reported having support and 56% (14/25) reported difficulties coordinating daily activities with caregiving.

With DISC-12, 72% (18/25) reported having been able to use their inner strength to cope with stigma and discrimination and 64% (16/25) had concealed or hidden the person's condition. Forty percent reported having been avoided or shunned by people who knew about the illness. Forty-eight percent (12/25) reported unfair treatment from family; 40% (10/25) in marriage or divorce and 36% (9/25) from mental health staff. Almost one-third (28%, 7/25) reported having stopped themselves from having a close personal relationship.

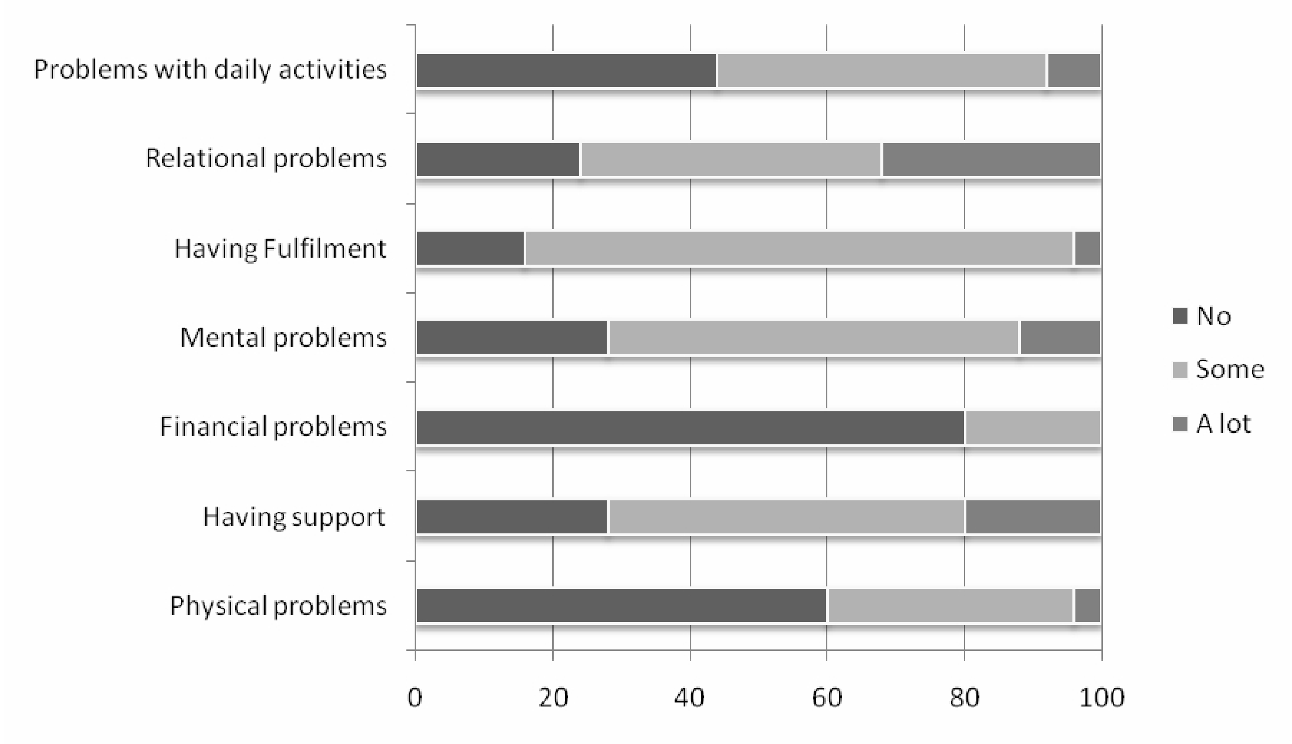
Participants' subjective assessment of the tool's usability was calculated using the system usability scale, resulting in a mean of 61.5 (range, 22.5-90; possible total value 0-100; >70=good). Most posts were written during weekdays (76/105, 72.4%) as compared to weekends (29/105, 27.6%), and between 4 pm and 12 am (64/105, 61.0%), 8 am and 4 pm (30/105, 28.5%), and 12 pm and 8 am (11/105, 10.5%).

The analysis of the forum posts resulted in 5 categories and subcategories describing areas of concern for the participants and their interactions in the forum, as described below.

Table 2. Results of DISC-12 (N=25).

Item	Not at all	Small	Moderate	Large	Overall (sum of small, moderate, or large)	Not applicable
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Perceived stigma						
Have you been treated unfairly by your family?	12 (48)	5 (20)	6 (24)	1 (4)	12 (48)	1 (4)
Have you been treated unfairly in marriage or divorce?	11 (44)	4 (16)	3 (12)	3 (12)	10 (40)	4 (16)
Have you been avoided or shunned by people who know that you have a mental health problem in the family?	15 (60)	6 (24)	3 (12)	1 (4)	10 (40)	None
Have you been treated unfairly by mental health staff?	12 (48)	5 (20)	2 (8)	2 (8)	9 (36)	4 (16)
Have you been treated unfairly in keeping a job?	16 (64)	4 (16)	1 (4)	None	5 (20)	4 (16)
Have you been treated unfairly by the police?	16 (64)	1 (4)	None	None	1 (4)	8 (32)
Self-stigma						
Have you concealed or hidden your family's mental illness?	9 (36)	4 (16)	7 (28)	5 (20)	16 (64)	None
Have you stopped yourself from having a close relationship?	12(48)	1 (4)	4 (16)	2 (8)	7 (28)	6 (24)
Overcoming stigma						
Have you been able to use your inner strength to cope with stigma and discrimination?	None	2 (8)	6 (24)	10 (40)	18 (72)	7 (28)

Figure 4. Percentages of problems/circumstances linked to the caregiving situation as reported in CarerQoL-7D.



Analysis of Forum Content

Balancing the Caregiver Role and Relationship to the Patient

Overview

The common ground for participating in the forum is being a relative or significant other of a person with depression. The patient's situation is thus central and participants describe it in more or less detail. Participants partially share information about the patient's general situation and treatment, what relationship they have to the patient, and their interaction with him/her and other family members. The situation gives rise to difficult thoughts and feelings, including wondering how to cope with the patient and the consequences of the illness on relationships and daily life.

Hypersensitivity

How to balance the relationship to the patient and the caregiver role stands out as a major issue for most participants. Knowing how and how much to help the ill person versus leaving him or her alone is difficult, especially with grown-up children. Finding a balance in helping a child versus encouraging independence seems difficult. Fear of severing the contact and bond with the patient makes participants reluctant to set limits, sometimes causing frustration and limiting relatives' own lives. Participants differentiate parent-child from partners' relationships. Parents mean that they can never let go of a child and stop worrying about his or her well-being, whereas an ill partner can be left, no matter how difficult. However, the will to support both (grown-up) children and partners and not to give up on either is strongly articulated. Participants describe their struggles and look for advice on how to find a fruitful balance. They reflect upon their interaction patterns with the patient and other family members, moving family dynamics and behavior patterns into the forefront. The nature of participants' relationships is gently questioned by fellow forum participants to stimulate reflection. Several participants describe hypersensitivity in their relationship and assessment of the patient, leading to a constant watchfulness and perhaps premature conclusions about the patient's status and needs. This hypersensitivity is lifted in the forum, shedding light onto the phenomenon and putting it in a new perspective for some participants.

A Lonesome Rollercoaster

Descriptions in the forum divulge strong feelings associated with a life with mental illness, such as sorrow, worry, fear, frustration, anger, pain, sympathy, and loneliness. The condition's difficulties mark daily life in several ways. Participants describe patients' self-centeredness and lack of consideration toward others' needs as frustrating, although they realize that it is linked to being ill and possibly remorse in patients. The participants take on a caregiver role for a loved one as a natural gesture; however, prolonged periods without leisure or rest take a toll on relatives' well-being and health. Constantly worrying about the patient's health and life seems wearying, not the least when the person isolates him- or herself without giving any life signs, again making it difficult for participants to balance their presence in patients' life. The fear of self-destructive behavior is looming.

Loyalty issues come out strongly through an expressed unease at mentioning troublesome aspects in participants' relationship to the patient; however, most participants' descriptions are suffused with empathy and caring. Participants wish the ill person the best, hoping for a brighter future. In partnerships, a growing loneliness can be seen due to the ill person's personality change and retirement from common activities and socializing. Dark thoughts are described as contagious and participants miss the closeness and dialogue with their partner. Thoughts about the future are overshadowed by the illness. Living with the illness for extended periods and experiencing inefficient help breed feelings of helplessness and hopelessness. Participants describe losing hope countless times, but also a vital need for hope to carry on. Shifting focus from negative thoughts to the patient’s progress is suggested as a strategy to reframe the situation and avoid tunnel thinking.

Participants’ Own Life and Support

Overview

“Take care of yourself and allow yourself to live your own life” are repeated suggestions to encourage fellow forum participants to pursue own activities. Giving up leisure and social activities, to stay close to the ill person or due to lacking energy, lead to isolation and frustration. Constantly focusing on the patient’s needs and ignoring their own needs and wishes eventually affect participants’ health negatively, sometimes seriously. “Save yourself, then you can help others” catches the spirit in some of the forum posts. It appears easy to recommend, but more difficult to apply without inducing doubts or guilt. The need for space and temporary freedom from worry is obvious.

The Need for Professional Help

Many participants describe declining health and a need for professional help. Frustration over not being offered or even refused support is expressed. The patients’ health professionals focus on patients and refer relatives elsewhere. The content analysis indicates that participants’ focus on patients’ health and insecurity about where to ask for support complicate a potential help-seeking process, both for patients and relatives. Thinking about their health issues seems to induce guilt feelings, because participants assess that the patient is worse off than themselves. A strong need and wish for professional support is thus expressed, for example, advice on how to help the patient and themselves.

Coping Strategies

Participants describe diverse coping strategies, both when prompted by the moderator and spontaneously. Participants’ experiences do not necessarily change their fundamental perceptions in life, as described in the forum, but they contribute to reinforce life’s vulnerability and enhance the appreciation of certain experiences in daily life. Not making plans and taking a day at a time are described as strategies to avoid disappointment for canceling plans. Other mentioned strategies are exercise, relaxation, focusing on work, hobbies, or companion animals, spending time with friends, or traveling. Another option is to keep regular contact and help the patient in order to feel useful and in control, but also occasionally deliberately not calling the patient and hoping for the best.

Resources and Patient Advocacy

Overview

Relatives sometimes become intermediaries between the patient and the health system and other authorities. Occasionally relatives seem to become the only working link between patients and society. This can happen in emergency situations, but also to alleviate the patient’s burden, for example, by booking appointments. Dealing with the diverse organizations can be experienced as taxing, especially when problems and faulty treatments add up. Maneuvering through patient rights and administrative landscapes is energy-consuming. Participants describe both positive and negative experiences of care and how they were treated. Most express a frustration at the lack of support and at ineffective resources, both for patients and families.

Treatment and Participation in Care

Participants describe different experiences relating to how they were treated by health professionals. They express wonder, frustration, and anger at being excluded from care, partly relating to health professionals’ focus on patients and confidentiality rules. They comprehend the latter and don’t want to intrude on patients’ integrity, but feel at a loss for help. Participants describe a frustration at not being heard or given support when seeking care for the patient. They question the fact that family members are not automatically offered support, considering the condition’s consequences for all parties involved. Positive experiences with helpful professionals and emergency teams are also mentioned.

When sharing experiences in the forum, participants differentiate partners’ from parent-child relationships and the subsequent aptness of participation in care, although they wish for support in both cases. In the shift from youth to adult psychiatry, participants express frustration at not being automatically included in their child’s care, especially when a grown-up child cannot take care of him- or herself and depends on parents’ support. Even participants with an ill partner express a wish be included in care and supported in helping the patient. They yearn for advice on how to help and want to share their knowledge of the patient’s health fluctuations with health professionals. Despite their own professional health care experience, which some participants seem to have, they describe their role as significant others as emotionally demanding. They share their knowledge of the health system’s strengths and weaknesses in the forum, but mention needing support beyond their factual knowledge.

A Looming Shadow on Leisure, Social, and Professional Life

Overview

The illness affects daily life in many ways. It restrains leisure and socializing. Participants chose to stay with the patient when he/she feels down and sometimes isolate themselves because of low energy levels associated with the home situation. Leaving the patient alone to travel or meet up with friends seems to induce guilt feelings in many participants. The situation can affect relatives’ professional lives and economy because the psychosocial situation prevents them from working full-time. Work can also be a welcome shift of focus, although the home situation may affect the ability to concentrate. Revealing the reason for low energy levels in the professional or social network is experienced as delicate due to (self) stigma.

Openness Versus Secrecy

Revealing a loved one’s condition seems problematic. Worries about others’ reactions and discrimination in social and professional areas make participants cautious. They do not want others to think badly of the patient or only associate him/her with their condition. If at all most participants only mention the home situation to a few trusted friends, family members, and occasionally colleagues. Contradictory encouragements can be seen in the forum, where participants write that families should not hide and be ashamed, but rather speak up and ask for help. Simultaneously, caution is recommended in certain situations to prevent discrimination.

Interaction and Social Support

Overview

Although some participants ventilate their home situation with trusted friends, they worry about burdening them. They also wish to talk about other things than their troublesome situation and hence choose not to talk about it extendedly. Some participants describe a thinning social network due to people's tendency to withdraw from troubled individuals. Nevertheless, when given, support from friends, family, colleagues or support groups is highly valued.

The analysis of the interaction and support in the forum shows an exchange of several dimensions of social support, including more or less equal levels of information, emotional and esteem support respectively.

Informational, Emotional, and Esteem Support

Participants ask about and provide informational support in the form of advice, for example, coping strategies and referrals to sources of help for patients and relatives. They exchange information on pharmacological, psychological, and other treatment alternatives and sources of support for patients and families. Participants exchange emotional and esteem support by showing sympathy and understanding of each other's situation and by validating each other's experiences. Participants can partially recognize themselves in others' stories and realize that they are not alone in their situation. They support fellow participants through encouragement and by trying to convey hope. Offers of an online or offline presence, as suggested by some participants, may enlarge the social network.

Ventilating, Sharing, and Reflecting Give a Sense of Perspective

Reading others' narratives gives a sense of perspective and contributes to seeing one's situation from new angles, giving insight into diverse ways of handling the circumstances. To put experiences into words and ventilate them in the forum appear to be, directly or indirectly, beneficial. It contributes to clarify thoughts and patterns, especially when a response is provided by fellow participants. It helps them to reflect on the situation and discover new approaches. By sharing experiences with similar others in the forum, the social network can be unburdened, reducing potential guilt feelings and offering another type of support availability.

Empowerment, Loneliness, and Alienation

When sharing stories, some participants discover that they are not alone in their situation, partly reducing feelings of isolation. Some participants describe that they feel strengthened in their experiences and understanding of their situation when reading about others' similar experiences. Single participants describe that they have acted or plan to do so on received advice, pointing to an empowerment process.

Expectations and Suggestions

The forum's activity level is limited and the time lapse between postings and responses can be extended, which is described as a disadvantage. Sharing experiences with similar others is appreciated, however, the participants' respective situations differ in some aspects, for example, the type of relationship to the patient, making it more difficult to relate to each other's positions. Nevertheless, the interaction indicates an exchange of support regardless of the above. One flaming incident occurred due to the participant's unmet expectations on the present intervention and was handled by the moderator. Some participants fear that their message will be badly received or interpreted due to the lack of physical clues, which affects how or if they write in the forum. Face-to-face contact is described as easier in that respect.

At early stages of the test period, fear of being negatively affected and further burdened by others' stories was expressed. Participants seem to feel limited in their ability to help each other as fellow relatives without professional input. Some participants describe their role in the forum as empathic and supportive auditors. They appreciate that fellow participants take time to respond and to read about others' experiences. Participants mention expectations and a strong wish for professional feedback in the forum. They show appreciation of the psychoeducation module, but also put forward suggestions such as cognitive behavioral therapy online, further literature tips, and increased guidance in the forum, for instance through the suggestion of specific themes or literature for discussion in the forum and professional feedback.

Discussion

Caregiver Balance

Caring for a person with depression can produce additional burdens [1]. Living close to a depressed person affects family dynamics and the relationship to the patient, not the least in the form of hypervigilance, as expressed in the forum. Constantly worrying, whether living together or not, can lead to a feeling of not living one's own life, as seen in previous research [31]. Balancing relationhips seems difficult and energy-consuming. Participants yearn for advice on how to relate to and help the patient, also strenghthening previous findings [31]. In this study, 76% (19/25) reported relational problems and 72% (18/25) reported their own mental health problems, which is more than that in Flyckt et al's (2011) study [32]. However, the latter included informal caregivers to persons with psychoses, in which a fourth lived with the patient as compared to the present 48% (11 always, 1 sometimes). A longstanding relationship, shared living with the patient, daily caregiving, and negative appraisal of caregiving are known factors that can increase experiences of burden [33]. More than half of all participants reported difficulties coordinating daily activities with caregiving, from which most nevertheless experienced fulfillment as also seen in other studies [31,32].

Although many participants received support in caregiving tasks, one-third (7/25) did not. The need for professional support for caregivers is flagrant and participants express frustration over the unavailability and inefficiency of resources to support patients and families. Lacking participation in care and not being acknowledged by professionals as an asset with valuable knowledge of the patient seem to be recurrent problems, as shown by previous research [34,35]. Participants reported experiences of stigma and discrimination from mental health staff, confirming previous research on patients' experiences [36], but also positive encounters with attentive staff. A recent study shows that siblings of persons with mental illness do not experience openness, confirmation, and cooperation through health professionals' approaches, leading to a sense of powerlessness and social isolation in relation to care [35].

As seen in this study, not knowing who to ask and what to ask for, for example, family interventions, may be barriers to professional help. Information and effective implementation of family interventions, known to contribute to better outcomes and lower relapse rates [9,10], are hence called for. It seems that participants' and professionals' focus on patients may hinder relatives' own help-seeking process. Through participation in the forum, relatives' experiences are validated. Effects on their own lives and health are made visible through comparison with similar others, which may become a first step in seeking support. Participants can put their experiences into words and read about others' experiences, giving a sense of perspective and shedding new light onto their narratives. Exploring how living with a chronic disease affects daily life and storytelling have been identified as empowering methods [37], creating a sense of mastery over one's life [38]. Besides a social network and sense of community, self-help groups offer several advantages such as the provision of role models, coping strategies, opportunities for confession, catharsis, and mutual criticism, and an antidote to a sense of being different [39].

Dealing with stigma and self-stigma are salient issues in the forum and known barriers to treatment [2]. Most participants used their inner strength to cope, but concealing or hiding mental health problems is common, confirming previous research [40]. Participants reported unfair treatment from the family and having been avoided or shunned by people who know about the person's condition. Almost one-third (7/25) stopped themselves from having a close personal relationship, pointing to further interpersonal consequences. Fear of describing the patient in negative ways in the forum shows strong loyalty issues and guilt feelings. Choosing to keep silent may increase isolation and hinder seeking help. Being validated and feeling strengthened in one's experiences, as seen in this study, may help break the vicious cycle and be a first step toward greater openness and lessened stigma. Participants described sharing information about their home situation with caution for fear of others' reactions. Secrecy takes energy and isolates and assigning words to stressful experiences can help release some of the pressure [41]. In a support group like the forum, participants don't need to fear fellow participants' reactions; they are all gathered for the same reason, which may help reduce feelings of loneliness [35]. The lack of physical cues, a limitation with online communication, can create insecurity in interacting with others. The sender can't see how the receiver interprets the message. Nonetheless, anonymity has been identified as one of the advantages with OCs, allowing users to come out and express themselves more freely. By meeting similar others, users' identities can be strengthened [42] especially in stigmatized groups. As seen in this study, different types of social support, that is, informational, emotional, and esteem support [15] are exchanged, which can affect mental health positively [16,17,43]. Even if differences among group members make it more difficult to relate to each other, the same differences can give new perspectives on the situation.

The literature shows that Internet searches on mental health issues are common [44,45], with worry about someone's health being a main motivation for seeking health information online [45]. Factors such as sex (female), age (middle-aged), education, and Internet experience (high) [45] can be associated with higher levels of such searches. This goes in line with the characteristics of the sample that wrote in the present forum. Research also shows that systems that offer a sense of anonymity can have a disinhibitory effect on seeking information online [46], which was also an essential factor in this study.

Limitations

The sample was restricted, limiting activity levels in the forum and possibly discouraging participation. Large groups can also result in less intimacy and overwhelming message volumes [21,47]. Only 10 people wrote actively in the forum, limiting representativity. The limited participation also makes it difficult to look further into possible differences in discussion subjects in the forum. Further studies with larger samples are needed to discern potential significant trends. Identification of such themes on a larger scale may help tailor interventions depending on sociodemographic factors (eg, age, shared household) and other factors, such as the type of relationship to the patient. Nothing can be said about lurkers in this study, but lurkers can represent 80%-90% of an OC population and lurking can be associated with, for example, personal or group characteristics, external constraints, and stages of membership [48]. The moderator's prompts may have affected the discussions' content. Nevertheless, some prompted topics were also broached spontaneously by participants, whose responses can be interpreted as an interest in the prompts. Data were analyzed by an additional researcher (second author), strengthening the results' reliability. The length of the test period was determined in advance. It is short in relation to a life with depression with fluctuating needs of support. Nevertheless, participants' descriptions suggest that different stages of illness could be seen in the persons with depression throughout the test period. Recollections of diverse illness periods and subsequent needs were also described, although memories can be biased.

In this study, participants suggested professional feedback or thematic discussions in the forum. For health information to be purposeful, the needs and requirements of involved parties need to be taken into consideration [49]. Feedback on this tool can be processed and integrated into future versions to better address participants' needs, enhancing the tool's usability and possibly preventing further ill health and additional costs to society. Online comunities can be valuable both for exploring and addressing families' needs and concerns, but also entail shortcomings such as delays in answering posts and unanswered questions. Further studies are needed to explore how support through OCs can be optimized, including explorations of the moderator role and potential involvment of health professionals. Studies are needed to collect evidence on Internet support groups' relation to depression to inform decision making among concerned parties [50]. Areas for further exploration are factors influencing acceptability of and satisfaction with Internet support groups, including group size, moderation, board rules, accessibility, and naturalistic comparative studies of groups that differ in these aspects [50].

Conclusions

Living close to a person with mental illness affects daily life and the relationship with the person with depression, including difficulties in balancing the caregiver role. Participants' need for help in supporting the patient and themselves is flagrant. Lack of resources, stigma, focus on patients, and not knowing who to ask or what to ask for can hinder seeking help. Web-based support can help explore and alleviate the burden through the exchange of experiences and support among similar others, possibly reducing feelings of social isolation and alienation. Nevertheless, further studies are needed to optimize online support, for example, through the inclusion of professional feedback.

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Conflicts of Interest

None declared.

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Abbreviations

CarerQoL7-D: 7-item care-related quality of life for depression questionnaire
CarerQoL-VAS: care-related quality of life visual analogue scale
DISC-12: 12-item discrimination and stigma scale
OC: online community

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Original Paper

Using the Internet to Seek Information About Genetic and Rare Diseases: A Case Study Comparing Data From 2006 and 2011

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Abstract

Background: The Genetic and Rare Disease Information Center (GARD) is a major provider of Web-based information on genetic and rare diseases. Little is known about the type of Web-based information individuals seek about genetic and rare diseases or their reasons for seeking.

Objective: The objective of this paper is to describe the types of Web-based information sought about genetic and rare diseases and the reasons for seeking it from GARD by examining inquiries from 2006 and 2011.

Methods: There were 278 English-language email and Web-based inquiries posed to GARD by lay individuals (ie, patients, parents, and relatives), which were randomly selected from inquiries in 2006 (n=68) and 2011 (n=210) and examined using content analysis.

Results: Most often in both years, individuals sought basic disease information (51/68, 75.0% and 132/210, 62.8%; *P*=.067) and information about treatment (17/51, 33.3% and 62/132, 47.0%; *P*=.095). Specifically, inquirers requested information about their disease prognosis (6/51, 11.8% and 23/132, 17.4%; *P*=.347) and made requests for specialists (8/68, 11.8% and 31/210, 14.8%; *P*=.536). In both 2006 and 2011, a substantial subset of inquirers requested information related to undiagnosed symptoms, representing 16.2% (11/68) and 11.9% (25/210; *P*=.362) of inquiries, respectively. Inquirers were significantly more likely to have seen a health care provider before contacting GARD (99/210, 47.1% vs 20/68, 29.4%; *P*=.010) and to ask about clinical research studies in 2011 than in 2006 (24/210, 11.4% vs 2/68, 2.9%; *P*=.037). In the 2011 data set, the majority of the inquirers were women (201/210, 95.7%). In our 2006 sample, men were the majority source of inquiries (54/68, 79.4%).

Conclusions: Findings from this study indicate that lay people contacting a genetic and rare disease information center most often seek information about disease prognosis, finding a specialist, and obtaining a diagnosis for symptoms. Unique characteristics of individuals searching the Internet for genetic and rare diseases information, includes a growing interest in participating in clinical research studies and a desire to supplement or better understand information discussed during a visit with a health care provider. These efforts represent advancements in patient self-advocacy.

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KEYWORDS

rare disease, genetic disease, patient education, information seeking, Internet use

Introduction

Findings from a 2012 national survey of more than 3000 US adults by the Pew Research Center's Internet and American Life Project revealed that 1 in 3 Americans have used Internet resources to better understand a medical condition [1]. In order to determine a potential diagnosis for themselves or another person, 35% of US adults have used Internet resources [1]. Other research has shown that the number of Web-based health information seekers is increasing. The results from multiple surveys have shown that, people turn to the Internet for disease-specific information [2-4], diagnosis of symptoms [5], and for help in determining whether to seek medical attention [6]. Collectively, Web-based health seekers tend to be younger, more educated, and more affluent than other health information seekers [7].

Although previous studies have examined Web-based searching for health information in general, limited information is available about the Web-based searching experience of people who are living with a rare or genetic disease. A 2001 study on use of the Internet for genetics-related information found that a majority of individuals surveyed searched the Internet for genetics-related information after visiting a genetics clinic. The top reasons cited for searching the Internet for genetics information, included to find information in layman's terms, to get information about treatment, and to get information about genetic research [8].

A 2011 national study of Internet users by the Pew Internet and American Life Project found that the majority of those surveyed who had a rare disease said that they turned to other people with the same health condition for advice and support. Much of their interaction with fellow patients happened online because they did not live near people affected by the same conditions [9]. Prior research has demonstrated that obtaining information about a diagnosis and disease management can be challenging and frustrating for individuals with rare diseases. Rare diseases are defined as those with a prevalence of fewer than 200,000 affected individuals in the United States (approximately 1 in 1500 people) [10-15]. Accessing information is a challenge for individuals living with a rare disease, resulting in informational challenges for several reasons. Often, achieving a definitive diagnosis is delayed and requires significant effort and resources from patients, their families, and their health care providers; some patients' conditions are never diagnosed [16]. Even once a diagnosis is made, it often leads to a cascade of questions whose answers may be limited by an uncertain prognosis, limited information, and lack of treatment options [10,11,17,18]. A 2013 study on the Internet user profile of Italian families with rare diseases found that at least 90% of responders searched the Internet for information on diagnosis, treatment, and finding a physician specialist for their child's disease [19]. For many rare diseases, there are inadequate resources for patients, including few health care providers who have experience with their conditions. The lack of knowledge about rare diseases among health care providers leaves patients and their families to become as knowledgeable as possible on their condition. Patients and families may feel isolated and even desperate for any information that can help inform decisions about their clinical management or adaptation to their condition [10].

Previous research has indicated that individuals living with stigmatizing conditions, which is common to many genetic and rare diseases, may demonstrate greater use of Web-based health information seeking [9,20]. Unlike traditional Web-based health information seekers, individuals living with a genetic or rare disease may be seeking information about their health via the Internet because of the lack of any other available resources [9]. Therefore, the type of information and motivations for seeking Web-based health information may be influenced by the rarity of an individual's condition. As a case example, this study sought to describe the type of information individuals contacting the Genetic and Rare Diseases (GARD) Information Center were seeking as well as their motivations for obtaining that information.

Methods

Data Source

The GARD Information Center, supported by the National Center for Advancing Translational Sciences, Office of Rare Diseases Research, and the National Human Genome Research Institute, was established to assist the general public, including patients, family members, and health care providers, in finding reliable and timely information about genetic and/or rare diseases. GARD information specialists are genetic counselors who provide information about genetic and rare diseases in English and Spanish via a toll-free hotline and personalized written responses to inquiries. GARD also provides access to its database of disease-specific information on the Internet. Many replies to inquiries are posted on the GARD website question and answer section and inquirers are directed to our website (and external websites for additional resources). Through this public resource, Internet users can search for information on more than 6000 genetic and/or rare diseases and pose questions directly to an information specialist. In 2006, 54% of all inquiries were received via email. In 2008 the Web-based form was added to the GARD website. In 2011, 7% of inquiries were received via email and 53% via the Web-based form. As of 2013, GARD information specialists have responded to over 40,000 inquiries from the public. On average, GARD currently receives 22 inquiries per day with 77% coming from within the United States and 13% from an international location (10% are not reported). Approximately one-third of all inquiries received are from patients or at-risk individuals.

Inquiries

Data Collection

Among the approximately 34,000 inquiries in the GARD database, there were 2000 written inquiries from 2011, 98% of which were in English. The sample of inquiries were randomly obtained from the GARD dataset of inquiries from 2006 and 2011 through a computer-generated randomized software applied to a chronological list of annual inquiries. Our analysis, was conducted on a random sample of 250 English-language inquiries (10%) posed to GARD by lay individuals (ie, patients, spouses, relatives, friends, and parents/guardians) in 2011. We also analyzed a sample of 68 inquiries made in 2006 that were randomly drawn from inquires in 2006. To provide a focus for the qualitative analysis, we chose to only examine information-seeking by lay individuals without specialized knowledge. Inquiries from health care providers, social workers, and students were therefore excluded. We also excluded inquiries made by fax, letter, phone, or voicemail, as well as international inquiries and foreign-language inquiries. Finally, we excluded inquiries for which we could not determine the person's reasons for contacting GARD (ie, the person asked a question but did not provide context). Inquiries that were complicated, confusing, or out-of-scope were also excluded.

The final sample yielded 278 inquiries, each of which contained the person's verbatim initial inquiry, inquiry origin (domestic), type of contact (email and Web-based form), gender, date received at the information center, the specific condition for which they were inquiring, primary language (English), and their reason for inquiry. No other demographic information was collected.

Data Analysis and Coding Schema

All inquiries were de-identified and analyzed using thematic analysis through the QSR Nvivo software. Our aim was to identify the reasons for seeking information and the type of information sought by individuals contacting GARD. We were interested in finding broad themes with which to characterize information-seeking behavior of those with questions concerning genetic and rare diseases. We then identified similarities and differences in themes between inquiries from 2006 and 2011. To test the reliability of our coding, a second individual coded 20% of the inquiries from 2006 and 2011. Coding discrepancies were discussed systematically among the 2 coders and any differences were reconciled. Since the coding was quite literal, there were very few initial discrepancies in the coding.

Results

Data Sampling

A random sample of 278 English-language email and Web-based inquiries posed to GARD by lay individuals (ie, patients, parents, and relatives) in 2006 (n=68) and 2011 (n=210) was analyzed (Table 1). A majority of participants from both datasets self-identified as patients and female.

Participant Demographics

Tables 1 and 2 highlight the characteristics of inquirers from 2006 and 2011. In both years, the inquirers were most often patients. There were more spouses/relatives and females in 2011 than in 2006 ($P \leq .05$); there were no male inquirers in the 2011 data set.

Table 1. Inquirer user category.

User category	2006 (n=68), n (%)	2011 (n=210), n (%)
Friend	5 (7.4)	4 (1.9)
Parent/guardian	13 (19.1)	52 (24.8)
Patient	34 (50.0)	94 (44.7)
Spouse/relative	10 (14.7)	60 (28.6)
Not stated	6 (8.8)	0 (0.0)

Table 2. Inquirer gender.

Gender	2006 (n=68), n (%)	2011 (n=210), n (%)
Male	54 (79.4)	0 (0.0)
Female	14 (20.6)	201 (95.7)
Did not state	0 (0.0)	9 (4.3)

Basic Disease Information

Most of those who inquired about a specific condition requested general disease information. The majority of individuals (51/68, 75.0% in 2006 and 132/210, 62.8% in 2011; P=.067) seemed to have very little information on a condition and were looking for any disease information that might be helpful to their understanding of the condition:

> *I recently was diagnosed with Pattern Dystrophy, but was not given any real information on this eye disease. Do you have a website I could go to and gather information. Anything at all you could tell me would be truly appreciated.*

Individuals also requested more specific disease information related to obtaining a diagnosis, signs and symptoms, management and treatment, and prognosis.

Diagnosis

In 2006 and 2011, 16% of inquirers (2006: 8/51, 15.7; 2011: 21/132, 15.9%; P=.970) requested information on obtaining a clinical diagnosis for their particular medical condition. Individuals wanted to know how diagnoses were made, including the clinical work-up or particular test, along with where to go to obtain a diagnosis for a suspected condition:

> *I would like information on this or how I can get a specific diagnosis. They ran a blood test but it came back non-specific. What would be the best way and the best kind of doctor to find out exactly what I have?*

Signs and Symptoms

About 7.8% (4/51) of inquirers in 2006 and 15.9% (21/132) of inquirers in 2011 requested information on the signs and symptoms of a condition (*P*=.154):

> *It is my understanding that hyperostosis frontalis interna can be a symptom of Morels syndrome. What are the symptoms of Morels syndrome?*

Management/Treatment

Of those who requested basic disease information, 33.3% (17/51) in 2006 and 47.0% (62/132) in 2011 (*P*=.095) requested information about management and treatment options, indicating that they found it difficult to find effective treatment options or providers who knew how to treat their condition:

> *I have a 15 year old daughter who was recently diagnosed with AAA syndrome... I would like to know if there is anything that can be done about her abnormal sweating she sweats profusely when she is cold it doesn't matter how many layers of clothing she wears she sweats through them all. We have tried various types of treatments and so far none have worked. We welcome any ideas thank you for your time.*

Prognosis

Among those who wanted information about a specific condition, 11.8% (6/51) and 17.4% (23/132) of inquirers in 2006 and 2011, respectively, requested information on prognosis (*P*=.347). Frequently, inquirers wanted to know what issues they could expect to encounter when living with a particular condition:

> *I have a two year old who looks like he has this according to the genetic blood test done. A geneticist has not been assigned to his case yet and we lose our insurance coverage in 20 days. There is not a lot of information out there on what to expect in terms of how this can affect one's life and was hoping for more information.*

Finding a Specialist

Many inquirers were looking for a specialist in their particular condition (8/68, 11.8% in 2006 and 31/210, 14.8% in 2011; *P*=.536). Some individuals reported having already seen a health care provider who was not particularly knowledgeable about their condition; therefore, they were hoping to find an expert:

> *She begged me to help her find someone that specializes to help her. I have looked but could not locate information as to where I might direct her for help. Can you supply the names of facilities or doctors in the Atlanta or Knoxville TN area that we could send her to for consultation?*

Undiagnosed Symptoms

In both 2006 and 2011, requests for information related to undiagnosed symptoms represented 16.2% (11/68) and 11.9% (25/210) of inquiries, respectively (*P*=.362). More specifically, inquirers with undiagnosed symptoms requested information about obtaining a specific diagnosis for their condition, getting the appropriate treatment, and finding a provider:

> *My daughter and I need a diagnosis for a rare disease we both have. We are both HLAB27. Both have duplicated urinary tracts, kidney both right sided. Both have cervical rib, severe joint pain, SI joint pain, migraines, carpel tunnel…and so much more. We need to find out the name of what we have. All rheumatologists we have seen are stumped plus other specialists. We are told over and over I have never seen this before- very strange.*

Previously Seen by a Health Care Provider

Several inquiries mentioned visiting a health care provider prior to contacting GARD. Many individuals reported seeing various doctors who were unable to either diagnose their condition or provide effective treatment. Inquirers from 2011 were statistically more likely to have seen a health care provider than inquirers from 2006 ((99/210, 47.1% vs 20/68, 29.4%, *P*=.010):

> *I am a 29 year old woman and I have symptoms of a rare illness for the past two years. I have visited several doctors and did numerous tests however the doctors were not able to determine what my illness is. I would like to know what this organization does and if you can be of any help to me. I would be grateful for any information. I am a 29 year old woman and I have symptoms of a rare illness for the past two years. I have visited several doctors and did numerous tests however the doctors were not able to determine what my illness is. I would like to know what this organization does and if you can be of any help to me. I would be grateful for any information.*

Research Studies

Often inquirers requested information about participating in research studies. In 2011, inquirers were significantly more likely to ask about clinical research trials as compared with those in 2006 (24/210, 11.4% vs 2/68, 2.9%; *P*=.037):

> *Asking if there is a clinical trial for treatment of oligodontia for children? I have five grandchildren and three of them are afflicted with a form of this malady but none of the three have the same symptoms.*

Discussion

Principal Findings

The 2013 Pew research study found that half of Web-based health information searches are typically done on behalf of someone else [1]. In both 2006 and 2011, the most common type of GARD inquirers were those self-identified as patients. This novel finding may reveal the extent to which patients with genetic and rare diseases act as their own health care advocates. Patients in need of genetics-related information are often seeking more information after they have seen a health care provider [21], suggesting that health care providers frequently have limited resources and/or knowledge about many genetic and rare diseases. As a result, at least some patients may do their own research about their diagnosis or symptoms after visiting a provider. A study of Web-based health information seekers found that over 40% of Internet users had already sought help from a health professional for the same health issue prior to their Internet search [22]. Approximately 29% of inquiries in 2006 and 47% of inquiries in 2011 mentioned having already seen a health care provider prior to contacting GARD. The difference in inquiries may also reflect changes in health care delivery that suggest physicians have less time to spend with patients during clinic visits [23].

Inquirers in 2006 and 2011 were most often looking for information related to a specific disease or health concern. They also wanted to know about treatment and management options for a particular condition (33% in 2006 and 47% in 2011). The need for information on a specific condition and treatment options is a primary reason for Web-based health searches in more general samples. Previous research indicates that 66% of Internet users look for Web-based information about a specific disease or health concern and 56% look for information about medical treatment options [1]. The Web-based, information-seeking habits of parents of children with a rare health condition has been suggested to be rooted in an attempt to manage parental uncertainty [24]. Furthermore, prior findings in the literature on Web-based health information seeking for genetics-related information indicate that the prognosis for a condition and help finding a specialist is often desired [21]. Taken together, these categories are likely to be unique to the genetic- and rare-disease population because they reflect the difficulty patients have in finding information on their long-term outlook and providers with expertise in their particular condition.

Prior research on Internet searching for genetic information found that 46% of surveyed users visiting a genetics information website (ie, AsktheGeneticist) did so in order to find information about a possible diagnosis for themselves, their child, or other family relatives [21]. We showed that many inquiries in our 2006 and 2011 samples were related to finding a diagnosis for undiagnosed symptoms and conditions. The literature on “Web-based diagnosers” finds that 1 in 3 Americans have reported using the Internet to find a medical diagnosis for their symptoms and 1% of Web-based diagnosers say their follow-up conversation with a clinician regarding their suspected diagnosis was inconclusive [1]. Some of the inquirers dealing with undiagnosed symptoms in our sample may be Web-based diagnosers who have had inconclusive outcomes with their clinicians. Such inquiries were typically from individuals who had a long-standing medical condition for which they were unable to receive a diagnosis. These inquirers had often already seen several specialists and had extensive medical evaluations prior to requesting information from GARD. Taken together, the data suggest that existing resources, such as the Orphanet database are underused.

Between 2006 and 2011 there was a significant increase in the number of inquirers asking questions about participating in research studies. This finding may suggest an increase in people’s awareness of or interest in participation in research. The rising interest in clinical research participation among patients with genetic or rare diseases may have implications for health care providers in their decision to inform patients about these studies as well as explaining and facilitating the process of clinical research participation. Additionally, the need for more research in rare diseases is apparent in the numerous conditions that have no active clinical research studies available.

The results of this analysis have the potential to help improve GARD services. Knowing who is contacting GARD, what health-related information is of greatest interest, and how queries have changed between 2006 and 2011 will help GARD information specialists provide better, more targeted answers to future inquiries. The results of this study could also be shared with other groups to guide the development of targeted educational materials about genetic and rare diseases. For example, the increasing number of inquirers interested in research studies suggests a need for more information resources about participation in clinical research. Additionally, the number of individuals with undiagnosed diseases supports the need for more access to programs such as the National Institutes of Health Undiagnosed Diseases Program. Finally, these findings promote the relevance of the goals of the International Rare Disease Research Consortium for funding more research into better diagnostics and therapeutics for rare diseases.

Limitations

The limitations of this study pertain to the sampling design. First, data was sampled from two distinct time points, which limits our understanding of patients’ changing information needs over time. Second, the analysis was constrained by what was provided in an inquiry, without context about patients’ previous experiences. Additionally, since confusing or complicated inquiries were not analyzed as part of this study, our data may not include some of the reasons for seeking information from individuals with particularly challenging information needs and difficult situations. Third, in our qualitative analysis, a kappa statistic was not calculated. However, the independent coders concurred on the final coding. Fourth, because personal identifiers were not collected or were removed from the inquiries, we could not examine patterns based on many sociodemographic characteristics (ie, education level, income level, etc.) nor could we control for multiple inquiries coming from the same person. Fifth, in the 2011 data set, the majority of the inquirers were women. In our 2006 sample, men were the majority source of inquiries. This proportion arose from sampling bias because two-thirds of all GARD inquirers in 2006 were female, whereas only 18% were male and in 16% of cases, gender was not indicated. Randomization of the inquiries was key to the design in avoiding attention to specific types of inquires and deemed more important than drawing a sample representative of the sociodemographics.

Conclusions

This study aimed to describe the types of information individuals contacting the GARD Information Center were seeking and the motivations behind obtaining this information. We determined that some types of information individuals contacting GARD requested was similar to those requested by other Web-based health information seekers. However, patients with genetic and rare diseases had unique types of queries regarding disease prognosis, identification of a disease specialist, and obtaining a diagnosis for undiagnosed symptoms and conditions. We also noted increased interest in participation in clinical research studies from 2006 to 2011. Further quantitative research is needed to examine predictors and outcomes of Web-based health information seeking among a larger population of patients with genetic and rare diseases.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

GARD: Genetic and Rare Diseases

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Original Paper

Internet Protocol Television for Personalized Home-Based Health Information: Design-Based Research on a Diabetes Education System

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Abstract

Background: The use of Internet protocol television (IPTV) as a channel for consumer health information is a relatively under-explored area of medical Internet research. IPTV may afford new opportunities for health care service providers to provide health information and for consumers, patients, and caretakers to access health information. The technologies of Web 2.0 add a new and even less explored dimension to IPTV's potential.

Objective: Our research explored an application of Web 2.0 integrated with IPTV for personalized home-based health information in diabetes education, particularly for people with diabetes who are not strong computer and Internet users, and thus may miss out on Web-based resources. We wanted to establish whether this system could enable diabetes educators to deliver personalized health information directly to people with diabetes in their homes; and whether this system could encourage people with diabetes who make little use of Web-based health information to build their health literacy via the interface of a home television screen and remote control.

Methods: This project was undertaken as design-based research in two stages. Stage 1 comprised a feasibility study into the technical work required to integrate an existing Web 2.0 platform with an existing IPTV system, populated with content and implemented for user trials in a laboratory setting. Stage 2 comprised an evaluation of the system by consumers and providers of diabetes information.

Results: The project succeeded in developing a Web 2.0 IPTV system for people with diabetes and low literacies and their diabetes educators. The performance of the system in the laboratory setting gave them the confidence to engage seriously in thinking about the actual and potential features and benefits of a more widely-implemented system. In their feedback they pointed out a range of critical usability and usefulness issues related to Web 2.0 affordances and learning fundamentals. They also described their experiences with the system in terms that bode well for its educational potential, and they suggested many constructive improvements to the system.

Conclusions: The integration of Web 2.0 and IPTV merits further technical development, business modeling, and health services and health outcomes research, as a solution to extend the reach and scale of home-based health care.

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KEYWORDS

consumer health information; diabetes mellitus; health literacy; Internet; IPTV; patient education; social media; telemedicine; television; Web applications

Introduction

Broadcast television has an almost universal presence and prevalent influence in homes. It remains the preferred mass information and communication medium among substantial numbers of people who do not use an Internet-connected device as their primary source of news and entertainment. Unfortunately for consumer health information and patient education, broadcast television does not provide health information that is reliably understandable and appropriate for any individual viewer.

Internet protocol television (IPTV) offers services not provided by broadcast television, for example, replays of television shows at viewer-selected times, interaction with live television shows, or video on-demand. IPTV is defined as “where television services are delivered using Internet Protocol over a managed broadband network”, and is thus distinct from simple Internet-connected TV, unmediated access to Internet content, or a hybrid of these [1]. IPTV has been described as “the killer application” of broadband Internet [2]. Although that prediction seems so far unfulfilled, it is in active use in many countries and it is the focus of ongoing international standards development [3]. A recent industry report identifies over 100 vendors and 940 service providers [4].

IPTV as a medium for consumer health information is a relatively underexplored area of medical Internet research. The idea that providing health information via television may improve engagement among people with literacy deficits has been around for some time: interactive TV among culturally diverse groups of patients and their health care providers was mentioned as an area for research in 2006 [5]. A recent systematic review identified 25 studies in the broad area of using IPTV and other interactive or digital television technologies in health, and noted the need for further evidence on which to base specification of user requirements [6]. Subsequent research papers have described designs for IPTV systems for consumer health information, for instance to provide medication reminders [7] and health videos [8]. A recent survey of potential providers and consumers of health information via IPTV offers in-principle support for such systems [9]. However, there is a gap in implementation and evaluation research.

The technologies of Web 2.0 add a new and less explored dimension to IPTV’s potential [10]. In general it has become technically possible to integrate Web 2.0 technologies with television to build systems that enable intelligently personalized recommendations and selections of television content [11,12]. The authors’ review of research literature has found just one example of a proposed design for health care services of this type [13].

Our research aimed to explore an application of IPTV for personalized home-based health information in diabetes education, in the context of a national high-speed broadband Internet infrastructure [14]. Type 2 diabetes is a major chronic health issue and health literacy is a factor in its prevention and management [15]. The Internet has created the challenge for diabetes educators to “push situation and user-specific quality knowledge to users based on their actual individual needs, circumstances and profiles at any given time” [16]. The Internet has also created the challenge for people with diabetes to become competent computer and Internet users or risk missing out on the flow of recent Web-based information and education.

Health literacy is “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” [17]. Better levels of health literacy can increase quality of life, optimize utilization of health care services, and reduce the burden of disease [18]. However, health literacy levels are surprisingly low [19,20] and there is a complex interdependency among different kinds of literacies that contribute to health and eHealth literacy [21,22]. To improve health literacy levels experts have recommended more personal forms of communication and educational outreach with “significant widening of the content and methods used” [23]; this approach has given rise to a wide range of information technology solutions for diabetes self-management [24].

We hypothesized that it is technically feasible to develop an integrated “IPTV 2.0” system. We theorized that such a system can enable diabetes educators to deliver personalized health information directly to people with diabetes in their homes; and that this system can encourage people with diabetes who make little use of Web-based health information to build their diabetes literacy via the interface of a home television screen and remote control. This paper aims to report empirical findings about the implementation and evaluation of an integrated IPTV 2.0 system.

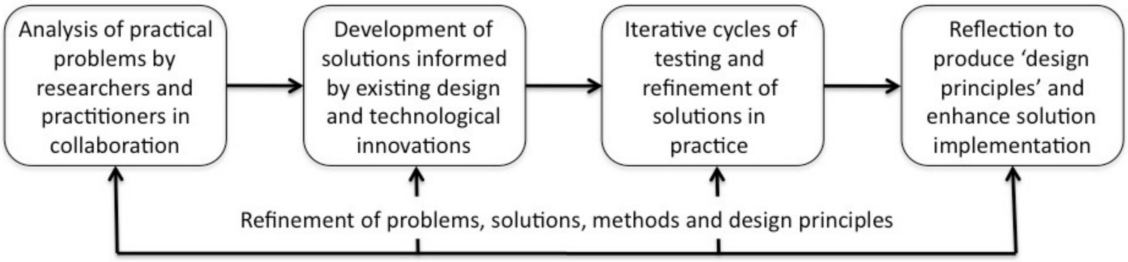
Methods

Design-Based Research

It is not a simple matter for designers of Internet-based health interventions “to take a learner-centered, needs-based approach and to consider how all technology features (eg, text, graphics, interactivity, video, and games) can be used in ways to best meet the needs of learners" [25]. Because of the complexities of working ethically with an innovative Internet technology among people with diabetes and low literacies, this project took a design-based approach as illustrated in Figure 1.

Stage 1 of our research, corresponding to the analysis and development steps in Figure 1 and described further below, comprised a feasibility study into the technical work required to integrate an existing Web 2.0 platform with an existing IPTV system, populate it with content, and implement it for user trials in a laboratory setting. Stage 2 of our research, corresponding to the testing and reflection steps in Figure 1 and described further below, comprised an evaluation of the system by consumers and providers of diabetes information (ie, people with diabetes, their carers, and their diabetes educators). Our evaluation protocol was derived from a framework for measuring the International Standards Organization concepts of software product quality and system quality in use, based on capturing usability and user experience from different stakeholder perspectives [26]. Our participant numbers (4 providers and 13 consumers) met conventions for evaluation of usability [27]. Stage 2 proceeded with human research ethics approval from The University of Melbourne and Diabetes Australia-Vic (DA-Vic), and with the informed consent of all participants. The research was conducted from 2012 to 2013.

Figure 1. Design-based research process (attributed to David T Jones, sourced from Flickr and reproduced under a Creative Commons License).



Stage 1: Development of SeeCare Ericsson IPTV (S-IPTV) System at the Australian Broadband Applications Laboratory for Diabetes Australia (Vic)

The Web 2.0 service underlying this project was SeeCare [28], a service that enables consumers to manage their own home- and community-based care and support. Personalized health information content is provided based on people's specific needs, goals, and health conditions as these change over time. A consumer has their own SeeCare account and through this manages their own care, or they can give permission to a family member or an informal carer to act in this role if unable to do so for themselves. The Web tool provides a directory of care services and support agencies through which the consumer can arrange various forms of assistance with independent living at specified times. The care services and support agencies have Web-based access to only the level of information about the consumer that the latter chooses to make visible to each one.

Ericsson's IPTV network infrastructure used in this project has been described elsewhere [29] as has the potential to develop a community education application as a partnership between Ericsson and SeeCare [30]. This partnership was fostered in the Australian Broadband Applications Laboratory (ABAL), a high-capacity broadband test-bed at the University of Melbourne's Institute for a Broadband Enabled Society [31]. DA-Vic, the health service partner in this project, is a well-established not-for-profit peak body representing people affected by diabetes and those at risk [32]. The video content for the trial was supplied by Real Time Health, a company that specializes in providing digital video of patient narratives [33].

Video content in this project consisted of filmed interviews with people with diabetes and their carers, each interview relating their experiences with many aspects of this health condition such as symptoms, lifestyle choices, exercise, diet, mental health, and other issues. Each interview was segmented into several 5- to 10-minute videos, and each short video was identified with one or more health condition–related categories using keywords such as "depression" or "medication". The videos were loaded onto the IPTV server and allocated an identification (ID) tag.

The SeeCare system can match a particular video's ID tag automatically with a health care consumer's needs, as specified by the health condition–related keywords they have in their account profile (this function was not trialed in this project). Alternatively a health educator logged into the SeeCare system at their workstation, and with permission to access a client's S-IPTV account, can manually allocate appropriate videos to their client based on their expert opinion of the client's information needs and wants (in this trial educators' expert opinion was formed through a telephone conversation with each client).

After matching in SeeCare, ID tags and condition categories are then forwarded to the Ericsson server via the middleware, which acts as the intermediary in the transactions. This application programming interface specifies how the software components interact with each other to overcome any data format and exchange issues between the two separate systems. For privacy reasons the two systems share information only about the videos and health condition–related categories required for display, and not any other personal or medical information about the health care consumer.

Through this process videos on distinct topics are made available, often more than one in each category, for a specific client to watch when they log in to their S-IPTV account. Figure 2 illustrates the data flow and Figure 3 illustrates the workflow.

The consumer interface consists of a large screen television connected to the Internet via a set top box, which decodes the incoming broadband data from the remote Ericsson IPTV video server and provides a high definition picture. The client must log in to the S-IPTV system via their television screen using a remote control before they can watch their assigned videos. This is not a technical limitation but part of the privacy requirements to ensure no one else can access a user's account without authorization. The log-in process is as close as a consumer gets to requiring computer skills. In this trial, users had three different remote controls they could choose: a standard TV remote as well as two different types for the set top box. The first of these was a standard hand-held device with alpha-numeric buttons, and the second was a special keyboard-style remote to make typing of usernames and passwords easier for users who needed this.

After log-in the user can see a menu of health condition–related categories down the left side of the screen with thumbnails and text descriptions of each video title to the right. The remote control can be used to scroll down and across to the desired selection and the video can be played, paused, and fast forwarded as if the television were connected to a video player in the room, even though the content is being streamed over a broadband network from a distant server.

The system can handle multiple accounts and passwords so that family members and carers can access their own video selections; for example, there might be videos on meal preparation or wound management that carers specifically need to see.

Figure 2. Dynamic user-specific data passed from SeeCare to Ericsson server.

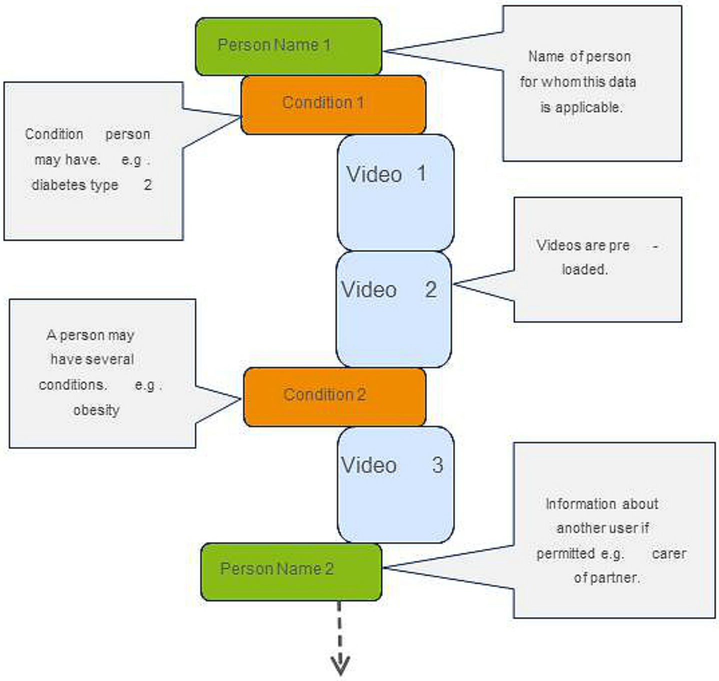
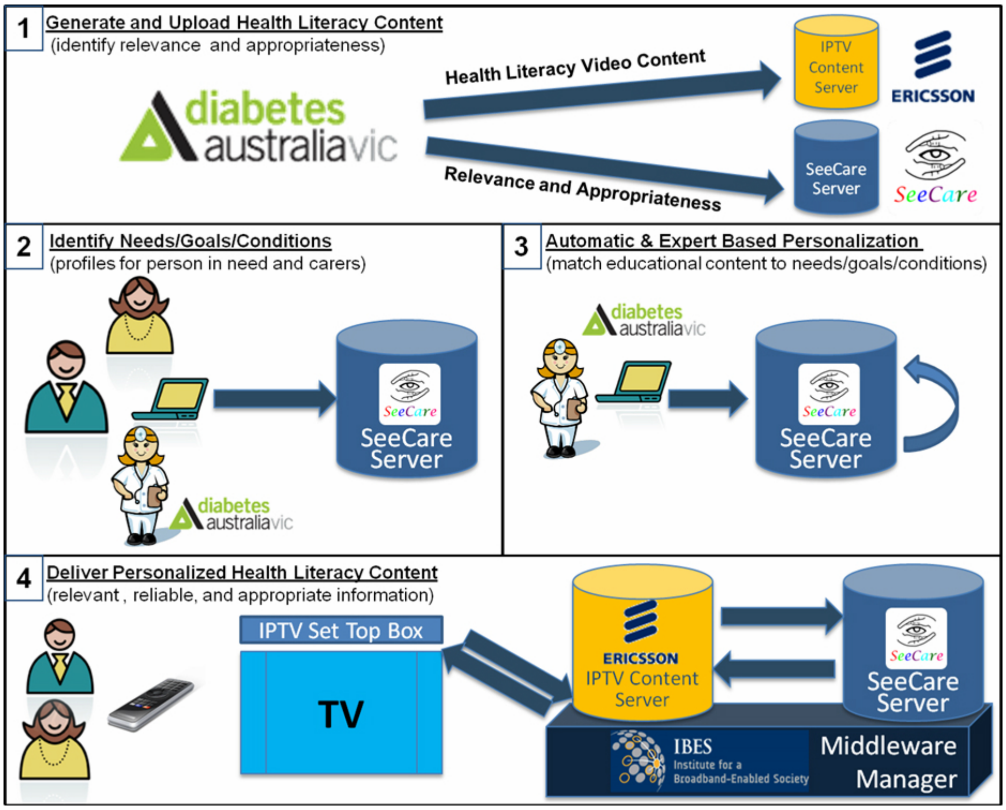


Figure 3. SeeCare IPTV workflow.



Stage 2A: Evaluation by Diabetes Educators

Participants

Four DA-Vic educators participated in the S-IPTV trial. Screening questions established their computer and Internet literacy. All educators used computers routinely for work and were competent at sending and receiving emails, working with standard word processors and spreadsheets, using an enterprise database, doing Web-based searches, and using mainstream social media platforms.

Measures

A researcher noted any initial barriers or enablers encountered by educators as they learned to use the S-IPTV system on a desktop computer at ABAL. Educators were asked to comment later about their experience with S-IPTV based on questions shown in the Textbox.

Procedures

A researcher set up a SeeCare user account for each educator. Educators attended a 1-hour long group presentation by researchers at ABAL, during which they had hands-on instruction on a personal computer about the basic functions of S-IPTV, including how to match video content from the system with the individual interests of a client. Each educator was allocated several participating DA-Vic clients, not previously known to them. From their workplace, using a script devised for this project, educators telephoned these clients to determine what each one would like to know about diabetes. While on the phone, the educator logged on to SeeCare on their desktop computer, selected video content suited to the client's expressed information needs, and triggered its loading into the client's S-IPTV account. After the client trials concluded, educators took part in a semistructured 1-hour group interview.

Stage 2B: Evaluation by People With Diabetes and Their Caregivers

Participants

Participants were adult members of DA-Vic who had been diagnosed with Type 2 diabetes in the previous 12 months and had a low level of computer literacy. We chose to focus on computer literacy as a factor in health literacy based on evidence of a clear correlation between these two [34]. Initial recruitment of people with diabetes was done through advertisements posted in the DA-Vic main office and mailed to those on the DA-Vic mailing list. Volunteers phoned a researcher who used screening questions to exclude those with average or above average computer and Internet literacy.

Ten people with Type 2 diabetes participated, plus their spouse who acted as their informal caregiver in three cases, representing appropriate genders, ages, and fair to poor computer literacy levels. All participants used a television at home and some other technologies. Table 1 shows participant demographics and technology usage details.

Table 1. Participating people with diabetes and their caregivers (N=13).

Characteristics	n (%), N=13
Gender	
Male	8 (62)
Female	5 (38)
Age	
65-80	9 (69)
45-65	4 (31)
Computer at home	
Yes	8 (62)
No	5 (38)
Internet connection at home	
Yes	5 (38)
No	8 (62)
Computer/Internet uses	
Word processor/spreadsheet	7 (54)
Searching the Web and visiting websites	5 (38)
Email	4 (31)
Social media	4 (31)
Frequency of computer use	
More than once a week but less than once a day	5 (38)
No more than twice a month	8 (62)
Other information and communication technologies at home	
Television	13 (100)
Landline phone	13 (100)
DVD player	12 (92)
Mobile phone	5 (38)
Gaming console	2 (15)

Measures

A researcher noted any initial barriers or enablers encountered by people with diabetes and their carers as they learned to use the S-IPTV system at ABAL. People were asked to comment later about their experience with S-IPTV based on questions shown in Textbox 1.

Textbox 1. SeeCare IPTV evaluation protocol.

1. Health information providers and consumers.

- What videos did you watch on the S-IPTV system?
- How informative or uninformative did you find the S-IPTV videos?
- How relevant or irrelevant to your circumstances were the S-IPTV videos?
- What did you think about the variety and quality of the videos that the S-IPTV system made available to you?
- How would you describe the information for system users that the S-IPTV system made available to you?
- What reflections or related thoughts occurred to you while you were using the S-IPTV system?
- To what extent did you feel confident or unconfident about using the S-IPTV system?
- To what extent did you find it easy or difficult to use the S-IPTV system?
- To what extent did you find the S-IPTV system responsive or not responsive to your commands?
- To what extent would you say that the S-IPTV system was safe or risky to use?
- To what extent did you find the S-IPTV system enjoyable or problematic to use?
- To what extent did you like or dislike using the S-IPTV system?
- What was most interesting to you about the S-IPTV system?
- Would you want to use the S-IPTV system in future? Why or why not?
- What suggestions would you make for improving the S-IPTV system?

2. Health information providers only.

- For which people with diabetes did you select videos from the S-IPTV system?
- What was it like to use the S-IPTV system while on the phone with these people?
- What was it like to speak with these people about the S-IPTV system?
- To what extent do you think these people would find it easy or difficult to use the S-IPTV system?

3. Health information consumers only.

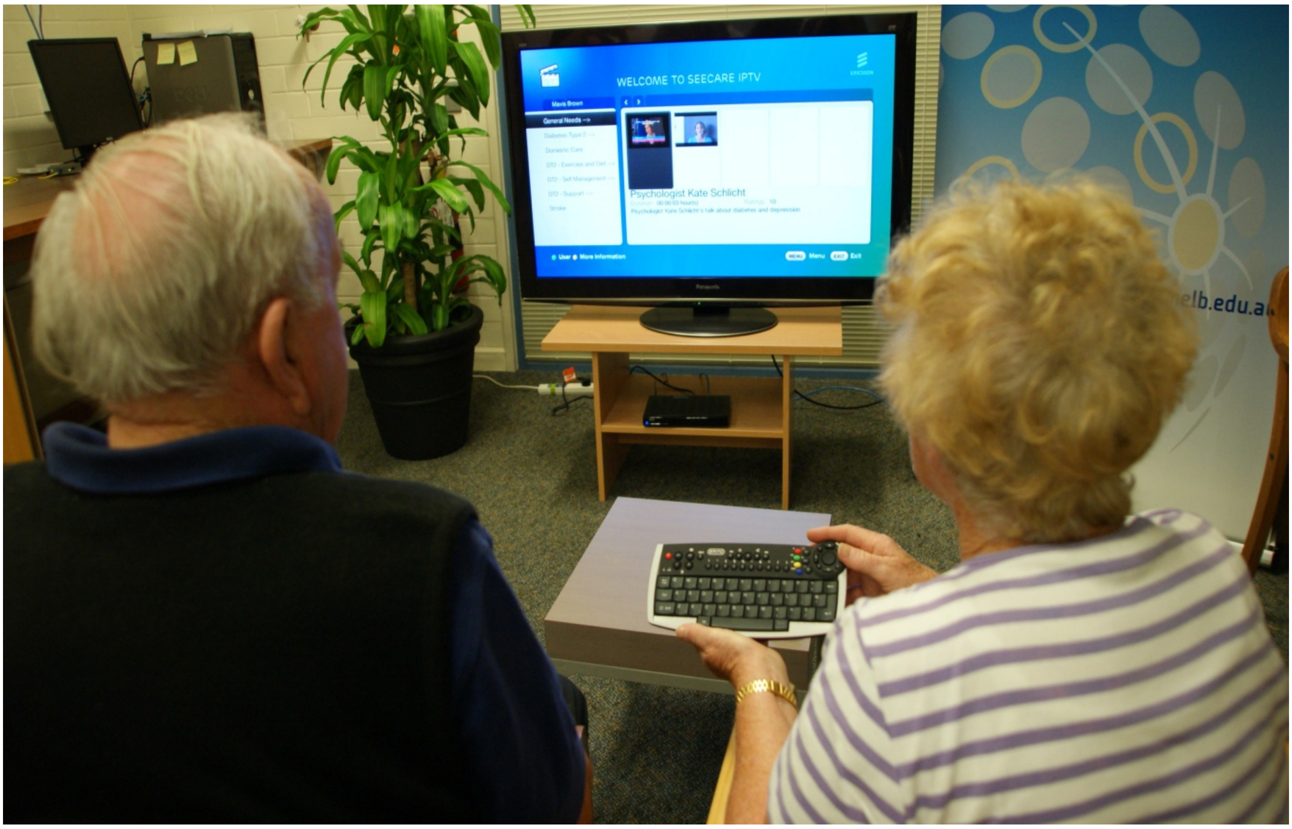
- To what extent would you say that you learned something from the S-IPTV videos?
- To what extent would you say that the S-IPTV videos inspired you to do something about your health?
- To what extent do you think your family, caregiver or doctor would use S-IPTV with you?

Procedures

Before the trial, each person with diabetes had an S-IPTV user account created for them and each person's contact details were passed to a participating DA-Vic educator. They received a phone call from the educator inviting them to discuss their health condition, their knowledge of diabetes, and what diabetes information they would like to access on S-IPTV.

To trial the system, each person with diabetes (along with their carer in three cases) attended ABAL separately for a 1-hour private session with a researcher. There, to make the trial as natural as possible, they worked in a simulated domestic lounge or living room furnished with a television, easy chairs, and a coffee table as shown in Figure 4. Each participant was given a brief orientation to the project, including instructions and hands-on practice in using the basic functions of S-IPTV. Then they were invited to log in to their S-IPTV account, browse the menu of videos that their diabetes educator had created for them, and watch their choice of videos from this menu for 30 minutes. At the end of the session, they did a 20 minute semistructured interview about their experience.

Figure 4. ABAL trial of SeeCare IPTV by a patient and a carer.



Stage 2 Data Analysis

One of the researchers transcribed audio recordings of ABAL user sessions, and analyzed these transcripts using open coding to arrive at initial themes and concepts. The researchers' observational notes and video recordings of ABAL user sessions were reviewed to check and amend patterns in the interview data. Further thematic analysis was then conducted using selective coding; the initial themes were considered in relation to one another and regrouped in relation to the core concepts of usability and user experience. Coding was crossed-checked at several points by other researchers to ensure interrater reliability. Thematic analysis of consumer and provider groups was done separately, followed by comparison of findings from each group. Findings were arranged for presentation with regard to qualitative research reporting principles in health [35] and recommendations in eHealth [36], so as to provide rich description and interpretation rather than claims of statistical power.

Results

Key Findings

Key findings from the two groups' evaluations of S-IPTV are reported for the major themes of usability and usefulness. Findings are categorized as subthemes within these, and also as enablers, barriers, or desiderata. Subthemes are illustrated with selected quotes.

IPTV for Health Information Consumers

S-IPTV was found to enable health information access among people with diabetes and their carers through several usability and usefulness factors. Usability factors included familiarity with the television technology, simplicity of screen layout, and easy-to-launch video content. The major usefulness factors included a sense of affirmation, a sense of affinity, and a way to talk about the condition with family and friends. People with diabetes also identified usability barriers to health information access, namely the complexity of the remote controls, glitches in menus, and problems loading video content. They found usefulness barriers in terms of content that was unsettling, not relevant to their situation, or contrary to their idea of independently managing their condition. Their suggestions for improving the health information consumer experience of S-IPTV included work on manageability of remote control devices, screen readability, content metadata, richer types of content, follow-up features, and pathways to additional support. People with diabetes also made a number of suggestions about improving the S-IPTV log-in process and the graphical user interface, however researchers were not so concerned with this aspect of the pilot implementation as with more fundamental system quality observations. Examples of evaluation findings from this group can be found in Multimedia Appendix 1.

IPTV for Health Information Providers

S-IPTV was found to enable health information provision by health educators through several usability and usefulness factors. Usability factors were fairly routine navigation and ease of selecting videos; usefulness factors were client convenience, wide appeal of videos, enhancement of educational methods, and alternative ways of performing their role as educators. Diabetes educators also identified usability barriers to health information provision, namely insufficient feedback from the system and excessive email exchanges needed to work with clients. They found usefulness barriers in terms of potential insensitivity toward clients, gaps in covering the breadth of topics required, the risk of appearing to offer a stand-alone self-education system, and the potential for system responsibilities to add to educators' workload. Suggestions for improving the health information provider experience of S-IPTV included work on simplifying the educators' user interface, providing simulations for educator training and development, developing client user support tools, expanding expert content, building in educational feedback, and person-to-person follow-up. Diabetes educators also made a number of comments about needing more opportunities to practice with the system before they would feel confident using it professionally; researchers recognize that this one-off trial for evaluation purposes was not equivalent to routine user education and training. Examples of evaluation findings from diabetes educators can be found in Multimedia Appendix 2.

Discussion

Strengths of IPTV

The project succeeded in developing a Web 2.0 IPTV system for people with diabetes and low literacies and their diabetes educators. The performance of the system in the laboratory setting gave them confidence to engage seriously in thinking about the actual and potential features and benefits of a fully implemented system. In their feedback they pointed out a range of critical usability and usefulness issues related to Web 2.0 affordances and foundations of good learning, not unexpected at this stage of system development, but valuable information from users' perspectives. On balance, they described their experiences with the system in terms that bode well for its educational potential, and they suggested many constructive improvements to the system.

The outcomes of the technical feasibility stage of this project demonstrated that integration of an IPTV platform and a Web 2.0 platform can deliver functionality beyond that of "1.0 IPTV". This functionality can be considered in terms of major strengths, weaknesses, opportunities, and threats, reflecting the researchers' understanding of Web-based health information design and implementation issues.

The strength of S-IPTV is that it makes it possible not only to organize video content and optimize its use and reuse to meet the complementary needs of health information providers and consumers as groups but, further, to identify individuals in both groups and provide managed information services specific to each identity.

The weakness of S-IPTV is that it is not yet able to interoperate with other electronic health information management tools, such as patient records and patient monitoring devices, and has not been developed to meet health informatics standards, for example, in terms of metadata, access controls, or secure messaging, but, as an IP-enabled platform, it could be made to do so given sufficient time and effort.

The opportunity that S-IPTV affords is to develop business models that use a home television as a mode of communicating person-specific, professionally-selected health information, and thus to extend the reach and scale of home-based health services.

The threat that S-IPTV faces is that it may be superseded by an IPTV platform, which adds more Web 2.0 interactivity to the provision and consumption of health information, for instance user-generated content and shared feedback on content as seen in peer-to-peer health social networks.

Some of these considerations are echoed clearly in the findings from user evaluation of the project. For example, there are usability comments about the user-friendliness of the technology, the need to streamline email exchanges between educator and client, and improvements to the composition and description of videos. There are usefulness comments about the value of a close fit between the content and the viewer's personal situation, the need to think of this system in relation to other information systems, and the desirability of adding extensibility and interpersonal interaction functions.

Apart from personalization, some other characteristics associated with Web 2.0 interactivity (manipulating and enhancing multimedia content, sharing narratives, building social networks) also emerge from users' suggestions as possible directions for further convergence between IPTV and Web 2.0.

The findings from the evaluation stage of the project show considerable alignment in clients' and educators' perceptions about the potential for S-IPTV to enable health literacy. Both groups described or could envision user experiences that highlight important elements of learning, such as learner-centeredness, affective responses, contextualized content, time to reflect, timely feedback and follow-up, and making learning social.

Some clients' and educators' comments also flag nontrivial barriers to using S-IPTV for health literacy. There are consumer perceptions that the video content about diabetes may be uninformative or even distressing, and that watching videos is not an effective part of responsibility for health self-management. There are provider perceptions that the system needs additional elements to ensure safety and quality in the provision of information, and that the service needs to be more closely integrated with a range of complementary information and education services.

Limitations

No attempt was made to look for statistical inferences, given that data from a pilot study of this size are not likely to support quantitative analysis. This was the key limitation of this study. A larger sample size most likely would have yielded more significant results about the usability and usefulness of the system. Future research with a larger sample size of health information consumers would make it feasible to compare the perspectives of those with varying levels of literacies, and other demographic factors. Future research with a larger sample size of health information providers would similarly support quantitative findings about usability and usefulness in terms of professional work practices and quality of health care services. Nevertheless, this study was appropriate to evaluate an initial version of the S-IPTV platform with a group of computer illiterate consumers and a group of busy professional providers, and it has made an original contribution to expanding knowledge not only about the design of IPTV 2.0 for health care, but also about its implementation in a realistic setting.

Conclusions

To our knowledge, this was the first study of its kind to address consumer health information needs by building a working IPTV system that integrates Web 2.0 technologies, conducting an implementation trial with health information providers and their clients, and evaluating the user experience. This project achieved its aims. It succeeded in integrating a Web 2.0 approach to content personalization with an IPTV system, turning the television and remote control into much more than simply a different user interface to the Web. It demonstrated that such a system was seen to be usable and held much interest, among people with high self-management needs and low literacies and among their health educators. It yielded insights into the user experience of a Web 2.0 IPTV system for health information, from both consumer and provider perspectives.

Additional stepwise improvements taking account of these insights is consistent with a holistic view of process and outcome in successful eHealth innovation [37]. Further technical development of S-IPTV is needed to improve some of the current communication and interface issues, and to take greater advantage of opportunities for interactivity and interoperability. Further development of S-IPTV as an information and education system is needed to formulate a model for content production and use that is more sophisticated, and a model for service delivery that is more strongly integrated with other home-based care and support programs. Further research into S-IPTV is needed to study its use by a wider range of health information consumers and providers, in more naturalistic settings, particularly to understand the impact it may have on health care services and health outcomes.

This research has contributed empirical research evidence that IPTV influenced by Web 2.0 has the potential to transform the apparently old technology of the home television into an innovative and wide-reaching tool to improve health literacy, especially among some under-served groups. The implications of low health literacy for population health and for the sustainability of health care services are so great that IPTV merits substantially more attention than it has received so far.

Acknowledgments

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Conflicts of Interest

CH is an employee of Diabetes Australia−Vic, GT is a company director of LivBetter, formerly known as SeeCare, and FF is an employee of Ericsson Australia.

Multimedia Appendix 1

Evaluation by people with diabetes (caregivers [C] are identified in relation to the person [P] they accompanied, eg, C8 was the caregiver who accompanied P8).

[PDF File (Adobe PDF File), 135KB - resprot_v3i1e13_app1.pdf]

Multimedia Appendix 2

SeeCare IPTV evaluation by diabetes educators.

[PDF File (Adobe PDF File), 201KB - resprot_v3i1e13_app2.pdf]

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Abbreviations

ABAL: Australian Broadband Applications Laboratory
DA-VIC: Diabetes Australia–Vic
ID: identification
IPTV: Internet protocol television
S-IPTV: SeeCare Ericsson IPTV

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Original Paper

A Cross-Sectional Study on the Diet and Nutritional Status of Adolescent Girls in Zambézia Province, Mozambique (the ZANE Study): Design, Methods, and Population Characteristics

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Abstract

Background: There is very little published work on dietary intake and nutritional status of Mozambicans. We conducted a population-based cross-sectional study on the diet and nutritional status of adolescent girls in different types of communities in Zambézia Province, Central Mozambique, in two distinct seasons.

Objective: The purpose of this paper is to present the design, methods, and study population characteristics of the Estudo do Estado Nutricional e da Dieta em Raparigas Adolescentes na Zambézia (the ZANE Study).

Methods: Data was collected in January-February 2010 ("hunger season") and in May-June 2010 ("harvest season"). A total of 551 girls in the age group 14-19 years old were recruited from one urban area and two districts (district towns and rural villages). The study protocol included a background interview, a 24-hour dietary recall interview, a food frequency questionnaire, anthropometric measurements, bioimpedance, hemoglobin measurement, and venous blood, urine, buccal cell, and fecal sampling.

Results: Adolescent motherhood was common in all study regions. Stunting prevalence for the total study population as a weighted percentage was 17.8% (95/549; 95% CI 14.3-22.0) with no regional differences. Overweight was found mainly in the urban area where the prevalence was 12.6% (20/159; 95% CI 7.5-17.6), thinness was rare. There were regional differences in the prevalence of malaria parasitemia and intestinal helminth infestation, but not human immunodeficiency virus.

Conclusions: The fully analyzed data from the ZANE Study will yield results useful for setting priorities in nutrition policy and further research on the diet and nutritional status in Mozambique and other countries with similar nutritional problems.

Trial Registration: ClinicalTrials.gov: NCT01944891; http://www.clinicaltrials.gov/ct2/show/NCT01944891 (Archived by WebCite at http://www.webcitation.org/6L9OUrsq8).

(JMIR Res Protoc 2014;3(1):e12) doi:10.2196/resprot.3109

KEYWORDS

methods; cross-sectional study; adolescent girls; diet; nutritional status; Mozambique; sub-Saharan Africa

Introduction

Undernutrition in Mozambique

Mozambique is one of the least developed countries in the world with almost 60% of the population living below the international poverty line [1]. Chronic undernutrition is a severe public health problem in Mozambique, as evidenced by a stunting rate of 42.6% in children below the age of 5 years [2]. The majority of the population is rural [3]. Poor households suffer from both chronic and seasonal food insecurity characterized by reducing the number of meals during times of shortage [4]. Problems of widespread poverty and food insecurity, in addition to other factors such as lack of education, poor water and sanitation systems, and frequent infections, are recognized as underlying contributors to undernutrition [5].

While the problem of undernutrition persists in Mozambique and much of Southern Africa, the region is also experiencing the phenomenon of nutrition transition [6]. This epidemiological transition is characterized by three conditions: (1) increased consumption of foods such as energy-dense snack foods, carbonated sweetened beverages, added sugar and fat; (2) decreased physical activity; and (3) increased rates of overweight and noncommunicable diseases [6]. Typically in East and Southern Africa, the increase in overweight and obesity prevalence has been higher in urban than in rural areas [7]. However, in an analysis of nutrition transition indicators [8], Mozambique was shown to be at an earlier stage in the nutrition transition process than some other sub-Saharan African countries, for example neighboring South Africa.

Lack of Published Work

There is a lack of published work on dietary intake and biochemical indicators of the nutritional status of Mozambicans, especially in age groups other than children below 5 years in age. There are two studies, one for women [9] and one for children [10], that found low median or mean proportions of dietary energy from protein (10% to 11%) and fat (7% to 11%). A review of dietary studies of women in other Sub-Saharan African countries found that intakes of folate, zinc, and iron are often below recommended nutrient intakes [11]. The previous study in Mozambican women mentioned above, conducted during the season of high mango consumption, showed that the prevalence of adequate intake for riboflavin, niacin, folate, vitamin B_{12}, calcium, and iron was below 50% [9]. It has been shown, in Mozambique [12] and elsewhere in sub-Saharan Africa [13,14] that energy and micronutrient intakes may fluctuate substantially from season to season. Therefore, studies that cover more than one season are needed in order to have a more complete picture of the diet.

With regard to biochemical indicators of nutritional status, anemia is known to be a severe problem in Mozambique—the Demographic and Health Survey 2011 found that 54% of girls and women of 15 to 49 years of age were anemic [2]. Furthermore, vitamin A and iodine deficiencies are prevalent among children [15,16]. Beyond these indicators, little is known on micronutrient deficiencies in the Mozambican population.

The ZANE Study

In the *Estudo do Estado Nutricional e da Dieta em Raparigas Adolescentes na Zambézia* (ZANE Study), our aim was to explore the diet and nutritional status of adolescent girls in Zambézia Province, Mozambique, in two seasons and in different types of communities. Adolescent girls, as a group, are vulnerable to the adverse effects of malnutrition. However, this age group is less studied than young children. The ZANE Study was conducted in 2010 and was a population-based, cross-sectional study with an observational design. In this paper, we describe the study design, fieldwork methods, and characteristics of the study population. We also present prevalence estimates for household hunger, overweight, thinness, stunting, human immunodeficiency virus (HIV), malaria parasitemia, and intestinal helminths. Results on the diet and the biochemical indicators of nutritional status are subject of forthcoming publications.

Methods

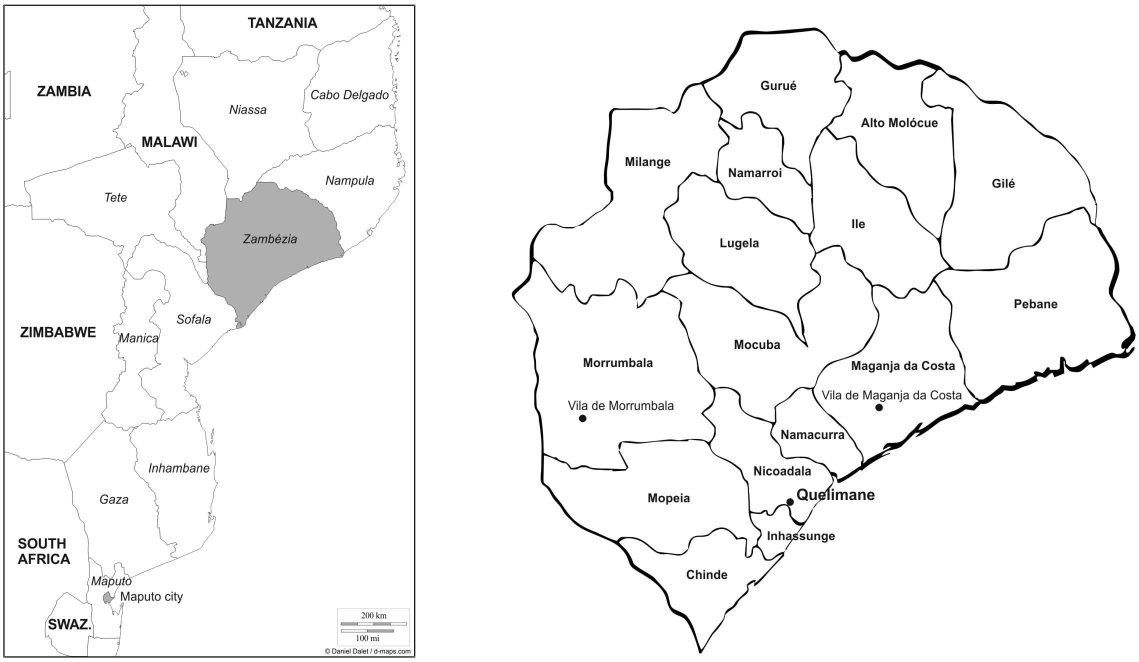
Setting

The Bioethical Committee of the Ministry of Health in Mozambique approved the study plan.

Zambézia Province with 3.89 million inhabitants [17], located in Central Mozambique (Figure 1 shows this location) [18] was selected as the study area after discussions with Mozambican authorities. The provincial health directorate decided upon the provincial capital (Quelimane) and two districts (Maganja da Costa and Morrumbala) as the specific study regions.

Quelimane City has 196,000 inhabitants [17]. Economic activities in the city include fishing, coconut production, and sea salt production in addition to the informal commerce of fresh food, clothes, and basic household items. Maganja da Costa is a coastal district with a population of 280,000 inhabitants and Morrumbala is an inland district with 362,000 inhabitants [17]. The main source of livelihood in the rural areas is subsistence agriculture and fishing. The most important crops cultivated are cassava, maize, sweet potato, and rice. Other important crops include cowpeas, pigeon peas, sorghum, groundnuts, cashew nuts, and coconut [19,20]. The rainy season in Zambézia usually lasts from October-November to March-April. The “hunger season” usually lasts from October-November to February-March [21,22], and the main harvest of maize, cowpeas, and groundnuts is in April-May [22].

Figure 1. Map of Zambézia Province. The original maps are from d-maps.com [18] and Instituto Nacional de Estatística (Anuário Estatístico, Província da Zambézia, 2003).



Sampling and Recruitment

Adolescent girls in the age range of 15 to 18 years old, residing in the selected study regions, constituted the target study population. The sample size of 600 girls was determined based on the resources available. A sample size of 100 girls from each region per season was considered feasible. The number of primary sampling units (PSUs) selected from each region was dependent on practical considerations. The aim was to have an equal sample size from each PSU.

For purposes of the study, the two districts were divided into district towns and rural areas. The sampling was carried out in five areas: (1) Quelimane City, (2) the district town of Maganja da Costa (*Vila de Maganja da Costa*), (3) rural villages in Maganja da Costa, (4) the district town of Morrumbala (*Vila de Morrumbala*), and (5) rural villages in Morrumbala. The sampling was carried out in two stages in each of the areas, where the first stage involved selection of the PSUs, for example, neighborhoods (*bairros*) or villages, and the second stage involved the selection of households within each PSU.

In the city and two district towns, data from the 2007 Census provided information on the population sizes of the neighborhoods. One neighborhood with a small population size was removed from the sample framework. In the two rural areas, locally obtained maps provided information on the villages. Villages located within a 45 to 60 minute drive from the study centers (health centers and hospitals) were considered as PSUs. There were no available listings of households in the PSUs.

The study was undertaken in two seasons—January-February, 2010 (“hunger season”) and May-June, 2010 (“harvest season”). The PSUs were selected using probability proportional to size (in the city and the district towns) or random sampling (in rural areas). In the city, sampling was carried out only in the catchment areas of three health centers out of the nine health centers across the city for practical reasons. The same PSUs were used in both seasons. For the second stage, the recruiters sketched a map of each selected PSU with the help of local leaders. The recruiters were instructed to follow a recruitment plan which included randomly selected starting points on the map and randomly selected directions to walk in order to chart the households. The recruiters were instructed to select households using preset intervals.

Girls in the target age range, who were able to visit the study center and did not have any significant illness preventing participation, were considered eligible. Eligible girls along with their parent, husband, or guardian were given an informed consent letter. The purpose of the study, the measurements and tests taken, the voluntary nature of participation, and the right to refuse to participate in any part of the study were also explained orally. The girl signed the informed consent form. If she was under 18 years of age, a parent, husband, or guardian also signed the form. If the girl or the adult was illiterate, a fingerprint or a signature of a witness indicated informed consent. The date of birth was verified by checking identity cards whenever possible. Alternatively, the time of birth was estimated with the help of family members. No incentives to participate in the study were given. The recruited girls were invited to come to the study center on the following day, and participants who lived far from the study center were provided with transport.

The total number of eligible girls refusing to participate is not known. Reasons for refusing to participate included refusal of parents to give permission to be part of the study, not having the time, and fear of the hospital or of blood sampling. A total of 639 girls agreed to participate, of whom 551 actually participated in the study (Figure 2 shows the sampling design). There were twenty-seven 14-year-olds and four 19-year-olds that were included in the final sample due to mistakes in checking the age during recruitment. However, their data was kept in the analysis since according to the World Health

Organization (WHO) definition, persons 10 to 19-years-old are considered adolescents [23].

A total of 143 participants were assigned to a subsample for an additional 24-hour dietary recall interview in January-February 2010 and two additional 24-hour recalls in May-June 2010. There was a total of four 24-hour recalls for the participants of this subsample. Because most of them did not have a precise address or a phone number, recontacting the participants of this subsample proved to be difficult. In January-February 2010, we were able to recontact 109 of the subsample participants for the second interview. In May-June 2010, 96 of those were successfully recontacted for a third interview, and 84 of those for a fourth interview. The additional 24-hour recalls were conducted on nonconsecutive days.

There were practical difficulties obtaining all information needed for multi-stage cluster sampling, for example, detailed maps with demarcation of all PSUs were not available and the population size of eligible girls in all PSUs was not known. Furthermore, recruiting an equal sample size from each selected PSU turned out not to be successful. In some cases, nonrandomly selected PSUs had to be included. For example, a selected village had to be replaced by another one when the leaders of the village were not supportive of the study. Taking into consideration all of these factors, sampling weights were calculated using the total population sizes of 15-19-year-old girls in the five areas from the 2007 Census. The population sizes used for calculating the sampling weights are shown (underlined) in Figure 2. The sampling weights were used when data from the different study areas were pooled for analysis.

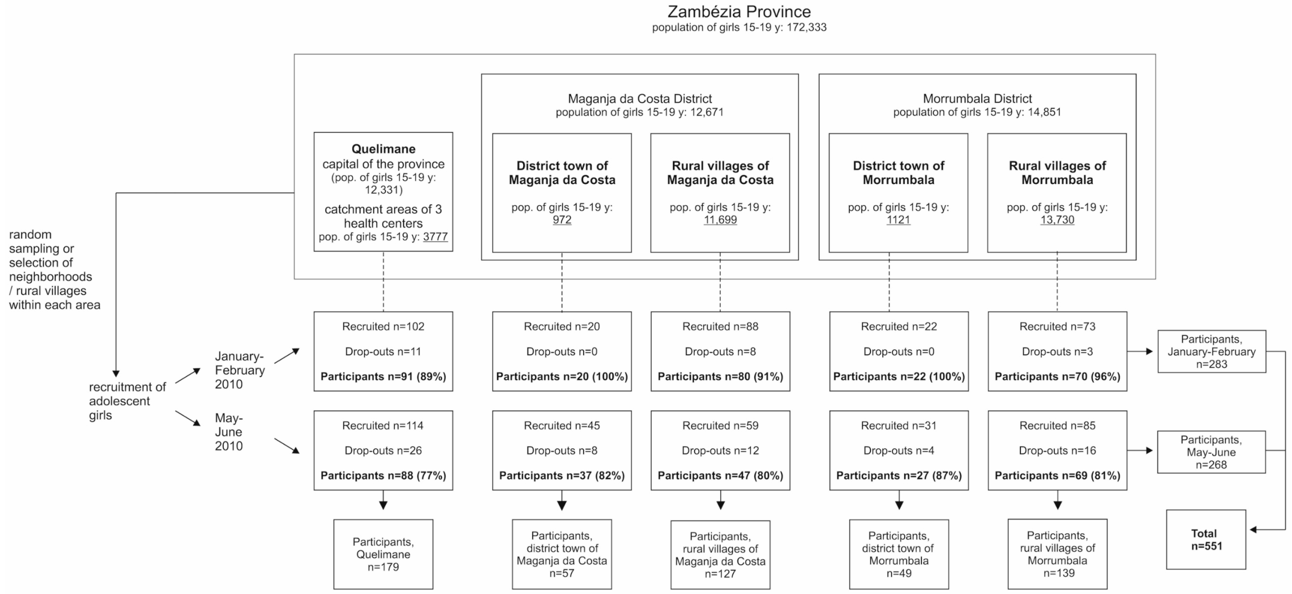


Figure 2. Implemented sampling design. The population figures are from the 2007 Census. y=years.

Background Interview

All forms and questionnaires used in the study were in Portuguese. However, if the participant was not comfortable in Portuguese, the questions were explained by field workers and appropriate interpreters in a language understood by the participant. The background questionnaire included questions about the characteristics of the participant and her household, for example, schooling, mother tongue, marital status, the number of children, pregnancy and breastfeeding status, self-reported health status, usage of mosquito net, cigarette and alcohol use, exposure to media (television, radio, newspaper), ownership of livestock and other assets, sanitation, and the type of housing. Asking each participant to read out a short test sentence in Portuguese tested literacy; being literate was defined as the ability to read the whole sentence. The background interview also included a Portuguese version of Household Food Insecurity Access Scale (HFIAS) questions [24,25]. These questions were used to calculate a more recently developed measure called Household Hunger Scale (HHS) [26], which is based on selected questions from the HFIAS. Locally recruited interviewers with varying backgrounds conducted the background interviews.

Food Frequency Questionnaire

A 7-day food frequency questionnaire (FFQ) was designed specifically for this study. The list of foods included in the FFQ was based on the experience accumulated during preliminary fieldwork and questionnaires on dietary diversity or food consumption from previously published [25] and unpublished surveys conducted in Mozambique. The FFQ was peer reviewed by a team of Mozambican nutritionists. It was not validated. The FFQ included a list of 37 commonly consumed foods, additional lines for other items belonging to selected food groups, and a line for dietary supplements. The interviewer requested participants to estimate the number of times they had consumed any of those food items during the previous 7 days. The response categories were: none; 1 to 2; 3 to 4; 5 to 6; 7; and, more than 7 times. With regards to oil and margarine, the respondent was asked to specify the type, or preferably brand name, in addition to the consumption frequency. The same interviewers who conducted the background interviews filled in the FFQs.

Twenty-Four-Hour Dietary Recall Interview

For the 24-hour dietary recall interview, the participant was asked to recall and report on the main activities that she had engaged in during the previous day. She was then asked to report all the food and beverages she had consumed during that period. The information gathered from the participant on the daily activities was used for probing. With regard to composite dishes, the participant was asked to describe all the ingredients in the dish. For the data collection period of May-June 2010, a separate question about the use of iodized salt was added to the form.

A set of food photographs was shown to the participant to help her with the estimation of portion sizes (Figure 3 shows an example of these photographs). Experiences gained from a validation study [27] were used when producing the set of photographs; the new photographs were scaled down from life-sized by approximately 5%, and the presentation of the foods was slightly modified. A plate (same as in the photographs), cup, spoon, and two different ladles that were typical of the location were also used in the portion size estimations. Finnish nutrition students and Mozambican nutrition technicians conducted the 24-hour dietary recall interviews. The Finnish interviewers spoke English, which was interpreted by local interpreters. In some cases, the Mozambican interviewers or interpreters did not have a common language with the participant and, when needed, additional *ad hoc* interpreters were used.

To calculate nutrient intake, a Mozambican food composition database was compiled. The majority of the food composition data was taken from the United States Department of Agriculture National Nutrient Database for Standard Reference [28]. Other literature sources included composition tables of other African countries and journal articles. Samples of 35 foods were also collected during preparatory fieldwork in 2008-2009 and analyzed in Finland. A detailed list of sources of data for each food item is available on the Internet [29]. The food composition database is freely available for those interested in conducting future work on dietary intake in Mozambique [30].

Recipe data was collected during visits to local households by recording the weight of each ingredient and the prepared dish. Of the collected recipes, 24 were relevant and directly useable, or could be modified by changing some ingredients. In addition, yield factors (to adjust for weight changes during cooking) for a few foods that include only one main ingredient in addition to water, for example, thick maize porridge, were collected. Some yield factors were also adapted from other sources [31,32]. Nutrient retention factors (to adjust for nutrient losses during cooking) were taken from the literature [33]. NutriSurvey [34] was used for data entry and analysis. The main ingredients of composite dishes were modified in the data entry as reported by each participant.

Figure 3. Example of food photographs used in portion size estimation: 270 g, 408 g, and 610 g of thick maize porridge.

Anthropometric and Other Measurements

For the most part, anthropometric measurements were carried out according to the WHO technical instructions [35]. The participants were barefoot and dressed in their normal light clothing. Their heights were measured by a portable statiometer. If a participant's hairdo prevented exact measurement, the thickness of the hairdo was measured by a dipstick and subtracted from the measured height. Weight was measured using a digital scale.

The participants' waist circumference, right upper arm length, and mid-upper arm circumference were measured after marking of the anatomical sites [35,36]. Total arm length was measured as the distance between the acromion and the tip of the middle finger. Inelastic circumference measuring tape was used and the recordings were taken to the nearest 0.1 cm. The mean of two measurements was used.

The participants' triceps and subscapular skinfold measurements were measured using a Harpenden Skinfold Caliper (Baty International, UK) according to the instructions of the manufacturer. The anatomical sites were marked [36] and three measurements of each skinfold were taken without releasing the grasp of the skinfold. The final value was the mean of the three measurements. If the three measurements varied by more than 1 mm, the measurements were repeated.

Hand-to-foot bioimpedance (Bodystat 1500 DMM, Bodystat Ltd, UK) was used to measure body composition of the participants. Bioimpedance measurements were taken in the standing position [37] instead of the usual lying position due to limitations of the study center facilities.

A member of the field team used a digital automatic blood pressure monitor (Omron M6, Omron Healthcare, Japan) to measure the blood pressure and pulse of the participants. Only one measurement was taken as most participants were unfamiliar with the procedure and the protocol did not allow time for them to become accustomed to it.

Participants' forearm muscle strength measurements were taken using a hydraulic hand dynamometer (SH5001, Saehan Corporation). The participant was encouraged to grip the handle with all her strength. There were two successive measurements that were taken for both hands. The result used in the study is the higher reading from each hand.

Laboratory Procedures and Biological Samples

The recruiters gave participants a fecal sample container and instructed them to deposit the sample at home. The laboratory technicians performed a direct wet mount with saline and examined the specimen (n=353) for the presence of helminth eggs or larvae under a microscope.

During the study center visit, the participants were asked to provide a spot urine sample. The samples were tested for pregnancy (Insight-HCG, Tulip Diagnostics, India; or Onsite HCG Combo Rapid Test, CTK Biotech, USA) and aliquots were frozen for further analyses. Although it was not part of the study protocol, unprompted, the laboratory technicians of Morrumbala District checked suspect (samples with dark brown or red coloration) urine samples for the presence of *Schistosoma haematobium* (*S haematobium*) by microscoping the sediment that was obtained after centrifugation. The positive cases (n=12) were provided with the appropriate medication.

Buccal cells were obtained by scraping the inside of the cheek of each participant with a new toothbrush [38]. Bottled drinking water was used for rinsing the mouth and the toothbrush. The samples were transferred to 15 ml conical bottom centrifuge tubes for centrifugation at 4500 rpm (1900 x g) for 10 minutes. The supernatant was discarded and the sediment was suspended in 1 ml 0.9% saline and stored in -15 to -20 °C freezer.

Venous blood samples (n=515) were taken from the antecubital vein using 21 g needles in serum tubes (10 ml) and 3 ml tubes containing potassium ethylenediaminetetraacetic acid (EDTA) (K3EDTA) (BD Vacutainer, Becton Dickinson International, Belgium). The EDTA-blood sample was centrifuged to plasma at 4500 rpm (1700 x g) for 10 minutes and aliquots were frozen and stored at -15 to -20 °C. The serum tubes were allowed to stand at room temperature (22-36 °C) for 30 minutes, and then centrifuged and frozen as described above. The study team purchased freezers to ensure adequate cold storage in the study centers. The samples were transported to Maputo in a portable freezer by car where they were packed in dry ice and shipped to Finland. In Finland, they were stored at -70 °C.

EDTA-blood was used for hemoglobin determination with HemoCue Hb 301 System (HemoCue AB, Sweden). The presence of malaria (*Plasmodium falciparum*) antigens (histidine-rich protein II, or HRP-II, antigens) was determined by using a one-step test (SD BIOLINE Malaria Ag P.f, Standard Diagnostics, Korea). Antibodies to HIV-1/HIV-2 were detected principally using Determine HIV-1/2 (Inverness Medical Japan, Japan) test kits, and positive results were confirmed with another test (Uni-Gold HIV, Trinity Biotech, Ireland). In some cases, capillary blood was used for hemoglobin, malaria, and HIV tests when EDTA-blood was not available. HIV testing was permitted by 372 of the participants.

Drops of EDTA-blood were applied to the sample collection area of Whatman 903 Protein Saver Cards, dried, and packed in Ziploc storage bags with desiccant packs. The cards were kept at room temperature until delivered to Finland, where they were stored at -20 ˚C.

A local nurse gave the results of the pregnancy, hemoglobin, malaria, and intestinal helminth infestation tests to the participants, and provided iron supplements for those with hemoglobin levels below the local cut-off, 110 g/l. Antihelminthics and malaria treatments were also provided for those participants whose test results indicated these conditions. Participants who tested positive for HIV were referred to the physician who was responsible for the study in a particular region in order to have counseling and subsequent treatment.

Statistical Analyses

Numbers and proportions of participants for selected background characteristics were computed. It should be noted that pregnancy was defined based on a urine test result or the participant being visibly pregnant. If this information was not available, those who self-reported not being pregnant were coded as not pregnant and those who self-reported being pregnant were coded as missing.

Z-scores for body mass index-for-age (BMI) and height-for-age were calculated using a macro by WHO [39], which uses the WHO 2007 growth reference for school-aged children and adolescents. Participants with a height-for-age z-score < -2 SD were classified as stunted. Nonpregnant participants with a BMI-for-age z-score < -2 or > 1 SD were classified as thin or overweight, respectively.

Prevalence estimates with 95% confidence intervals (CI) were computed for the categories of BMI-for-age and height-for-age z-scores, HHS, HIV, malaria parasitemia, and presence of intestinal helminths. For these analyses, the data from the district towns and rural areas were aggregated in each district in order to present results that are representative at district level. Seasonal differences in each area were examined before combining the two seasons, and regional differences were examined with the seasons combined. Proportions were compared using Pearson's chi-square tests with the Rao and Scott second order correction. Prevalence estimates for the aggregated total study population were also computed for selected variables. Sampling weights, as described above, were used in the analyses. Analyses were carried out using the survey package in R version 3.0.1.

Results

Date of Birth

The exact date of birth was known for 75.5% (416/551) of the participants, and for 92.1% (383/416) of those, the recruiters reported having verified the date of birth from an identity card or other official documents. For 24.5% (135/551) of the participants, only the year or year and month of birth were recorded.

Background Characteristics

The background characteristics (Table 1) showed that literacy rates varied from 11.2% (15/134) in rural Morrumbala to 81.5% (145/178) in Quelimane. There were one in five to almost one in three girls that had already given birth or were pregnant at the time of the study. Sanitation was poor; in the rural areas many households had no toilet at all. The most commonly reported mother languages (or dialects) were Chuabo and Portuguese in Quelimane, Nyaringa in Maganja da Costa District, and Sena in Morrumbala District.

Table 1. Characteristics of the study population.

		Quelimane	Maganja da Costa District		Morrumbala District	
			District town	Rural villages	District town	Rural villages
		n=179	n=57	n=127	n=49	n=139
Age, n (%)						
	14 years	10 (5.6)	2 (4)	5 (3.9)	1 (2)	9 (6.5)
	15 years	52 (29.1)	19 (33)	45 (35.4)	21 (43)	62 (44.6)
	16 years	39 (21.8)	9 (16)	27 (21.3)	9 (18)	30 (21.6)
	17 years	46 (25.7)	13 (23)	22 (17.3)	7 (14)	18 (12.9)
	18 years	32 (17.9)	13 (23)	27 (21.3)	11 (22)	18 (12.9)
	19 years	0 (0.0)	1 (2)	1 (0.8)	0 (0)	2 (1.4)
	Missing data, n	0	0	0	0	0
Currently attending school or studying						
	n (%)	170/177 (96.0)	49/56 (88)	77/127 (60.6)	42/49 (86)	91/134 (67.9)
	Missing data, n	2	1	0	0	5
Literate [a]						
	n (%)	145/178 (81.5)	28/53 (53)	39/124 (31.5)	20/48 (42)	15/134 (11.2)
	Missing data, n	1	4	3	1	5
Married [b]						
	n (%)	10/179 (5.6)	7/56 (13)	30/127 (23.6)	4/49 (8)	40/133 (30.1)
	Missing data, n	0	1	0	0	6
Currently pregnant [c]						
	n (%)	18/178 (10.1)	6/56 (11)	20/125 (16.0)	1/49 (2)	15/135 (11.1)
	Missing data, n	1	1	2	0	4
Has given birth or is currently pregnant						
	n (%)	38/176 (21.6)	16/55 (29)	38/125 (30.4)	10/49 (20)	41/133 (30.8)
	Missing data, n	3	2	2	0	6
Currently breastfeeding						
	n (%)	9/177 (5.1)	8/55 (15)	9/127 (7.1)	6/49 (12)	23/135 (17.0)
	Missing data, n	2	2	0	0	4
Type of sanitation, n (%)						
	No toilet	16/179 (8.9)	2/56 (4)	54/127 (42.5)	2/49 (4)	79/135 (58.5)
	Pit latrine	141/179 (78.8)	53/56 (95)	72/127 (56.7)	47/49 (96)	56/135 (41.5)
	Flush toilet	22/179 (12.3)	1/56 (2)	1/127 (0.8)	0/49 (0)	0/135 (0.0)
	Missing data, n	0	1	0	0	4
Main source of energy for cooking, n (%)						
	Firewood	2/178 (1.1)	28/56 (50)	114/127 (89.8)	19/49 (39)	121/136 (89.0)
	Charcoal or coal	175/178 (98.3)	27/56 (48)	13/127 (10.2)	30/49 (61)	15/136 (11.0)
	Electricity or gas	1/178 (0.6)	1/56 (2)	0/127 (0.0)	0/49 (0)	0/136 (0.0)
	Missing data, n	1	1	0	0	3

[a] able to read a full test-sentence in Portuguese

[b] married or traditionally married, includes divorced or separated and widowed

[c] positive—urine test result positive/visibly pregnant; negative—urine test result negative, or if test result not available, self-report of not being pregnant

Anthropometry

The majority of the girls had a BMI-for-age in the normal range and overweight was found mainly in the city (Table 2). There were eleven participants that were classified as thin. None were obese (>2 SD). The prevalence estimate for stunting among the total study population as a weighted percentage was 17.8% (95/549; 95% CI 14.3-22.0) with no regional differences. There were no seasonal differences in the BMI-for-age and height-for-age categories.

Household Hunger

There were eleven participants that were classified as living in households suffering from severe hunger according to the HHS. The two categories "moderate" and "severe household hunger" were combined for analysis. Household hunger prevalence estimate for the total study population as a weighted percentage was 17.0% (101/541; 95% CI 13.6-21.1) with no statistically significant regional differences.

Table 2. Prevalence estimates (weighted percentages) for categories of height-for-age and BMI-for-age z-scores, and Household Hunger Scale in the study regions[a].

	Quelimane, n=179	Maganja da Costa District, n=184	Morrumbala District, n=188	P [b]
Height-for-age z-score				.329
normal (≥ -2 SD), n (weighted %)	156/178 (87.6)	149/183 (83.0)	149/188 (80.2)	
95% CI	82.9-92.4	76.9-89.0	74.1-86.3	
stunted (< -2 SD), n (weighted %)	22/178 (12.4)	34/183 (17.0)	39/188 (19.8)	
95% CI	7.6-17.1	11.0-23.1	13.7-25.9	
Missing data, n	1	1	0	
BMI-for-age z-score [c]				< .001
normal (-2 to 1 SD), n (weighted %)	136/159 (85.5)	150/154 (98.7)	159/168 (95.5)	
95% CI	80.2-90.9	96.9-100	92.1-98.8	
thin or severely thin (< -2 SD), n (weighted %)	3/159 (1.9)	2/154 (1.0)	6/168 (4.0)	
95% CI	0-4.0	0-2.8	0.7-7.3	
overweight (> 1 SD), n (weighted %)	20/159 (12.6)	2/154 (0.3)	3/168 (0.5)	
95% CI	7.5-17.6	0-0.7	0-1.1	
Missing data or pregnant, n	20	30	20	
HHS				.274
little or no HH, n (weighted %)	137/177 (77.4)	148/179 (81.9)	155/185 (85.4)	
95% CI	71.4-83.4	75.5-88.2	80.0-90.8	
moderate or severe HH, n (weighted %)	40/177 (22.6)	31/179 (18.1)	30/185 (14.6)	
95% CI	16.6-28.6	11.8-24.5	9.2-20.1	
Missing data, n	2	5	3	

[a] Sampling weights were used. Seasonal differences within each area were tested with chi-square test before pooling data from two seasons and significant differences were found for HHS in Quelimane (Jan-Feb: weighted percentage 30%, 27/90, vs May-June: weighted percentage 15%, 13/87; P=.02).

[b] Overall test (chi-square) of regional differences after pooling data from the two seasons. This test was followed by pairwise tests.

[c] In pairwise comparisons, Quelimane differed significantly from Maganja da Costa (P<.001) and from Morrumbala District (P<.001).

HIV, Malaria Parasitemia, and Intestinal Helminths

The prevalence estimate for HIV among the total study population as a weighted percentage was 6.0% (29/372; 95% CI 3.8-9.3); there were no differences between regions (Table 3). Of the 510 participants tested, 46 were positive for malaria parasitemia. Of these positive malaria cases, 42 were found in Maganja da Costa.

The prevalence estimate for intestinal helminth infestation among the total study population as a weighted percentage was 11.7% (48/353; 95% CI 8.4-16.1). Significantly higher prevalence of intestinal helminths was found for Quelimane as compared to the districts (Table 3). All positive intestinal helminth cases in Maganja da Costa District were from the rural villages. Nearly all cases of *Ascaris lumbricoides* (*A lumbricoides*) and *Trichuris trichiura* (*T trichiura*) were found in Quelimane, whereas all cases of *Strongyloides stercoralis* (*S stercoralis*) were found in the districts. *Ancylostoma duodenale* (*A duodenale*) was found both in the city and in the districts.

Table 3. Numbers of positive cases and prevalence estimates (weighted percentages) for HIV, malaria parasitemia, and intestinal helminth infestation in the study regions[a].

	Quelimane, n=179	Maganja da Costa District, n=184	Morrumbala District, n=188	P [b]
HIV				
n (weighted %)	10/103 (9.7)	10/117 (7.4)	9/152 (4.5)	.32
95% CI	4.1-15.3	2.0-12.7	1.2-7.9	
Missing data, n	76	67	36	
Malaria parasitemia [c]				
n (weighted %)	2/164 (1.2)	42/168 (26.2)	2/178 (0.9)	< .001
95% CI	0-2.9	18.6-33.7	0-2.3	
Missing data, n	15	16	10	
Intestinal helminth infestation [d,e]				
n (weighted %)	28/105 (26.7)	7/138 (6.8)	13/110 (13.1)	.007
95% CI	18.4-35.0	2.0-11.7	6.4-19.9	
Missing data, n	74	46	78	

[a] Sampling weights were used. Seasonal differences within each area were tested with chi-square test before pooling data from two seasons and significant differences were found for intestinal helminths in Maganja da Costa (Jan-Feb: weighted percentage 12%, 7/71, vs May-June: weighted percentage 0%, 0/67; P=.002) and in Morrumbala (Jan-Feb: weighted percentage 20%, 10/58, vs May-June: weighted percentage 6%, 3/52; P=.04).

[b] Overall test, chi-square, of regional differences after pooling data from the two seasons. This test was followed by pairwise tests.

[c] In pairwise comparisons, Quelimane differed significantly from Maganja da Costa (P<.001), and Maganja da Costa differed significantly from Morrumbala District (P<.001).

[d] In pairwise comparisons, Quelimane differed significantly from Maganja da Costa (P<.001) and from Morrumbala District (P=.02).

[e] The species identified: *A duodenale*—18 findings, *A lumbricoides*—12 findings, *T trichiura*—10 findings, *S stercoralis*—7 findings, and *S mansoni*—2 findings. One participant was infested with two species.

Discussion

Purpose of the Study

We have collected data that will provide in-depth information on the nutritional situation of adolescent girls in Zambézia Province, Central Mozambique. The purpose of this paper is to describe the design and methods of the ZANE Study and to present descriptive results on the characteristics of the study population.

Food Insecurity, Stunting, and Overweight

The proportion of adolescent girls living in households suffering from at least a moderate level of hunger is markedly lower in our study compared to the 57% [40] found in two previous surveys in other central provinces of Mozambique. This difference could be explained by numerous factors including differences in the geographical area, year and season of data collection, and the fact that in our study the respondents were adolescent girls. In contrast, the age and sex of respondents of the previous surveys were unspecified [25]. HHS measures a severe range of household food insecurity including such experiences as not having any food to eat and going to sleep at night hungry [26]. Thus, even the smaller proportions of households suffering from food insecurity found in our study indicate that this is a problem in the area.

Although thinness was found to be rare, close to one in five of the adolescent girls in our study area were stunted. Previously, a school-based study in the capital city Maputo found that of 2.3% of girls 6 to 18 years of age were stunted [41]. Differences in the sampling and growth reference used prevent detailed comparisons with Maputo girls, but, nevertheless, it is clear that the prevalence of stunting was higher among our population-based sample.

We found that overweight was more common in the city compared to the districts. Although this result is based on cross-sectional data, it could be interpreted as an early sign of nutrition transition in the urban adolescent girls in Central Mozambique. The finding also supports nationally representative data on adults [42], which showed that the proportions of overweight/obese people were higher in urban areas compared to rural areas for both men and women.

HIV and Intestinal Helminth Infestation

The estimate for HIV prevalence was similar to the national prevalence among 15-19-year-old girls, 9.3% [43]. The reasons for participant refusals for HIV testing were not recorded, but some of the participants who refused were already aware of their HIV-positive status. The prevalence of intestinal helminth infestation in our study was clearly lower compared to the previous study of Augusto et al [44], where the prevalence of soil-transmitted helminth infestation in Zambézia among 7-22-year-olds was found to be as high as 51%. Differences in the prevalence estimates between this study and that of Augusto et al may be due to differences in the methodology and age ranges of the participants. In our study, only 67.5% (372/551) of the participants agreed to be tested for HIV and 64.1%

(353/551) provided fecal samples for testing for intestinal helminths, and this may have reduced the accuracy of the prevalence estimates.

Fieldwork Challenges

Challenges were encountered during the fieldwork. The lack of detailed maps made it difficult to plan the sampling beforehand, and the sampling design had to be adjusted during the fieldwork. Although the field team had strong local representation through the inclusion of district agricultural and health workers, in a few cases building trust with the local community leaders was not successful, and for that reason not all villages initially selected in the sampling were included in the study. The timetable for carrying out the sampling was restricted, and when recruitment was not possible at a chosen location, a village had to be chosen nonrandomly as a replacement in order to ensure the continuity of the daily flow of participants throughout both study periods. Despite these limitations in the sampling design, recruitment of participants was largely successful, and the data provides a good representation of the target population in the areas studied.

Informed Consent

Informed consent is a critical component of study ethics. It has been shown in other studies that participants may have difficulties understanding all aspects of the informed consent; this applies for both low-income country and high-income country settings [45]. In Uganda, it was shown that the majority of participants in observational studies reported having enough information about the study *per se*, but about one third did not have full knowledge about their right to voluntarily withdraw from the study at any time [46]. The understanding of the informed consent was not assessed in our study, but the fact that there were refusals to participate due to fear of blood sampling suggests that some eligible candidates may not have fully understood their freedom to refuse blood sampling while being free to participate in other parts of the study. On the other hand, many participants refused HIV testing, which is a positive sign that some of the participants did exercise their right to refuse to participate in specific aspects of the study. A number of girls (n=88) who consented to participate did not arrive at the study center (Figure 2). The reason for this remained unknown for the majority, and it is possible that many simply forgot and the study team was not able to find them again. However, some candidates did mention they had changed their mind or that the head of household or community leader refused for them to participate even after informed consent had been given.

Summary of the Results

To summarize, the results on the characteristics of the study population of the ZANE Study indicate that the girls suffer from deprivation; the regions studied are characterized by poor sanitation facilities, and adolescent girls suffer under the burden of household hunger, infectious diseases, and intestinal helminths. The rate of adolescent motherhood is high in all the study areas, and literacy rates are particularly low in the rural areas. The forthcoming results on dietary intake and nutritional status will be useful for setting priorities in nutrition policy, and for further research on adolescent girls in Mozambique or countries with similar nutritional problems.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
CI: confidence interval
EDTA: ethylenediaminetetraacetic acid
FFQ: food frequency questionnaire
HFIAS: Household Food Insecurity Access Scale
HHS: Household Hunger Scale

HIV: human immunodeficiency virus
PSU: primary sampling unit
WHO: World Health Organization
ZANE Study: Estudo do Estado Nutricional e da Dieta em Raparigas Adolescentes na Zambézia

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Protocol

A Population-Based Intervention for the Prevention of Falls and Fractures in Home Dwelling People 65 Years and Older in South Germany: Protocol

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Abstract

Background: Falls and fall-related injuries pose a major threat to older peoples' health, and are associated with increased morbidity and mortality. In the course of demographic changes, development and implementation of fall prevention strategies have been recognized as an urgent public health challenge. Various risk factors for falls and a number of effective interventions have been recognized. A substantial proportion of falls occur for people who are neither frail nor at high risk. Therefore, population-based approaches reaching the entire older population are needed.

Objective: The objective of the study presented is the development, implementation, and evaluation of a population-based intervention for the prevention of falls and fall-related injuries in a medium sized city in Germany.

Methods: The study is designed as a population-based approach. The intervention community is a mid sized city named Reutlingen in southern Germany with a population of 112,700 people. All community dwelling inhabitants 65 years and older are addressed. There are two main measures that are defined: (1) increase of overall physical activity, and (2) reduction of modifiable risk factors for falls such as deficits in strength and balance, home and environmental hazards, impaired vision, unsafe footwear, and improper use of assistive devices. The implementation strategies are developed in a participatory community planning process. These might include, for example, training of professionals and volunteers, improved availability of exercise classes, and education and raising awareness via newspaper, radio, or lectures.

Results: The study starts in September 2010 and ends in December 2013. It is evaluated primarily by process evaluation as well as by telephone survey.

Conclusions: Physical activity as a key message entails multiple positive effects with benefits on a range of geriatric symptoms. The strength of the design is the development of implementation strategies in a participatory community planning. The problems that we anticipate are the dependency on the stakeholders' willingness to participate, and the difficulty of evaluating population-based programs by hard end points.

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KEYWORDS

falls; accidental falls; population-based intervention; fall prevention; community; aged; risk factors

Introduction

Falls and Fall-Related Injuries

Falls and fall-related injuries pose a major threat to older peoples' health and well-being, and are associated with an increased morbidity and mortality. Moreover, fall-related morbidity poses a substantial burden on caregivers and families, and the economic burden on health care systems is highly relevant [1]. With the number of older people constantly increasing, fall-related injuries such as fractures will rise dramatically [2]. The development and implementation of strategies to prevent falls and fall-related injuries have therefore been recognized as an urgent public health challenge.

A variety of risk factors for falls have been identified, and a number of interventions have shown to be effective. Among these are, for example, different types of exercise, removal of environmental hazards, and improvement of vision [3]. Recommendations and guidelines for the prevention of falls that advocate identifying high risk persons, screening for modifiable risk factors, and the targeting of appropriate interventions have been developed [4-7]. Efforts by the US Centers for Disease Control and Prevention (CDC) are an example of such a high risk approach. "Stopping Elderly Accidents, Deaths, and Injuries" is a fall prevention tool kit for health care providers developed by the CDC that incorporates risk assessment, treatment of underlying risk factors, and referral to community-based fall prevention programs [8]. However, such case finding is time consuming, and the cost effectiveness of high risk approaches is unclear [9,10].

Population Strategies

In contrast to high risk approaches, Rose proposed a "population strategy" for common health problems by shifting "the whole distribution of exposure in a favorable direction" [11]. He argued that when risk is widely distributed in a population, small changes in behavior across the whole population are likely to yield greater improvements than large changes in a few people. Therefore, targeting preventive interventions only at high risk individuals would have minimal effect on the population's health. The risk of falling can be regarded as widely distributed among the general older population, and a substantial proportion of falls occur among people who are neither frail nor identified as being at a high risk of falling [12]. A population shift with regard to fall prevention in this case means, for example, an overall increase of physical activity in the older population, enhanced participation in exercise and fall prevention classes, or reduction of home and environmental hazards. To achieve this, various strategies such as policy development, raising awareness, or influencing of architecture have to be implemented. This approach primarily aims at a shift from preventive to health promoting interventions.

Few population-based programs for fall prevention provide evidence on their effectiveness and information on successful strategies for implementation and motivation [13]. An example of a successful population-based intervention is the Australian "Stay On Your Feet" program. The four year multi-strategic approach addressed fall-related risk factors, knowledge, attitudes, and behaviors targeting home dwelling people 60 years and older. The strategies included, for example, raising awareness, policy development, education, or home hazard reduction. It was delivered via brochures, advertisements, television, and radio; and cooperated closely with local physicians and health care professionals [14,15].

The impact of fall prevention on a population level depends on the participation rates and on the wide availability of fall prevention strategies. There are few data on population-based interventions in the interest of estimating the exact participation rate to achieve an impact on the overall fracture rates. Based on Australian data, Day et al calculated 5440 falls prevented, assuming that 1.9% of the eligible Australian population 70 years and older took up Tai Chi classes [16]. In general, implementation of new activities is a complex process that requires new knowledge, skills, and abilities. These must be taught, learned, and used to change the practice of the involved providers, organizations, and the system in which these new activities are delivered [17]. Consequently, the implementation of effective interventions has to be routinely addressed. A challenge specific to the implementation of fall prevention is the need for coordination and integration of more than just one setting and provider. As an example, fall preventive exercise classes must be tailored to different target groups; and sports clubs, charity and health care organizations, or community services might provide them. Such classes might be instructed by therapists, nurses, exercise instructors, or qualified volunteers at peoples' homes, sports clubs, gymnasiums, community centers, or nursing homes. Financing for the classes might be provided by the health care system, local or state governments, communities, donations, or by fees. Hence, the implementation of just one single effective activity in a community setting requires profound knowledge of the context in order to address all the relevant institutions and individuals. Even more so, the implementation of a variety of activities requires a multi-strategic approach with a high degree of coordination between settings, providers, and systems [18].

Fall prevention activities require a substantial effort from the older people themselves; therefore, motivation is a key issue. However, older people are reluctant to get involved in fall prevention activities and uptake rates for interventions in the community are typically low [9,19]. Although older community dwelling people consider falls to be an important health issue, they tend to minimize their personal risk [20-22]. While raising awareness can improve knowledge about falls, such activities do not necessarily improve the self-perceived risk of falling [23]. Research on motivational aspects has improved the understanding of older peoples' views and opinions regarding fall prevention. In line with these findings, a recommendation developed by the Prevention of Falls Network Europe advocates to focus on the dissemination of knowledge that physical activity can improve strength and balance, and to promote the immediate benefits of fall prevention interventions [24].

In Germany, to the best of our knowledge, no population-based program for the prevention of falls in older people has been implemented so far. Therefore, the overall aim of the study presented in this paper is the development, implementation, and evaluation of a population-based intervention for the prevention of falls and fall-related injuries in a medium sized city in

Germany. In the design of the study, two main measures are defined: (1) the increase of physical activity, and (2) the reduction of modifiable risk factors for falls using existing structures within the community. The strategies to implement these measures are developed in a participatory community planning. In this paper we describe the background and design of the study.

Methods

Context

In Germany, care for the elderly by municipalities implies the coordination of services, policy making, planning, and building of infrastructure such as nursing homes. Self-employed physicians, therapists, and hospitals provide health care. The nursing care is provided by for-profit and nonprofit home care services and nursing homes, which are financed by compulsory long-term care insurances with considerable copayment from the older people themselves. Financing of health services is granted by health insurances and reimbursement of services is highly regulated by federal laws.

To date, there is no national German guideline or policy on fall prevention [25]. Over the last few years fall prevention programs have been implemented in many long-term care facilities, but there have been no similar initiatives targeting community dwelling older people [26]. Numerous institutions, such as the German Red Cross, member organizations of the German Federal Sports Organization, and individual therapists offer fall prevention exercises. In most cases course content is based on scientific evidence, but these programs have not been formally evaluated in controlled trials. The quality of instructors varies considerably, ranging from therapists with special qualifications, to qualified volunteers. The fall prevention activities are not usually covered by health insurance plans. Municipalities or housing associations offer counseling on home modifications. The costs of housing adaptations are partially covered for people in need of care by long-term care insurance. The preventive home modifications depend mainly on the initiative of the older people and their caregivers.

Physical activity in the general older population is promoted and offered by sports clubs and numerous local nonprofit providers, further exercise classes are offered by churches, welfare, and volunteer organizations. Most nonprofit exercise class providers rely on qualified volunteers as instructors. Financing for these classes is based on fees, public funding, and fund raising activities. Increasingly, privately run sports clubs are attractive to older people as well for these classes [27].

Study Design

The study presented is designed as a population-based multi-strategic intervention. The author Last defines a community-based intervention when “the unit of allocation to receive a preventive regimen is an entire community” [28]. In the approach presented, all noninstitutionalized people 65 years and older are addressed. A multi-disciplinary research team comprising of members with a background in physiotherapy, gerontology, public health, and geriatrics conducts the study. It starts in September 2010 and ends in December 2013. It is financed by the Federal Ministry of Education and Research.

Intervention Community and Population

The intervention community is the city of Reutlingen, a mid sized city in southern Germany with a population of 112,700 people. About 20.00% (n=22,540) of the inhabitants are 65 years and older. The city was chosen for its proximity to the research center conducting the study (45 km), the medium size (compared to other German cities), and the willingness of local partners to cooperate. Reutlingen is characterized by the combination of an urban city center, and smaller rural districts. There are 103 clubs, various welfare, and volunteers’ organizations, as well as churches that all offer exercise classes. There are 73 general practitioners that are represented by a local body, and 16 for-profit and nonprofit ambulatory care services that provide nursing care. Policy making within the municipality has a strong focus on the prevention of institutionalization in old age, and on optimization of care for community dwelling older people with functional limitations. There is no policy regarding fall prevention. The geriatric unit conducting the study does not provide any services in the intervention community.

Intervention

The study is designed not to identify and target high risk persons, but to address the general older population as defined. To clarify the terminology of the population-based intervention being presented, “measure” is defined as a certain protective factor (eg, increased physical activity), whereas “strategy” refers to the means by which the measure is promoted (eg, education, improved availability) [29].

The two following main measures were up taken: (1) the increase of physical activity, and (2) the reduction of modifiable risk factors for falls such as deficits in strength and balance, home and environmental hazards, impaired vision, unsafe footwear, and the improper use of assistive devices.

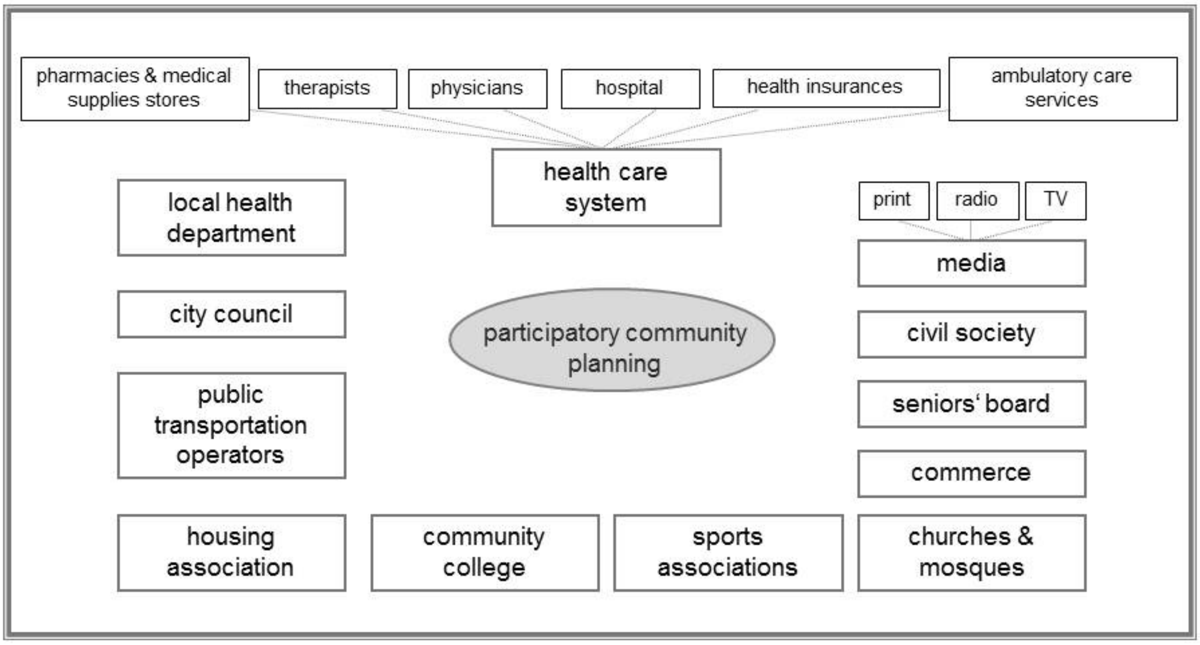
The population-based strategies to intervene on the individual, social, and environmental levels are developed in a participatory community planning. A variety of strategies are to be developed within the course of the study. These might include, for example, the training of professionals and volunteers; education and raising awareness via newspaper, radio, posters, and lectures; or improved availability of exercise classes in the form of the development of a directory. Physical activity and its benefits serve as the key message, whereas fall prevention is secondary to this. The immediate benefits, such as maintenance of independence and well-being, become embedded in the strategies as important messages. Consequently, the study is called “Schritt halten - Aktiv älter werden in Reutlingen” (“Keep Up - Active aging in Reutlingen”).

Process Structure

The study is structured in three stages: (1) Preimplementation period- from July 2010 to September 2011 stakeholders relevant for physical activity, fall prevention, and senior affairs in the community are identified and contacted (Figure 1 shows this organizational structure). The organizational structure of the study is set up. The baseline data is collected from May to July

2011. (2) Implementation period- in September 2011 the development of strategies started and the implementation teams are set up. This period is on going until May 2013. And (3) Follow-up period- after the follow-up data collection from May to July 2013, the financing ends in December 2013. Sustainability poses an important issue of the approach, therefore, the community coalition that is formed is encouraged to further cooperate and meet regularly. For dissemination, the creation of a Web-based portfolio of the developed strategies is planned. It is designed to serve as a template for other municipalities or institutions considering the implementation of fall prevention activities.

Figure 1. Local stakeholders involved in the participatory community planning.



Organizational Structure

Population-based intervention programs are characterized by the shared ownership of the problem and its solution by experts as well as by community members [13]. In this study, we propose a shared decision-making and responsibility for the implementation of strategies. The building of a community coalition for fall prevention is essential at the beginning. In several meetings, the concept of the study is explained and the potential partnerships and contributions from local agencies, organizations, and services are explored. The community coalition is led by a steering committee comprising of high rank representatives of the city’s council, in particular from the senior citizens' office and department of sports, representatives of the geriatric department of the district hospital, the local medical council, the association of sports clubs, the local health department, the building society, the council of senior citizens, the ambulatory care services, and the welfare organizations. The steering committee is built in order to prioritize possible strategies, name appropriate participants of focus groups and implementation teams, and to discuss and solve problems of implementation.

In a second step, focus groups are constituted consisting of local experts, both professionals and volunteers. They discuss and develop portfolios of possible strategies. In dialogue, the steering committee and the researchers rate the proposed strategies. For implementation, teams of local partners are set up with professionals as well as volunteers (so called implementation teams).

The role of the research team is to provide good-practice examples and information for the professionals and volunteers in the field, to set up organizational structures, to coordinate implementation strategies, and to evaluate the processes and outcomes.

Web-Based Platform of Exercise Classes Example

To illustrate the approach, an example of an already developed and implemented strategy is given, a Web-based platform of exercise classes.

An early conclusion of focus group meetings was the need for creating a directory of existing exercise classes for older people. After a positive vote by the steering committee, an implementation team was set up under the leadership of a researcher. It was decided by the implementation team not only to address older people, but also their caregivers, families, therapists, or exercise instructors with the intention for them to serve as mediators. The implementation team discussed the information need of older people with regards to usability in cooperation with therapists, physicians, and caregivers. The involved stakeholders and associations were the department of sports, association of sports clubs, community college, German Red Cross, senior citizens' office, and the local hiking club. A Web-based solution was chosen over a print version by the team. The pros for the website were that it was modifiable and updateable (eg, adding further information, categories, or new exercise classes), as well as the availability for mediators such as doctors, therapists, or relatives. A con was the fact that a minority of older people are equipped with Internet access. According to that, we assume mediators to be the key to success in order to motivate older inactive persons to exercise. In the future, the website could also serve as a template for an eventual print version. It was decided by the team to offer a detailed description of training methods, information about appropriate target groups, and accessibility of the location, the costs, and the details of contact. An Australian website was chosen as a template, and the same Web service provider was contracted. A questionnaire was sent out to all known providers of exercise classes. When their responses were received, their information was first checked for completeness, and then entered into the Web-based platform by a physiotherapist. The website was presented to and tested with senior citizens, and modified accordingly. The materials for promotion, such as flyers, posters, and newspaper articles were prepared and distributed. The platform [30] started on the Internet in November 2011 with 90 classes, in April 2013 it presents 320 exercise classes. For process evaluation, for example, links to other local websites or page hits are documented.

Evaluation

The study is evaluated primarily by process evaluation as well as by telephone survey.

Process Evaluation

To guide other communities in future activities in the field of fall prevention, a process evaluation of strategies implemented in this study is planned. The appropriate evaluation methods have to be developed according to the strategies. Since the development of implementation strategies is part of the on going project, and will be done together with the local stakeholders, the final evaluation methods used cannot yet be presented. Possible methods might be, for example, the uptake of fall prevention activities by the institutions involved or compliance of the target group. To present the results of the evaluation, a website offers interested parties a “construction kit”, from which various measures and strategies for action can be “taken”. The platform shall inform, for example, about aims, procedures, costs, involved stakeholders, experiences, and barriers and catalyzers for implementation.

Telephone Survey

A control region is identified with the city of Ludwigsburg. The city of Ludwigsburg with 88,600 inhabitants, 18.96% of them 65 years and older (n=16,800), is situated 70 km northwest of the intervention region. The political and socioeconomic structure is comparable to the intervention region.

Recruitment

At baseline and at follow-up (two years later), we plan to recruit two independent samples of home dwelling people 65 years and older in both the intervention and in the control region. The baseline and follow-up samples are independent. The potential participants are identified with the help of two health insurance companies: (1) a random sample of 1000 members is identified in both cities, and (2) the health insurance company will contact them. Health insurance is mandatory for all employee and pensioners in Germany. The socioeconomic structure of the health insurance members is expected to be similar in both cities due to federal regulation of mandatory health insurances. Together, both health insurances cover approximately 12,500 members 65 years and older in Reutlingen, and 7000 members 65 years and older in Ludwigsburg. Those willing to participate are invited to contact the study team by post or telephone, resulting in a self selected sample. A response rate of 20% is expected. We will not control for multiple identification of members.

The Questionnaire

The respondents are asked for a written informed consent. The interview is conducted via telephone by a trained interviewer. An interviewer manual will be developed.

Physical activity is measured by the physical activity questionnaire recommended for older people [31,32]. The general self-rated health status is assessed by one item of the Short-Form Health Survey [33] (“In general, would you say your health is excellent, very good, good, fair, or poor?”). The Rivermead Mobility Index is used to measure the mobility of the participants. [34]. To assess changes in behavior, for example, concrete plans to start doing physical exercises within the next weeks/months, Prochaska’s transtheoretic model (the stages of change in the modification of problem behaviors) is used [35]. The participants’ fall rates are measured by the retrospective history of falls during the last year. Concerning the fear of falling, a single item asks, “In general, are you afraid of falling over?” (Possible answers = not at all, a little, quite a bit, very much) [36]. Furthermore, an open question about the knowledge of risk factors for falls was conducted (eg, impaired vision, indoor and outdoor environmental hazards, unsafe footwear, wrong medication). Additional questions in the follow-up questionnaire evaluate the reach of the developed and implemented strategies in the intervention community.

Statistics

The primary outcome is a change in physical activity between the baseline and the follow-up. The secondary outcome measures are a change in the fear of falling, change in behavior, and knowledge about risk factors. In descriptive analyses, frequencies and means/medians for discrete and continuous variables, respectively, will be calculated. Logistic and linear regression models will be applied to determine differences between the baseline and the follow-up. Adjustment for relevant covariates like age and sex will be performed. Adjusted odds ratios and regression coefficients will be shown with 95% confidence intervals. The Ethics Committee of Ulm University obtained institutional review board approval for the interviews (not for the design and implementation of the overall project).

Results

The study starts in September 2010 and ends in December 2013. It is evaluated primarily by process evaluation as well as by telephone survey. A detailed description of the process evaluation results will be presented at the Schritt Halten website [37].

Discussion

Aims of the Study

The aim of this study is to develop, implement, and evaluate a population-based intervention for the prevention of falls and fall-related injuries using existing structures and resources within the community.

The approach implies physical activity and its benefits as the key message, whereas fall prevention is secondary to this. Knowledge, skills, and attitudes concerning fall and fracture prevention are distributed primarily to health care professionals and exercise instructors. This decision is based on two reasons. First, the self-perceived risk of falling is often judged too optimistically, and older people might regard falls as a relevant problem for others, but not for themselves [20,22,38]. If older people do not believe that they are at risk of falling, they are unlikely to start fall prevention measures. There is a consensus that fall prevention, per se, should not be the headline of health promotion strategies. Rather, the wider benefits of exercise and fall prevention should be the key messages, with a focus on the maintenance of health and independence [22,24,39]. Second, many older people demonstrate more than one geriatric syndrome and more than one chronic condition. Distinct geriatric syndromes, such as falling, share risk factors with other syndromes and chronic conditions, and they contribute to one another [40]. It seems unrealistic to assume that older people are able and willing to adhere to several specific interventions at the same time [41]. Therefore, health promotion activities should define interventions with benefits on several risk categories. Physical activity entails multiple positive effects with benefits on a range of geriatric syndromes, such as loss of independence [42,43], and cognitive decline [44,45]. It offers a generic rather than a disease specific preventive intervention.

Study Strengths

The strength of the study design is the joint development of implementation strategies in a participatory community planning, involving partners, for example, from the health care system, the community, and older people themselves. The risk of falling shares parallels with other chronic conditions, such as diabetes. In both conditions, the occurrence of an acute event (a cardiovascular event in the case of diabetes, or a fracture in the case of a risk of falling) can be reduced by preventive efforts, like changes in lifestyle by older people themselves, through professionals and providers [18]. In line with the Innovative Care for Chronic Conditions framework of the World Health Organization, population-based fall prevention programs are operating within the structures of a community [13,46].

Study Limitations

A problem that we anticipate is the dependency on the stakeholders' willingness to be actively engaged in the project. To maximize cooperation, potential barriers and facilitators for each partner have to be identified at the beginning. A further difficulty of population-based programs is the evaluation of hard end points. Fracture rates, awareness, or lifestyles might not change within the three year duration of the study. These processes, as well as changes of structures and procedures in communities, might take many years and require longer observation periods. During this observation period, other factors, like migration or secular trends, can influence the effects of these community level approaches, which might lead to dilution bias. Therefore, Lindholm and Rosén, for example, state that hard end points are inappropriate options for community-based primary interventions [47]. Rather, our study intents to identify strategies that are feasible and acceptable in the context of the German social and health care system.

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Authors' Contributions

DK, KR, MK, CB, and PB contributed by conception of the study design, development, implementation of the measures and strategies, and by planning of the evaluation. DK and PB mainly drafted the manuscript. TF and GB contributed by conception and data management of the telephone-based evaluation. All authors read and approved this version submitted for publication.

Conflicts of Interest

None declared.

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Abbreviations

CDC: US Centers for Disease Control and Prevention

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Original Paper

Stress and Mental Health in Families With Different Income Levels: A Strategy to Collect Multi-Actor Data

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Abstract

Background: Several studies have focused on family stress processes, examining the association between various sources of stress and the mental health and well-being of parents and adolescents. The majority of these studies take the individual as the unit of analysis. Multi-actor panel data make it possible to examine the dynamics of the family context over time and the differentiating effects of individual roles within the same family. Accurate information about family processes allows practitioners to provide support that enhances family resilience and minimizes the risk of mental health problems.

Objective: Our study contributes to the research on family stress processes by focusing on families with different income levels, and by collecting panel data from mothers, fathers, and adolescents within the same family.

Methods: The relationship between mothers, fathers, and children (RMFC) study is an ongoing Flemish multi-actor panel study that aims to enhance our understanding of family processes that protect the mental health and well-being of two-parent families with a target adolescent between 11 and 17 years old. Mothers, fathers, and children provide information about various aspects of family life, including finances, sources of stress, health, mental health, parenting, and coping strategies. Measures have been chosen whenever possible that have sound conceptual underpinnings and robust psychometric properties. The study posed two challenges. First, economically disadvantaged families are difficult to reach. Second, the collection of multi-actor data is often plagued by high nonresponse. To ensure that the families were targeted as successfully as possible, the study employed a purposive nonprobability sampling method.

Results: The RMFC study is one of the largest triadic panel studies of its kind. The first wave of quantitative data collection was conducted between February 2012 and January 2013. A total of 2566 individuals of 880 families participated in our study. The second wave of data collection will be undertaken 6-12 months later.

Conclusions: The strength of the RMFC study is its multi-actor panel approach of data collection among families with different income levels. Strategies that were followed to address the empirical issues involved with the sampling design are discussed, together with theoretical and practical implications.

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KEYWORDS

stress; mental health; well-being; family process; multi-actor approach

Introduction

Background

Growing up and living with financial hardship is detrimental to one’s physical and mental health. Rates of psychopathology and various types of mental disorders (eg, depression, anxiety) are higher among individuals from low-income families than among individuals from middle- and high-income families [1,2]. Financial hardship creates a context of stress in which stressors build on one another and contribute to mental health problems for adults and children [3]. In addition, children from low-income families are more likely to engage in problematic behavior, such as aggressive behavior and substance abuse [4]. Most research on the negative influence of financial hardship or stress on families and children has been based on the family stress model [5,6]. This model specifies that high levels of financial stress have detrimental effects on parental psychopathology, interparental conflict, and parenting, and these parental problems damage children's mental health and well-being.

Despite strong support for the original and expanded family stress models (eg, including social support, health problems) in a variety of contexts, most studies use data from one family member to examine relationships between family members [7]. Our study expands upon previous studies on stress processes by including paired data from both parents and an adolescent. Given the lack of extensive research using a dyadic approach to consider family stress processes [8], research that takes into account the interdependence and mutual influence between mothers and fathers—or between parents and adolescents—could improve our understanding of the processes that protect the mental health and well-being of parents and adolescents. This understanding is essential for developing and implementing successful intervention programs. Accurate information about the mechanisms of stress allows practitioners to provide support that enhances family resilience and minimizes the risk of mental health problems.

Our paper describes how the dyadic approach to data collection and analysis differs from the more common individualistic approach. This is followed by a description of the aims and study design of a project entitled, “Relationships between mothers, fathers, and children” (RMFC). The unique contribution of the interuniversity RMFC project is its multi-actor panel approach to data collection: several types of information (eg, finances, various sources of stress, health, mental health, parenting, and coping strategies) were collected from mothers, fathers, and adolescents within the same families. The first wave of data collection started in February 2012 and ended in January 2013. The second wave of data collection will be undertaken 6-12 months later. The outcomes will include a detailed picture of family functioning and an enhanced understanding of processes that protect the mental health and well-being of both parents and adolescents.

Individualistic Versus Dyadic Approaches

One common shortcoming of many studies on family stress processes is that they focus on either mothers or fathers. Because mothers and fathers belong to the same family, however, they should not be viewed simply as two independent individuals. They share a characteristic known as nonindependence [9]. The characteristic of nonindependence can be assumed if two scores from two members of a dyad are more similar to one another than are two scores from two people who are not members of the same dyad. Information about nonindependence has theoretical and statistical implications. Theoretically, nonindependence can be used to infer reciprocity, synchrony, or influence within a dyad. Statistically, it requires that the data be analysed in ways that include both the dyad and the person as units of analysis. If it is ignored, nonindependence can bias tests of significance [9,10].

By administering data from two parents within the same family, both the person and the dyad can be used as units of analysis. The choice to focus on the person or the dyad in various constructs is related to actor-partner effects within the dyads [11]. An actor effect refers to the impact of an independent variable of a person on an outcome variable of the same person (eg, a mother who experiences high levels of financial stress is more likely to experience depressive feelings). A partner effect occurs when a person's score on an independent variable affects the partner's score on an outcome variable (eg, increased levels of stress experienced by one parent might be negatively associated with the partner's marital satisfaction). As such, the use of a dyadic approach enables researchers to study separate paths through which financial stress experienced by mothers and fathers affects depressive symptoms, health, marital problems, or parenting behaviors of both the person and the partner.

The dyadic approach to data collection and analysis is nevertheless not limited to mother-father dyads. Mother-adolescent or father-adolescent dyads can also be used as unit of analysis. Although several researchers advocate the use of multiple informants in studies on family functioning [12], the tendency to consider children or adolescents as active agents is quite recent [13]. Epstein and colleagues [14] described three reasons for considering the perceptions of multiple family members (ie, mothers, fathers, and adolescents) in the assessment of families. First, each family informant provides a unique perspective on events occurring within their families. Second, different family members may provide slightly different information based on their own experiences in the family and on differential knowledge about the others. Third, although family members can witness the overt behaviors of themselves and other family members, they can be aware of only their own internal states and perceptions.

We strongly believe that inclusion of multiple family members in studies on family stress processes could enhance knowledge concerning their mutual influence. For this reason, the RMFC project (as outlined below) applied a multi-actor panel design, including information on both of the married or cohabiting parents, as well as on a target adolescent between 11 and 17 years of age.

Aims

The overall aim of the RMFC project is to explore how various sources of stress affect the mental health and well-being of parents and adolescents. Our study contributes to previous research on family stress processes in several ways.

First, most previous research studies on family stress processes were conducted in the United States. Our study was conducted in the Dutch-speaking part of Belgium (Flanders), and it should be seen in this context. Because Belgium is quite different from the United States in terms of economic and social security, the experiences and responses of families might differ.

Second, the RMFC study focuses on low-, middle-, and high-income families. Although financial stress and ongoing strains seem to be more prevalent in low-income families compared to middle- or high-income families, it appears that low-income families are also more vulnerable to events and strains (ie, different sources of stress have more devastating impact in these families) [4]. An important issue is how to understand the processes that are responsible for the variability that exists among families with different income levels. This includes the identification of factors that cause some families, or family members, to experience mental health problems whereas other families seem not to be compromised. To do so, we collected information on various sources of stress (eg, financial stress, parental stress, marital stress, and daily stress) and coping strategies to manage that stress.

Third, the RMFC project is based on a family-system approach (as described above), in which the family is considered as a complex, integrated whole in which individual family members are necessarily interdependent [15,16]. For this reason, data were collected from mothers, fathers, and adolescents. These triadic data make it possible to examine pathways within and between family members.

Fourth, families were invited to take part in a follow-up study. One major advantage of the panel design stems from its ability to compare the same individual at different times, and hence permit within-individual analyses of individual change. From a multi-actor design standpoint, each family member can have a unique trajectory. The trajectories can differ in magnitude (eg, the rate of change can be more steep for mothers than that for fathers) or pattern (eg, change can be linear for mothers and nonlinear for fathers) [17].

Methods

Sampling

In general, probability sampling is the preferred approach for scientifically conducted surveys. A probability sample is defined as a sample in which individuals are chosen at random, such that each individual has a calculable, nonzero probability of selection. The RMFC project, however, used a purposively nonprobabilistic sampling design with oversampling of low-income families. The design was selected for two reasons.

First, the RMFC project involved gaining access to economically disadvantaged families, in addition to middle- to high-income families. This posed a challenge, given that many economically disadvantaged families are “hidden” and notoriously difficult to access in a systematic way [18]. In most studies in which the representative household survey is the golden standard for data collection, such hidden population segments are either lost by definition or, at best, grossly underrepresented [19]. Thus, most studies of low-income families use some form of nonprobability sampling in order to recruit participants [20]. The design has also the advantage of being affordable.

Second, multi-actor data are highly valuable for investigating questions about family functioning, and they improve the reliability of information on the subjective characteristics of household members. Nevertheless, the collection of such data is often plagued by high nonresponse [21]. For example, the recent “Divorce in Flanders” study, in which the sample was drawn from the Belgian National Register, applied a multi-actor design, including information on both currently and formerly married partners, as well as on their children aged 10 years or older. As noted by the researchers [22], the response rate for dyadic data (ie, both mother and father responded to the questionnaire) from married families was 31.41%, while the response rate for triadic data from married families (ie, mother, father, and a child responded to the questionnaire) was 12.75%. This made it difficult to generalize the triadic findings. One of the problems associated with a multi-actor approach is that data collection is complicated by nonresponse on the part of one family member. Whether a particular family member will respond depends upon individual characteristics, in addition to characteristics of the mutual relationships between all family members involved. In a study on nonresponse by secondary respondents in multi-actor surveys, Kalmijn and Liefbroer [21] reported that a parent is more likely to grant permission to collect data from the child if the relationship between the parent and the child is intensive and of good quality. The quality of the relationship also has a positive effect on the likelihood that children will return the questionnaire [21]. Relationship quality thus has an impact on the response process, regardless of the sampling design that is selected.

Taken together, given the lack of a sampling frame for our target population of families, a random selection from the study population was not a realistic option. As recommended by some authors [23,24], however, the RMFC project followed several strategies in order to address the empirical issues involved in the use of a nonprobability sample. More specifically, efforts were made to ensure that the study sample provided adequate statistical power for hypothesis testing. It has been shown that, other things being equal, large samples always produce estimates about true population parameters that are more efficient and unbiased than are those produced by small samples. Furthermore, the researchers engaged in multi-agency collaboration. Finally, a national sample, the European Union Statistics on Income and Living Conditions (EU-SILC) [25], was used to compare our data. Because the purpose of the EU-SILC is different from the purpose of our study, it was possible to use probability sampling.

Calculation of A Priori Sample Size

The power of a statistical test depends upon the following parameters: the reliability of the sample results, the sample size, the effect size, and the significance criterion. Following the proposed conventions described by Cohen [26], we adopted a desired power value of at least .80 and a desired alpha score of no greater than .05. Based on previous multi-actor research studies on family stress processes [7,27] and taking into account the number of measures that we wanted to include in our future family stress models (see below), we expect to study structural equation models with a maximum of 22 observed and 8 latent variables. Using the statistical program of Soper [28], the calculation of a priori sample size (with an anticipated medium effect size of 0.3) returned a recommended minimum sample size of 241 households. A more demanding effect size (ie, 0.1) would require us to recruit 625 households.

Recruitment

Two-parent families with a target adolescent in secondary school (ie, between 11 and 17 years of age) were recruited from February 2012 through January 2013. Families were recruited from five provinces of the Dutch-speaking part of Belgium (ie, Flanders), with assistance from undergraduate students from two institutes of higher education: the Higher Institute for Family Sciences and the University of Antwerp. A two-stage strategy was used to reach the households. First, each of the students from the Higher Institute for Family Sciences (n=85) was instructed to recruit low-, middle-, and high-income two-parent families. Students received course credit for their recruitment efforts. The average age of the students from the Higher Institute was 34.85 (SD 1.24) and most were working in the social services. As such, the project took advantage of the social networks of the students in order to obtain a large set of potential respondents. Each of the targeted families (mother, father, and target adolescent) was sent a letter explaining the purpose of the research. The families were subsequently contacted and asked to participate. In total, 1020 packages of envelopes and questionnaires were distributed (12 per student), and 824/1020 (80.78%) were returned by post. Second, four 21-year-old students from the University of Antwerp recruited 56 low-income families through community agencies, including centers for general welfare (CAW) and public centers for social welfare (OCMW), as well as through service and meeting centers. The students contacted 25 community agencies distributed across the different regions, and 14 volunteered to cooperate. Personnel in the community agencies selected potential families, and the students contacted them to assess their willingness to participate. Once they agreed, families were given the packages of envelopes and questionnaires.

Ethics and Data Collection

Each participant received a plain-language statement and a written informed-consent form. The study protocol was approved by the Ethics Committee of the University of Antwerp (Belgian registration number: B300201215397).

Each family received a package of three envelopes and questionnaires. A letter accompanying the questionnaire introduced the study as an investigation of “the relationship between mothers, fathers, and children” and provided information on the purpose of the study in lay terms. The first page of the questionnaire instructed the target participants to complete the booklets individually and not to discuss the content of the questionnaire with one another. The booklets were to be returned in a stamped envelope. Mothers, fathers, and adolescents were asked to sign written consent forms, which were to be returned by post in a separate envelope. All families were also asked if they were willing to take part in future research. It was made clear in the written informed-consent form that participation was voluntary. In total, 51.2% (418/817) families of the triads volunteered to be followed up.

Content of the Parent Questionnaire

The questionnaires for mothers and fathers were identical (except for such phrasings as “he/she” or “father/mother”) and contained 290 items. A small pilot study (six mothers and fathers) revealed that it took about 40 minutes to complete the parent survey.

The questionnaire included items on sociodemographic indicators, including age, education, nationality, country of origin, religiosity, occupation, civil status, length of relationship, number of household members, and, in the case of multiple children, the age of youngest and oldest child in the household. Parents were also asked to provide sociodemographic information on the target adolescent, including the age and gender of the adolescent, relationship to the adolescent (eg, biological mother, stepmother), education, school years repeated, and the presence of any developmental disorders.

To gain insights into various aspects of family functioning, measures have been chosen whenever possible that have sound conceptual underpinnings and robust psychometric properties. To assess parental mental health, the Hospital Anxiety and Depression Scale [29] and a short form of the CES-D [30] were included. The physical health item was drawn from the EU-SILC instrument [31]. Interparental relationship was measured using the O’Leary-Porter Scale [32], subscales from the Conflicts and Problem-Solving Strategies questionnaire [33], the Multidimensional Stress Questionnaire for Couples [34], and the Quality of Marriage Index [35]. Parent-adolescent relationship was assessed using the Parent-Adolescent Communication Scale developed by Barnes and Olson [36], subscales from the Parental Behavior Scale [37], and the Psychological Control Scale [38]. The questionnaire also included subscales from the Dutch version of the Parenting Stress Index [39] and the Parenting Sense-of-Competence Scale [40]. Information about the family’s financial situation was assessed with self-constructed items on savings, financial stress, financial insecurity and financial needs, as well as with items drawn from the EU-SILC [31]. Consistent with other studies involving fragile families [41,42], items on coping strategies and social support were included as well, like the Carver Coping Scale [43]. Finally, the questionnaire included items about the adolescent’s school competence, and the adolescent’s emotional and behavioral problems were assessed using the Child Behavioral Checklist [44].

Content of the Adolescent Questionnaire

The adolescent questionnaire contained 191 items and took about 25 minutes to complete. Sociodemographic questions included gender, age, number of brothers and sisters, education, and the marital status of parents. Information on stress was assessed with items drawn from the Sources of Stress Index [45]. Adolescents completed scales on parent-adolescent relationship twice, once for the mother-child relationship and once for the father-child relationship. Scales included were the Parent-Adolescent Communication Scale developed by Barnes and Olson [36], subscales from the Parental Behavior Scale [37], and the Psychological Control Scale [38]. Peer attachment was assessed with a subscale from the Inventory of Parent and Peer Attachment [46]. Finally, similar to the parent questionnaire but adapted to the adolescent perspective, items were included about adolescents’ school competence, coping strategies, and the adolescent’s emotional and behavioral problems.

Results

Sample Characteristics

Over the 12-month survey period, 880 households were recruited: 824 households in the first stage and 56 households in the second stage (see the above-mentioned recruitment procedure). The dataset contained information on 817 triads (mother, father, and adolescent) and 857 mother-father dyads. Table 1 provides an overview of the number of participants. The average ages of fathers and mothers were 46.03 (SD 5.10) and 43.72 (SD 4.56) years, respectively. Within our sample, 2.7% (23/848) of the mothers and 4.0% (34/850) of the fathers had completed preprimary or primary education; 33.7% (286/848) of the mothers and 41.5% (353/850) of the fathers had completed secondary education; and 63.6% (539/848) of the mothers and 54.5% (463/850) of the fathers had completed postsecondary education. With regard to work status, 95.3% (810/850) of the fathers and 84.3% (721/855) of the mothers worked either full-time or part-time. Furthermore, three-person households accounted for 10.4% (89/855) of the sample, four-person households for 46.8% (400/855), five-person households for 29.2% (249/855), six-person household for 9.6% (82/855), and households of seven or more people for 4.1% (35/855). Using the *modified OECD equivalence* scale [47], the average household income of our sample was €1592.95 (SD 604.17).

Table 1. Overview of the RMFC dataset (N=2566).

	Households, n (%)	Individuals, n (%)
Triadic data (mother, father, and adolescent)	817 (92.84)	2451 (95.51)
Dyadic data (mother and father)	40 (4.54)	80 (3.12)
Dyadic data (parent and adolescent)	12 (1.36)	24 (0.94)
Individual data (mother or father)	11 (1.25)	11 (0.43)
Total	880	2566

Comparisons Between the RMFC and EU-SILC Samples

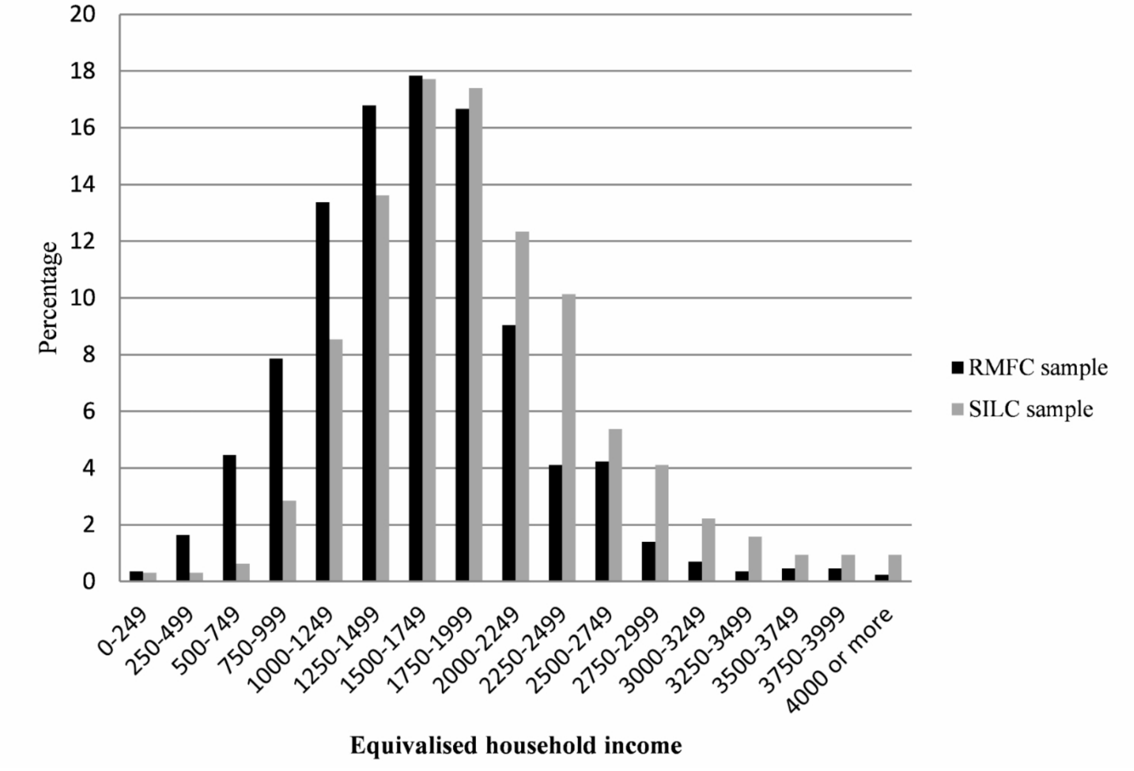
The EU-SILC is the EU reference source for microlevel data on income and living conditions. The dataset includes internationally and cross-temporary comparable variables for all EU Member States [48]. The reference population of the EU-SILC consists of private households residing in the participating countries at the time of selection. In this study, we selected households from the Dutch-speaking part of Belgium that had at least one child between 11 and 17 years of age (317/3084, 10.28%). Calculations are based on the EU-SILC 2011 user database.

Our findings revealed that the mean age of the mothers and that of the fathers did not differ significantly between the two samples ($F_{1,1156}$=3.25 for mothers and $F_{1,1156}$=2.25 for fathers). As shown in Table 2, the educational attainment of mothers in the RMFC sample was somewhat higher than was that of the EU-SILC sample (χ^2_4=18.66, *P*<.001). With regard to fathers' educational attainment, no significant differences were found between the two samples (χ^2_4=8.69, *P*=.069). With regard to the employment of parents (Table 2), no significant differences were found between the samples for mothers (χ^2_4=4.28, *P*=.369) or for fathers (χ^2_4=1.41, *P*=.888). As shown in Table 2, households in the EU-SILC sample were more likely to consist of three members and less likely to consist of five or more members (χ^2_4=14.28, *P*=.006). As expected, low-income households were oversampled in the RMFC dataset, relative to the EU-SILC dataset. Figure 1 presents an overview of household income.

Table 2. Characteristics of the RMFC and the EU-SILC sample.

	RMFC sample, (n=857) n (%)	EU-SILC sample, (n=317) n (%)
Educational level of mothers		
Preprimary education	12/848 (1.42)	3/317 (0.95)
Primary education	11/848 (1.30)	8/317 (2.52)
Lower secondary education	53/848 (6.25)	24/317 (7.57)
(Upper) secondary education	233/848 (27.48)	122/317 (38.49)
Postsecondary education	539/848 (63.56)	160/317 (50.47)
Educational level of fathers		
Preprimary education	23/850 (2.71)	3/317 (0.95)
Primary education	11/850 (1.29)	9/317 (2.84)
Lower secondary education	99/850 (11.65)	31/317 (9.78)
(Upper) secondary education	254/850 (29.88)	112/317 (35.33)
Postsecondary education	463/850 (54.47)	162/317 (51.10)
Employed		
Mothers	721/855 (84.33)	266/317 (83.91)
Fathers	810/850 (95.29)	296/317 (93.38)
Household members		
Three	89/855 (10.41)	54/317 (17.03)
Four	400/855 (46.78)	158/317 (49.84)
Five	249/855 (29.12)	71/317 (22.39)
Six	82/855 (9.59)	24/317 (7.57)
Seven or more	35/855 (4.09)	10/317 (3.15)

Figure 1. Equivalised household income of the RMFC and the SILC sample.



An Example of Future Research Directions

During the past two decades, a large body of research has focused on family stress processes [49], examining family-based pathways through which financial stress is associated with the adjustment of parents and adolescents. Most research on the negative influence of financial hardship on families and adolescents has been based on the family stress model [6,49]. This model predicts that high levels of financial stress have detrimental effects on parental mental health, interparental conflict, and parenting, and these parental problems damage children's mental health and well-being (see Figure 2). To date, studies that have applied the family stress model have typically analysed data on mothers and fathers separately [50]. These studies thus neglect the interdependence of the two parents and the mutual influence that they have on each other.

The RMFC study may contribute to the research on family stress processes by its multi-actor approach, which enables us to test more advanced theoretical models. For instance, as shown in Figure 3, analyses can be grounded in the actor-partner interdependence model (APIM) [9], a multi-actor approach which proposes that the predictor variable of both the respondent (actor effects) and the respondent's partner (partner effects) influence the respondent's outcome variable [51]. The APIM allows for the testing of both actor and partner effects, and may thus provide better insights into how mothers and fathers each respond to financial stress.

Figure 2. An individual approach of the family stress model.

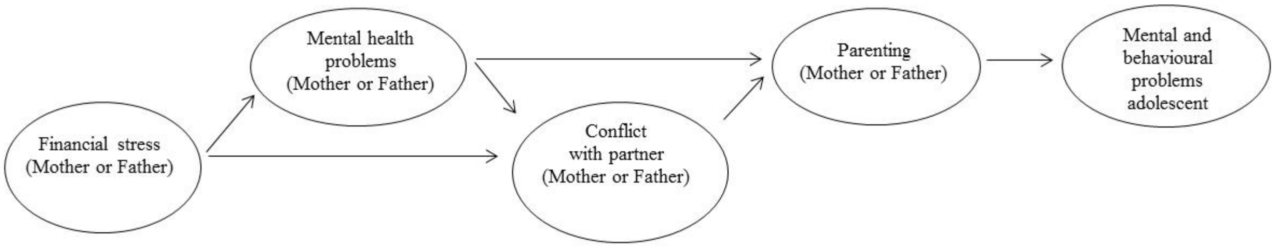
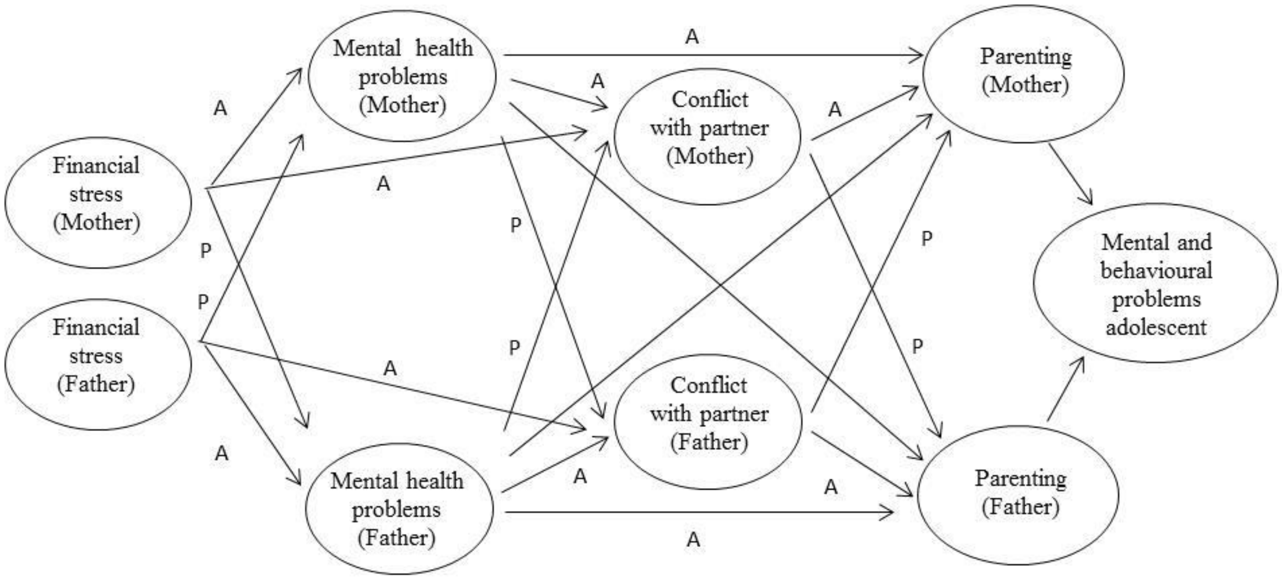


Figure 3. An actor-partner approach of the family stress model. A: actor effects; P: partner effects.



Discussion

Principal Findings

We described a strategy to collect multi-actor data from families with different income levels. The families participating in the study were living in the Dutch-speaking part of Belgium. To improve our understanding of processes that protect the mental health and well-being of both parents and adolescents, we collected information about various aspects of family life, including finances, stress, health, mental health, parenting, and coping strategies.

Gaining access to economically disadvantaged families and recruiting mothers, fathers, and adolescents to participate in a research study poses two challenges. As noted above, it would be impossible to obtain a random sample of the study population, given the absence of a comprehensive population list. The RMFC project therefore employed a nonprobability sampling method, purposive sampling, in order to ensure that this group was targeted as successfully as possible. One major drawback of purposive sampling is that it limits the ability to generalize results. To mitigate this problem, the researchers attempted to obtain a large sample size, and they engaged in multi-agency research collaborations. A posteriori comparisons between the RMFC sample and the EU-SILC probability sample revealed more similarities than differences between the demographic characteristics of the families in the two samples. For all of these reasons, the present nonprobability sampling procedure can be considered as an alternative or as a complementary strategy for attaining more comprehensive data with which to investigate research questions concerning family stress processes.

Conclusions

Multi-actor information on family functioning has both theoretical and practical implications. For example, one limitation in the current literature that can be overcome by researchers using the RMFC data involves the relative lack of attention to possible gender differences in the pathways from stress to parenting [52,53]. This limitation stems from the fact that early parenting research focused almost exclusively on mothers, partly due to the common assumption that mothers play a central role in child development [54].

By focusing on the dyad as unit of analysis, researchers can examine effects within and between parents and begin to understand the dynamic processes that constitute the relationship [17]. The multi-actor panel approach will make it possible to examine the dynamics of the family context over time and the differentiating effects of individual roles within the same family. In this manner, the study will provide better insight into differences in the ways in which family members respond to different sources of stress. This knowledge might subsequently help practitioners in their efforts to support fragile families. When the coping strategies are identified and matched to particular stressors and characteristics of the family members, practitioners may then teach the family members to use the strategies that best align to their particular situation and characteristics.

Acknowledgments

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Authors' Contributions

KP is the PI and leads the study. KP conceived the study and prepared the first draft of this paper which has been reviewed by EW.

Conflicts of Interest

None declared.

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Abbreviations

APIM: actor-partner interdependence model
EU-SILC: European Union Statistics on Income and Living Conditions
RMFC: relationship between mothers, fathers, and children

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Original Paper

Development and Content Validation of the Information Assessment Method for Patients and Consumers

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Abstract

Background: Online consumer health information addresses health problems, self-care, disease prevention, and health care services and is intended for the general public. Using this information, people can improve their knowledge, participation in health decision-making, and health. However, there are no comprehensive instruments to evaluate the value of health information from a consumer perspective.

Objective: We collaborated with information providers to develop and validate the Information Assessment Method for all (IAM4all) that can be used to collect feedback from information consumers (including patients), and to enable a two-way knowledge translation between information providers and consumers.

Methods: Content validation steps were followed to develop the IAM4all questionnaire. The first version was based on a theoretical framework from information science, a critical literature review and prior work. Then, 16 laypersons were interviewed on their experience with online health information and specifically their impression of the IAM4all questionnaire. Based on the summaries and interpretations of interviews, questionnaire items were revised, added, and excluded, thus creating the second version of the questionnaire. Subsequently, a panel of 12 information specialists and 8 health researchers participated in an online survey to rate each questionnaire item for relevance, clarity, representativeness, and specificity. The result of this expert panel contributed to the third, current, version of the questionnaire.

Results: The current version of the IAM4all questionnaire is structured by four levels of outcomes of information seeking/receiving: situational relevance, cognitive impact, information use, and health benefits. Following the interviews and the expert panel survey, 9 questionnaire items were confirmed as relevant, clear, representative, and specific. To improve readability and accessibility for users with a lower level of literacy, 19 items were reworded and all inconsistencies in using a passive or active voice have been solved. One item was removed due to redundancy. The current version of the IAM4all questionnaire contains 28 items.

Conclusions: We developed and content validated the IAM4all in partnership with information providers, information specialists, researchers and representatives of information consumers. This questionnaire can be integrated within electronic knowledge resources to stimulate users' reflection (eg, their intention to use information). We claim that any organization (eg, publishers, community organizations, or patient associations), can evaluate and improve their online consumer health information from a consumers' perspective using this method.

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KEYWORDS

information use; information retrieval; push technology; consumer health information; consumer-centered outcomes; content validity

Introduction

Background

The availability of the Internet and expectations of the public to become more involved in health care decisions have resulted in unprecedented demand of consumer health information, such as that provided by the National Library of Medicine (MedlinePlus). Consumer health information is about health problems, self-care, disease prevention, and health care services, and is intended for the general public, including patients and their relatives [1,2]. Accessing Web-based health information will increase as Internet access is almost ubiquitous in many countries. For example, a national survey of a representative population sample reveals that accessing Web-based consumer health information in the United States has doubled since 2001, while access from other sources has decreased, and the Internet is the most frequently used platform for accessing consumer health information [3]. In 2012, 35% of US adults reported using health information found online "to try to figure out the medical condition they or someone else might have" [4].

Using evidence-based health information may contribute to improving the health of populations, when this information use leads consumers to improve their knowledge and their participation in health decision-making [5-8]. Another potential impact of better-informed consumers is on the use of health services. For example, in one study, better-informed consumers were less likely to use emergency room services [9]. Such outcomes are particularly important in primary health care where patients, their friends, relatives, and home care aids, play an active role in health decision-making and frequently search for information [10]. For example, among adult Internet users in Canada, 54% have looked for health information online [11]. The aging of society and the prevalence of chronic diseases will continue to increase [12], which will, in turn, drive an increase in the use of Web-based consumer health information.

In line with more consumer-centered health services, health information providers are producing more Web-based resources for the general public and for patients [13]. However, there are no comprehensive instruments to evaluate whether Web-based consumer health information is valuable from a consumers' viewpoint. While existing tools typically focus on experts' evaluation of the quality of information sources [14], new tools are needed to better understand the role of the Internet in health, and specifically to evaluate and improve the impact of information on patients and their families [15]. Consequently, our objective is to develop and validate a questionnaire that can be used by the general public, including patients, to assess outcomes associated with seeking and receiving Web-based consumer health information. To do this, we engaged organizational partners, such as consumer health information providers who expressed a need for a clear and user-friendly, comprehensive assessment method. This method will be used to stimulate reflection on information, enabling a two-way knowledge translation between information providers and consumers, also referred to as participatory production of knowledge with lay people. In this paper, we report on the development and validation of the Information Assessment Method for patients and consumers (IAM4all). We will present the theoretical model, the literature review, the three-step content validation process, the results, and the discussion, including examples of application and further validation study.

Theoretical Model and Literature Review

Overview

The Information Assessment Method (IAM) is based on information studies [16], and a theoretical model, called the Acquisition Cognition Application - Level of Outcomes model (ACA-LO), which is presented elsewhere [17]. This model explains the value of information, (ie, how information is valuable from the user viewpoint). In this model, four levels of outcomes are associated with the retrieval or the reception of an information object (eg, a Web page): the situational relevance of the information [level 1], its cognitive/effective impact [level 2], the use of information [level 3], and subsequent health benefits [level 4]. There are four levels because situational relevance is necessary for information to have positive cognitive impact. In turn, a positive cognitive impact is necessary for applying information, which could eventually result in health benefits. The first three levels correspond to three iterative steps of human information interaction: acquisition, cognition, and application of information. Consumers may receive or retrieve Web-based health information (acquisition), understand and integrate it (cognition), and then use it (application), which may lead to health benefits. This process fits with the definition of eHealth literacy, "the ability to seek, find, understand, and appraise health information from electronic resources and apply the knowledge gained for addressing health problems" [18].

For clinicians, the ACA-LO model is operationalized using an IAM checklist that stimulates reflective learning within continuing education programs. With regard to Web-based health information, completing an IAM questionnaire will stimulate consumers' reflection on the relevance of retrieved information for the situation at hand, the cognitive/affective impact of information (eg, learning something new), the intention to use information (eg, for doing something differently), and the expected health benefits from using it. In line with studies of the mere measurement effect [19], such reasoning is important as this process can help consumers to better reflect on information-related behaviors, which could have been otherwise overlooked. In line with the latest version of the Theory of Reasoned Action [20], a relevant information object (level 1), the positive cognitive/affective impacts of this information (level 2), the intention to use information (level 3), and expected benefits from using it (level 4) constitute key determinants of consumer behavior (information use) when information is trusted and seen as reflecting a social norm. According to this theory, two other key determinants of behavior are independent from the information object: "the person has the skills necessary to perform the behavior", and environmental constraints do not completely block the behavior.

For the present work, we conducted a critical review of the literature (all disciplines) on the four levels of outcomes of information with regards to online consumer health information. We examined 27 articles reporting literature reviews, original studies, and doctoral theses. For each level of outcome, this review suggested a preliminary list of types of outcomes. There were (1) seven types of consumer objectives for assessing the situational relevance of information, (2) five types of cognitive/affective impact of information on consumers, (3) five types of consumer use of information, and (4) eight types of health benefits for consumers. Findings from this review were grouped in accordance with three types of information-seeking: professionally-mediated access (through clinicians and librarians), direct access, and peer-mediated access (through relatives and social media) to Web-based consumer health information. These types are complementary (eg, consumers can search by themselves and with peers, then check with a health professional). Consideration of all three types of information-seeking was important to propose a comprehensive list of types of outcomes.

Level 1 Outcomes: Situational Relevance (Acquisition)

Professionally-Mediated Access

The literature shows that consumers are provided with Web-based health information by professionals for an educational purpose. The acquisition of information is mediated by a nurse, a doctor, an allied health professional, or a librarian [21-26].

Direct Access

Web-based health information can be found by consumers to address the following objectives: answer their own clinical questions (about themselves or relatives); update their knowledge; find more information to complement what was provided by clinicians or librarians; check this information; and satisfy their curiosity [27-36].

Peer-Mediated Access

Peers usually provide Web-based health information based on personal opinions or experiences, and encouragement or emotional support (subjective); they can also provide information based on guidelines (normative), or research (objective), or a combination of subjective, normative, and objective information [31,35,37,38].

Level 2 Outcomes: Cognitive/Affective Impacts (Cognition)

Professionally-Mediated Access

A systematic literature review shows that cognitive/affective impacts of Web-based consumer health information on patients are mainly learning (patients learn something new) and reassurance for decision-making (patients feel reassured for making decisions about their health and health care) [39].

Direct Access

The literature suggests cognitive/affective impacts are commitment to change in health care (eg, a commitment to change in prevention or treatment of illness), learning (better understanding of health or health care), and reassurance for decision-making [28,32-34].

Peer-Mediated Access

An overview of the field by experts suggests cognitive/affective impacts of information from members of support groups are learning (better understanding of specific issues about health or health care), reassurance (gaining confidence), and confirmation that consumers are doing the right thing [31].

Level 3 Outcomes: Information Use (Application)

Professionally-Mediated Access

Web-based consumer health information is used by professionals to communicate with patients, and can be prescribed to patients (eg, in preparation for counseling and decision-making) [21-23,40].

Direct Access

Web-based consumer health information is used by people for themselves, their relatives, and friends. Direct access may lead to a consultation with a clinician to get an explanation or another opinion, and to modify health care when needed. Although rarely, using Web-based consumer health information may lead to disagreements between patients and clinicians. Clinicians may be defensive, or analyze the information with patients and guide them to high quality resources [28,32-34].

Peer-Mediated Access

In online support groups, the flow of information involves multiple members and moves in multiple directions; it may contain inaccuracies, but most inaccuracies are rapidly corrected by informal leaders and group members. Information from these groups may be often used to comply with health care management [31,41].

Level 4 Outcomes: Health Benefits

Professionally-Mediated Access

The use of Web-based consumer health information may be associated with an increase of patients' participation in health care, a gain in patient satisfaction, the prevention of health disease, and health improvement such as a reduction of depression and of the level of anxiety. Interactive interventions that tailor information to users' needs can be more effective compared with noninteractive booklet or email interventions [22-24,26,42-45].

Direct Access

The use of Web-based consumer health information may affect the relationships between health professionals and patients, as it may (1) augment information provided by clinicians, (2) help patients to make informed health care choices, and (3) enable shared decision-making when there are different options for health care. It may transform the traditional clinician-patient relationship (from the clinician with expertise-based power to the clinician sharing information with patients), which can be challenging for some clinicians and patients. For example, consumer health information may create frustration when cyberchondriac patients bring in lengthy printouts of Web-based information about illnesses they might have [28,30,34,35].

Peer-Mediated Access

There is no strong evidence regarding the positive or negative effects of Web-based consumer health information such as that from online support groups, discussion forums, and mailing lists. While online cancer support groups may help group members to cope more effectively with their disease, it has been suggested that people may rely on groups for too long, which can delay needed health care [37,38,41,46].

Methods

Study Design

In line with usual content validation procedures for psychometric assessments [47,48], we followed three steps that involved researchers, laypersons, and a panel of experts, respectively. These three steps are described in the "Data Collection and Analysis" section below. In step 1, we created a first version of the IAM4all questionnaire using the theoretical model, and items from the critical literature review and previous work [17]. In step 2, the second version was based on interviews with 16 laypersons. For step 3, experts contributed to produce the third version by rating all items for relevance, clarity, representativeness, and specificity. Ethical approval was obtained from the McGill University institutional review board.

Participants

Study participants were 16 laypersons (health information consumers), and 20 experts (co-authors) from McGill University, and 3 organizational partners. First, laypersons were recruited by co-authors from their adult acquaintances. They were fluent in English or French, and had no training or experience in health sciences or information studies.

Second, our partners were the Canadian Pharmacists Association (CPhA), the College of Family Physicians of Canada (CFPC), and the Centre for Literacy Québec (CLQ). We have been conducting participatory research since 2005 with the CPhA and the CFPC for the development of an IAM checklist for clinicians (nurses, pharmacists, physicians). The CPhA and the CFPC are nonprofit professional associations. The CPhA provides recommendations for clinicians (eg, patient self-care), and is starting to provide Web-based consumer health information. The CFPC produces Web-based patient education material for family physicians and patients. The CPhA and the CFPC are interested in assessing their products. For their part, the CLQ was interested in the development and assessment of effective interventions providing Web-based consumer health information. The 3 partners helped to formulate the objectives for this work. Our partnership followed the principles of participatory research with organizations, also called collaborative action research [49,50]. This approach leads to improve knowledge and practice (organizational learning), to engage organization members (as reflective practitioners), and to involve organization partners in all research aspects (integrated knowledge translation).

Data Collection and Analysis

Step I: Researchers (IAM4all Version 1)

We created the first version of the IAM4all questionnaire using the four levels of outcomes of information (ACA-LO model): (level 1) situational relevance of information, (level 2) its cognitive impact, (level 3) information use, and (level 4) subsequent health benefits. For each level, items were derived from our critical review of the literature on consumer health information. Then, we edited and revised these items using previous work on the IAM. Finally, items of the IAM4all questionnaire were then reviewed by 8 researchers who belonged to the Information Technology Primary Care Research Group (ITPCRG) at McGill University.

More than 34 papers and book chapters are published about our previous work on the IAM checklist for clinicians (Multimedia Appendix 1). This checklist systematically documents reflection on clinical information, delivered or retrieved from electronic knowledge resources. It enhances continuing education by stimulating clinicians' reflective learning, evaluation of knowledge resources, and enables a two-way knowledge exchange between information users and information providers. Through literature reviews, qualitative, quantitative, and mixed-methods studies, we have documented the feasibility, content validity, construct validity, and substantive validity (theoretical rationale) of the IAM checklist.

Step II: Laypersons (IAM4all Version 2)

The first version of the IAM4all questionnaire was tested using individual interviews with 16 laypersons (VG). The level of health literacy of participants was tested using the Short Test of Functional Health Literacy in Adults (S-TOFHLA) [51]. Participants were asked to describe their experience with accessing consumer health information online. Then, they read a public health leaflet, and completed the IAM questionnaire based on the information in the leaflet. Participants were asked to read and rate the public health leaflet they felt was most relevant to them out of the following five: Nutrition Labeling, Smog and Your Health, Summer Food Safety, Sunscreens, and West Nile Virus [52] (our interview guide is available on request).

Interviews were both inductive and deductive. Participants were asked to describe the overall experience of consumers looking for health information, which enabled the emergence of new items. Then, they were asked for their feedback on the existing items. For each level of outcomes, the interviewer asked open questions (eg, “when you find health information on the Internet, how do you use it?”) followed by semistructured questions for each item (eg, “let me know if the item is clear; if it is not clear, tell me why”), and ended with an open question, “would you suggest any other items?”. All interviews were recorded and summarized for analysis. For each questionnaire item, the interviewees’ responses were interpreted (VG) as a confirmation (item is clear), or a revision (change wording, move to a different question, merge with another item), an addition (new item), or an exclusion. Additional comments related to each item were also recorded and interpreted. All interpretations were reviewed with the first author (PP), thus creating the second version of the IAM4all questionnaire.

Step III: Expert Panel (IAM4all Version 3)

In line with the usual definition of content validity for psychometric assessments [47], we asked an expert panel to assess the item relevance, clarity, representativeness, and specificity. In psychometric terms, our constructs and facets were the four levels of outcomes of information and IAM4all items, respectively. Using a Web-based survey, the second version of the questionnaire was reviewed by a panel of 20 experts (12 information specialists and 8 health researchers) including our partners (CFPC, CPhA, and CLQ).

All experts rated each item for relevance and clarity. To rate item relevance, experts were asked whether the item was appropriate to document the corresponding level of outcomes (eg, they were asked if the item “I used (will use) this information to do it differently” was appropriate to document the use of information). Four response options were available ranging from “I strongly agree” to “I strongly disagree”. To rate clarity (readability), four response options were offered ranging from “I strongly agree (accept this item without revision)” to “I strongly disagree (reject this item because of a major clarity issue)”.

In addition, all experts rated the representativeness and specificity of items for each level of outcomes in the ACA-LO model. To rate representativeness, participants were asked whether the items were representative of all aspects of the corresponding level of outcomes (eg, participants were asked if the six proposed items covered all aspects [or dimensions] of the level health benefits). To rate specificity, participants were asked whether the items for each level of outcomes were specific (ie, no item is redundant with another).

For all questions, response options ranged from “I strongly agree” to “I strongly disagree”. Participants were asked to justify their “disagree” and “strongly disagree” responses in a comment box. All experts answered all questions, and we calculated the proportion of expert agreement by combining the number of responses “I strongly agree” and “I agree” (n=20). We considered 66% or more as an acceptable proportion of expert agreement (at least 14 experts agreed). In addition, experts provided suggestions for addition, revision, or exclusion of items. The analysis of experts’ ratings and suggestions led us to confirm, revise, add, and remove items. In line with ecological validity, which is defined as the usability and adaptation of a tool from the users’ viewpoint [48,53], expert suggestions were not retained when they were contradicted by interviews with laypersons. This survey of a panel of experts led us to build the third version of the IAM4all questionnaire.

Results

Overview

For each level of outcomes, results are summarized in Tables 1-4. Each table reports all steps of the content validation procedure. All interviewees reported frequently searching for health information on the Internet (16 of 16). The majority of interviewees were women (11 of 16). In terms of health literacy, all 16 interviewees had an Adequate Functional Health Literacy level [51] (ie, can read and interpret most health texts).

Table 1. Content validation of IAM4all items: level 1 - situational relevance.

Post interview items	Prepanel item development					Expert panel (N=20)			
	Theoretical model	Critical review	Previous work on the IAM	Consultation with 8 researchers	Interviews with 16 laypersons	Item relevance	Clarity	Representativeness	Specificity
Situational relevance	x	x	x	x	x			85%	50%
1. To answer a question about my health		x	x	x	x	100%	100%		
2. To address a question about the health of a relative or a friend		x	x	x	x	95%	90%		
3. To educate myself about health		x	x	x	x	90%	95%		
4. To satisfy my curiosity about health		x	x	x	x	80%	90%		
5. To follow-up on the information given by a health professional		x	x	x	x	100%	95%		
6. To prepare myself before talking to a health professional			x	x	x	100%	100%		
7. To make a decision about seeing a health professional					x	100%	95%		
8. To find options different from those given by a health professional					x	95%	95%		

Table 2. Content validation of IAM4all items: level 2 - cognitive impact.

Post interview items	Prepanel item development					Expert panel (N=20)			
	Theoretical model	Critical review	Previous work on the IAM	Consultation with 8 researchers	Interviews with 16 laypersons	Item relevance	Clarity	Representativeness	Specificity
Cognitive impact	x	x	x	x	x			75%	55%
9. I learned something new		x	x	x	x	100%	100%		
10. This information confirmed I did (am doing) the right thing		x	x	x	x	100%	85%		
11. I was reassured		x	x	x	x	80%	80%		
12. I was reminded of something I already knew			x	x	x	100%	95%		
13. I am motivated to learn more					x	95%	90%		
14. I understood this information		x	x	x	x	90%	95%		
15. I was dissatisfied			x	x	x	85%	75%		
16. There is a problem with this information			x	x	x	85%	85%		
17. This information could be harmful			x		x	65%	65%		

Table 3. Content validation of IAM4all items: level 3 - information use.

Postinterview items	Prepanel item development					Expert panel (N=20)			
	Theoretical model	Critical review	Previous work on the IAM	Consultation with 8 researchers	Interviews with 16 laypersons	Item relevance	Clarity	Representativeness	Specificity
Information use	x	x	x	x	x			55%	85%
18. I was doing or going to do something concerning my health, and I used (will use) this information to do it differently		x	x	x	x	95%	80%		
19. I did not know what to do, and this information (did) will help to justify a decision concerning my health			x	x	x	90%	80%		
20. I thought I knew what to do, and I used (will use) this information to be more certain about the management of my health (or health care)			x	x	x	85%	75%		
21. This information (did) will help to better understand a particular issue related to my health			x	x	x	90%	75%		
22. I used (will use) this information in a discussion with a health professional		x	x	x	x	100%	95%		

Table 4. Content validation of IAM4all items: Level 4 - expected benefits.

Postinterview items	Prepanel item development					Expert panel (N=20)			
	Theoretical model	Critical review	Previous work on the IAM	Consultation with 8 researchers	Interviews with 16 laypersons	Item relevance	Clarity	Representativeness	Specificity
Expected benefits	x	x	x	x	x			60%	60%
23. This information decreased my worries about a health problem		x	x	x	x	90%	85%		
24. This information increased my satisfaction with the care I receive		x	x	x	x	90%	90%		
25. This information allowed (will allow) me to receive additional information from a health professional		x	x	x	x	75%	70%		
26. Because of this information, I am (will be) more involved in decisions around my health		x	x	x	x	100%	90%		
27. This information helped (will help) me to better handle a problem with my health		x	x	x	x	100%	90%		
28. This information helped (will help) me to prevent a disease or the worsening of a disease		x	x	x	x	85%	80%		
29. This information helped (will help) to improve my health		x	x	x	x	100%	85%		

Step I: IAM4all Version 1

The ACA-LO model provided the four interdependent levels of outcomes of information targeted by the IAM4all questionnaire. Findings of our critical review suggested 25 items to operationalize these levels. There were (1) seven types of consumer objectives for the situational relevance of information, (2) five types of cognitive/affective impact of information on consumers, (3) five types of consumer use of information, and (4) eight types of health benefits for consumers. The consultation with 8 researchers yielded the first version of the questionnaire that included 26 items.

Step II: IAM4all Version 2

The analysis of interviews with 16 laypersons resulted in 18 items being confirmed, six revised, three excluded, and five added. All six revisions involved rewording of the questionnaire items. Interviewees suggested excluding the reason for searching item "to share information about health with members of a support group" and the information use item "I used (will use) this information to persuade a health professional to make a change in the management of my health" as they were not representative of the consumer experience. Interviewees brought to our attention two new reasons for searching: "To make a decision about seeing a health professional", and "to find options different from those given by a health professional". The three other added items reflected the interviewees experience with finding information that motivated them to learn more, using the found information to be more certain about the management of their health (or health care), and information being harmful. Six of 16 interviewees (37.5%) mentioned that retrieved information often increased their anxiety about health issues, and 2 (12.5%) said that information could be harmful:

> *I tend to over-worry, I tend not to look up for too much information and prefer to talk to the doctor about it. The more information I have the more I will worry.* [P02]

Another interviewee shared this feeling by saying:

> *Seldom, information on the Internet decreases your worries, it adds to the anxiety.* [P03]

To address this aspect using information, the item “this information made me more worried” was excluded as a cognition item and transformed as a new health benefit question: “Did something negative come out from using this information?” This analysis resulted in the second version of the questionnaire, which included 29 response items.

Step III: IAM4all Version 3

The analysis of experts’ ratings and suggestions resulted in nine items being confirmed, 19 revised (reworded), zero added, and one removed. Regarding the relevance and clarity of each item, expert agreement was satisfactory for 28 of 29 items (96.6%). Agreement was not satisfactory for the item “the information could be harmful”. Seven experts found this item problematic (eg, 2 suggested that the user would not be able to determine if the information is harmful). However, interviewees did not perceive this item to be problematic. In fact, 2 reported that this item is important. Thus, in line with ecological validity, the users’ viewpoint was prioritized, and the item was kept. Using experts’ comments, the wording was nevertheless improved to read “I think this information could be harmful”.

Representativeness and specificity of items per level of outcomes were discussed. For each level, expert comments were addressed as follows. Level 1: the item “to educate myself” was seen as redundant with the item “to satisfy my curiosity”, because 9 experts considered curiosity as the motivation that encompasses the will to educate oneself. As a result, the item “to educate myself” was excluded. Level 2: The item “I understood this information” was transformed into a response to a new screening question, “did you find the information you were looking for?”: “Yes but I did not understand it”. Level 3: The only changes consisted of rewording three items. Level 4: Five experts were concerned about the lack of negative types of outcomes. To address this issue, the question “did something negative come out from using this information?” was added with Yes/No response options and a comment box for those who answered yes.

Finally, the wording of 19 items and their readability for users with a low level of literacy have been improved, and inconsistencies in using a passive or active voice have been solved. For example, the item “to address a question about the health of a relative or a friend” was changed to “to answer a question about the health of someone else (eg, a family member)”. As another example, the concept of “health professional” has been explained using a parenthesis with examples (a nurse, a doctor, a pharmacist, or other clinician).

Discussion

Principal Findings

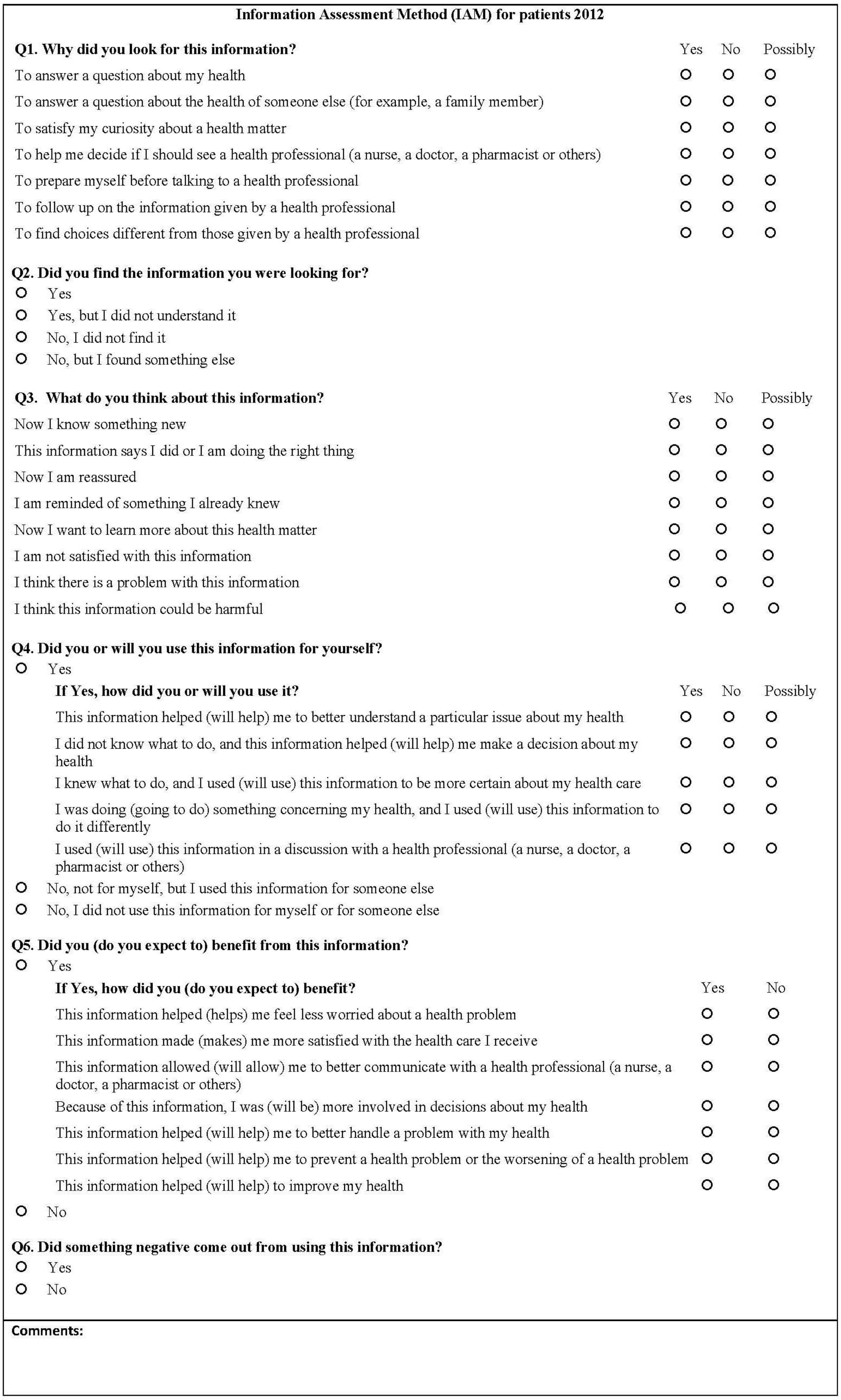
We developed and content-validated a questionnaire that can be used to assess four levels of outcomes associated with seeking and receiving Web-based consumer health information. For information seeking situations (pull: active acquisition of information), the current version of the IAM4all questionnaire is presented in Figure 1. The verb tense of questions and items must be adapted to the moment of the evaluation. For example, the future tense in the fourth question (will you use this information?) is appropriate for quasimomentary assessment (intention to use), while the past tense (did you use this information?) is appropriate for follow-up evaluation (self-reported use). In addition, we adapted this questionnaire for situations where information is received (push: passive acquisition of information) such as email alerts (push questionnaire available on request). To our knowledge, this validation study is the first to propose such practical method to evaluate how Web-based consumer health information objects are valuable from a consumer perspective, whatever the type of access to information (professionally-mediated, direct, peer-mediated), for pull and push situations, and for quasimomentary and follow-up evaluations.

The proposed questionnaire flow is as follows: (1) the title of the information object under scrutiny is displayed (eg, Web page title), (2) the last four questions are disabled when the answer to question #2 is “yes but I did not understand it” or “no” (did you find the information you were looking for?), and (3) the last two questions are disabled when the answer to question #4 is “no” (did you or will you use this information for yourself?). Negative answers to question #2 refer to information that is not relevant in the situation at hand. In accordance to our model, there is no level 1 outcome, which precludes levels 2, 3, and 4 outcomes (cognitive impact, information use, and health benefits). Negative answers to question #4 refer to information that is relevant, but not used. In accordance to our model, there is no level 3 outcome, which precludes level 4 outcome (health benefits).

Based on our literature review and the interviews with laypersons the following subitems can be displayed when there are negative answers to question #2 (information not relevant): the information was difficult to find; the search engine was difficult to use; there was too much information to look over; I did not have enough time; my Internet connection was slow; there was no information in a language I am comfortable in; it was hard to tell what information to trust. In addition, question #6 allows consumers to share their concerns with information use (can something negative come out from using this information?) since the question #5 may be seen as too positive (expected health benefits).

We claim that any organization wishing to evaluate and improve their Web-based consumer health information from a consumer’s perspective can use this method. By way of illustration, we are planning a project in partnership with Défibami (an association for patients living with cardioverter-defibrillators). The association emails a monthly newsletter to their members, and is interested to know how this information is valuable for their users. Members will be asked to read the main article of the newsletter, and rate it using the push IAM4all questionnaire (version named IAM4patient, available on request) as a contribution to the improvement of the information provided by their association.

Figure 1. Information Assessment Method for all (IAM4all).



Information Assessment Method (IAM) for patients 2012

Q1. Why did you look for this information?	Yes	No	Possibly
To answer a question about my health	○	○	○
To answer a question about the health of someone else (for example, a family member)	○	○	○
To satisfy my curiosity about a health matter	○	○	○
To help me decide if I should see a health professional (a nurse, a doctor, a pharmacist or others)	○	○	○
To prepare myself before talking to a health professional	○	○	○
To follow up on the information given by a health professional	○	○	○
To find choices different from those given by a health professional	○	○	○

Q2. Did you find the information you were looking for?
○ Yes
○ Yes, but I did not understand it
○ No, I did not find it
○ No, but I found something else

Q3. What do you think about this information?	Yes	No	Possibly
Now I know something new	○	○	○
This information says I did or I am doing the right thing	○	○	○
Now I am reassured	○	○	○
I am reminded of something I already knew	○	○	○
Now I want to learn more about this health matter	○	○	○
I am not satisfied with this information	○	○	○
I think there is a problem with this information	○	○	○
I think this information could be harmful	○	○	○

Q4. Did you or will you use this information for yourself?
○ Yes

If Yes, how did you or will you use it?	Yes	No	Possibly
This information helped (will help) me to better understand a particular issue about my health	○	○	○
I did not know what to do, and this information helped (will help) me make a decision about my health	○	○	○
I knew what to do, and I used (will use) this information to be more certain about my health care	○	○	○
I was doing (going to do) something concerning my health, and I used (will use) this information to do it differently	○	○	○
I used (will use) this information in a discussion with a health professional (a nurse, a doctor, a pharmacist or others)	○	○	○

○ No, not for myself, but I used this information for someone else
○ No, I did not use this information for myself or for someone else

Q5. Did you (do you expect to) benefit from this information?
○ Yes

If Yes, how did you (do you expect to) benefit?	Yes	No
This information helped (helps) me feel less worried about a health problem	○	○
This information made (makes) me more satisfied with the health care I receive	○	○
This information allowed (will allow) me to better communicate with a health professional (a nurse, a doctor, a pharmacist or others)	○	○
Because of this information, I was (will be) more involved in decisions about my health	○	○
This information helped (will help) me to better handle a problem with my health	○	○
This information helped (will help) me to prevent a health problem or the worsening of a health problem	○	○
This information helped (will help) to improve my health	○	○

○ No

Q6. Did something negative come out from using this information?
○ Yes
○ No

Comments:

Another example is a two-way knowledge translation project that we are planning with the Chagnon foundation that produces “Naître et grandir” (N&G). The objective of N&G are to inform parents and increase social awareness of the importance of early childhood development in order to create conditions and environments that are conducive to educational success. N&G comes in a variety of formats, including a website, a magazine, and a communication initiative. N&G also circulates content and maintains contact with parents through a free, personalized weekly newsletter and social networks like Facebook and

Twitter. Specifically, about 100,000 families receive the weekly newsletter that gives access to a highlighted Web page from where the public can browse other pages, thus creating a push-pull system and opportunities for serendipitous information retrieval. For part of this collaboration, a button will be available on each page offering access to the IAM4all questionnaire (version named IAM4parents, available on request). The reader's trajectory will be tracked. Users accessing Web pages from the newsletter will be offered a push-pull version of the IAM4all questionnaire, for which the first question was revised ("why did you look for this information?" was replaced by "why did you read this information?"). Users accessing Web pages from searching the Internet will be offered the pull version of the IAM4all questionnaire.

This project has already contributed to the development of the IAM4all questionnaire in three ways: the production of a push-pull version, a cross-cultural adaptation in French, and an adaptation for a broader topic (the well-being of children and their parents). The word "health" was replaced by "child" for all questions and items, and the sentence "improve my health" was replaced by "improve the well-being or health of my child" (fifth question). Based on the N&G experience with a Web-based survey, no difficulties are expected with regard to the number of responses due to the sense of community among information users (13,000 responses were obtained from an N&G survey in the past). In sum, the IAM4all questionnaire is expected to: stimulate N&G users' reflection, thus increase information use (mere measurement effect) [19], and continuously collect constructive feedback from the N&G users, which can be used by N&G providers to improve their information services.

The IAM4all is theory-driven, and unique in terms of comprehensiveness and content validity of items. However, it constitutes only a proposal, which needs to be further validated using statistical analysis of data collected from a larger sample (construct validity). Our content validation study faces one main limitation. The participants constituted a convenience sample of Web-based health information consumers, and were not representative of the general public in terms of demographic, educational, and sociocultural characteristics (eg, they had an adequate functional health literacy level). The implementation of the IAM4all with Défibami and N&G will allow us to conduct focus groups with diverse health information consumers for further content ecological validation study [54], and collect hundreds of completed IAM4all questionnaires for further construct validation study using classical test theory and/or item response theory.

By active involvement throughout the development of this innovative information assessment method, our partners ensured that it took their needs into account, which may improve its use. This method can respond to the needs of information providers because it can document the consumer information interaction, and enable a two-way knowledge translation between information providers and information end-users. The former updates and delivers the best available information. The latter assesses this information, and can submit constructive feedback. In turn, providers may use this feedback to improve their services, which is beneficial for all parties. Such two-way knowledge translation process constitutes a participatory production of knowledge with lay people (eg, N&G with IAM4all).

Conclusions

To our knowledge, the IAM4all is a unique and original method to assess how Web-based consumer health information is valuable from the consumers' viewpoint, specifically the use of information and its expected health benefits. The integration of the IAM4all within electronic knowledge resources can help information providers to evaluate and improve their Web-based consumer health information services. The IAM4all can stimulate reflection and feedback about health information; this feedback can then be used to improve information services.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The Information Assessment Method - published papers.

[PDF File (Adobe PDF File), 286KB - resprot_v3i1e7_app1.pdf]

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Abbreviations

ACA-LO model: Acquisition Cognition Application - Level of Outcomes model
CFPC: College of Family Physicians of Canada
CLQ: Centre for Literacy Québec
CPhA: Canadian Pharmacists Association
IAM: Information Assessment Method
IAM4all: Information Assessment Method for all
ITPCRG: Information Technology Primary Care Research Group
N&G: Naître et grandir
S-TOFHLA: Short Test of Functional Health Literacy in Adults

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Corrigenda and Addenda

Metadata Correction: Internet Protocol Television for Personalized Home-Based Health Information: Design-Based Research on a Diabetes Education System

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The author Mabel Kwong was inadvertently omitted from the list of authors during the production stage of the paper "Internet Protocol Television for Personalized Home-Based Health Information: Design-Based Research on a Diabetes Education System" (JMIR Res Protoc 2014;3(1):e13). The author Mabel Kwong (Institute for a Broadband Enabled Society, University of Melbourne, Parkville, Australia) should have been added after Ken Clarke in the original published manuscript. This error has been corrected in the online version of the paper on the JMIR Research Protocols website on March 18, 2014, together with publishing this correction notice. This was done before submission to Pubmed Central and other full-text repositories.

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Original Paper

Technology-Assisted Patient Access to Clinical Information: An Evaluation Framework for Blue Button

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Abstract

Background: Patient access to clinical information represents a means to improve the transparency and delivery of health care as well as interactions between patients and health care providers. We examine the movement toward augmenting patient access to clinical information using technology. Our analysis focuses on "Blue Button," a tool that many health care organizations are implementing as part of their Web-based patient portals.

Objective: We present a framework for evaluating the effects that technology-assisted access to clinical information may have on stakeholder experiences, processes of care, and health outcomes.

Methods: A case study of the United States Department of Veterans Affairs' (VA) efforts to make increasing amounts of clinical information available to patients through Blue Button. Drawing on established collaborative relationships with researchers, clinicians, and operational partners who are engaged in the VA's ongoing implementation and evaluation efforts related to Blue Button, we assessed existing evidence and organizational practices through key informant interviews, review of documents and other available materials, and an environmental scan of published literature and the websites of other health care organizations.

Results: Technology-assisted access to clinical information represents a significant advance for VA patients and marks a significant change for the VA as an organization. Evaluations of Blue Button should (1) consider both processes of care and outcomes, (2) clearly define constructs of focus, (3) examine influencing factors related to the patient population and clinical context, and (4) identify potential unintended consequences.

Conclusions: The proposed framework can serve as a roadmap to guide subsequent research and evaluation of technology-assisted patient access to clinical information. To that end, we offer a series of related recommendations.

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KEYWORDS

personal health record; United States Department of Veterans Affairs; patient access to records

Introduction

The Blue Button

Patient engagement is associated with desirable outcomes, including increased satisfaction with care, improved well-being, and better medical adherence [1-4]. Critical to engagement is the ability for patients to access and manage their personal health information [4,5]. Information has long been understood as an essential resource for managing health problems [6], and interacting with health-related information is an integral component of that work [7,8]. “Personal health information management” refers to the activities that support individuals’ access, organization, and use of information pertaining to their own health [9,10]. “Clinical information”, a core subset of personal health information most often stored in health records, is patient-related information that can be used to support decisions and facilitate tasks related to a patient’s care. Typically, this includes, but is not limited to, doctor’s notes, patient health history and status, medication lists, lab results, and data regarding usage of services.

Historical policies, workflows, and technologies have often limited patient access to clinical information. Traditionally, file cabinets, and later, electronic health records (EHRs), were the domains of clinical information, secure vaults that were inaccessible to patients except upon written request, and typically after a delay and the payment of requisite fees. Today, however, many public and private health care organizations are exploring ways to facilitate patient access to and exchange of personal health information, including clinical information. Policies are changing, and legislation has been signed into law to support increased patient access to clinical information [11-13]. EHR-connected (ie, tethered) patient portals and personal health records (PHRs) [14,15] are now being positioned as a means to achieve the patient-centric objectives of Meaningful Use, including direct patient access to clinical information [16,17].

In this paper, we examine the movement toward augmenting patient access to clinical information-using technology. Our analysis focuses on “Blue Button,” a tool that many health care organizations are implementing as part of their Web-based patient portals. The Blue Button concept originated at a January 2010 meeting of the Markle Foundation Consumer Empowerment Workgroup [18], in which representatives from government and private industry envisioned that adding a “big blue button” to patient portals would enable patients to have more direct access to view and download their clinical information. The United States Department of Veterans Affairs (VA) partnered with the Department of Defense and Centers for Medicare & Medicaid Services, mobilizing to release the first Blue Button on each agency’s beneficiary portal within the next 8 months. Since that time, Blue Button has evolved from a basic idea to a national movement to put health information into the hands of consumers in a way that they can use it. The Office of the National Coordinator for Health Information Technology, part of the Department of Health and Human Services, has embraced the concept and set multiple supporting initiatives in motion, including the Blue Button Pledge to inspire industry commitment, various challenges and contests to optimize information presentation through Blue Button, and efforts to improve consumer awareness and to articulate a vision for Blue Button expansion. Over 450 organizations have now taken the Blue Button Pledge and committed themselves to advancing patient access to and use of personal health information as a way to improve health and the delivery of care [19,20]. Support for Blue Button was further underscored in a Markle Foundation survey that found that 70% of patients and 65% of doctors agree that patients should be able to download and keep copies of their own clinical information [21]. Providing patients the ability to view, download, and transmit their health information is also an objective of Stage II Meaningful Use [22].

Using the VA as a case study, we characterize the experiences that one organization has had as it mobilized to make increasing amounts of clinical information available to its patients. Building from this foundation, we present a framework to evaluate the effects that access to clinical information may have on stakeholder experiences, processes of care, and outcomes. We conclude with a series of recommendations to guide future research in this rapidly evolving area.

Making Clinical Information Accessible

Facilitating patient access to clinical information has been discussed as a means to improve the transparency and delivery of care as well as interactions between patients and health care providers [5,23]. Although earlier research showed that patients were not only eager to access clinical information, but also quite capable of understanding the information that they obtained [24], persistent concerns have remained among physicians that such access could result in patient harm [25,26]. These concerns center on both the medical jargon often present in clinical information and the inclusion of diagnoses and other content that might be viewed unfavorably by patients [24].

The movement toward making clinical information more accessible to patients has been framed as part of broader efforts to promote effective health information exchange across organizations [27]. It is also frequently discussed in the context of eHealth, a subdomain of consumer health informatics that involves the use of information technology to deliver health information and services to patients and family members [28-30]. Improved access to and sharing of clinical information is anticipated to enhance patient-provider communication, provider-provider communication in disparate settings, patient self-management practices, and to facilitate appropriate usage of services [31,32]. Patients value having increased access to their information and see it as a way to better understand and become more involved in their health [33-36].

Open Notes

Most recently, the “Open Notes” Project provided a new assessment of outcomes associated with patient access to clinical information. Studying primary care practices at three medical facilities (Beth Israel Deaconess Medical Center in Massachusetts, Geisinger Health System in Pennsylvania, and Harborview Medical Center in Washington), DelBanco and colleagues [37] found that providing Web-based access to the notes that physicians wrote following a patient visit was perceived positively by the majority of the patients in the study: 77% to 87% across the three sites reported that access to their doctor’s notes helped them to feel more in control of their care. Despite physician’s initial concerns about patient access to notes causing unnecessary worry [32], 99% of the participating physicians wanted access to continue at the end of the study. Furthermore, few of the participating physicians reported that the practice of Open Notes negatively impacted their workload, and none elected to stop providing access to their notes at the conclusion of the study [37]. At one of the three study sites (Harborview Medical Center) a higher proportion of patients (14%) described their notes as confusing [32]. As we explore below, this finding raises important questions about patient population characteristics and the clinical context in which increased access to clinical information transpires.

Methods

Case Study: Blue Button in VA

Drawing on established collaborative relationships with researchers, clinicians, and operational partners, we examined the efforts underway in the VA to make increasing amounts of clinical information available to patients through Blue Button. We assessed existing evidence and organizational practices through key informant interviews with VA researchers and representatives from relevant VA program offices, reviewed historical documents, usage reports, data documentation, and other materials describing Blue Button, and conducted an environmental scan of the published literature and websites of other health care organizations to contextualize our findings.

Veterans using the VA PHR patient portal, My Healthe*Vet*, have consistently provided feedback that they value increased access to their medical records [38]. In response, VA Blue Button was added to My Health***e***Vet in August 2010, enabling Veterans to view, print, or download a single electronic file with all of their available personal health information. Registered portal users can include self-entered information in their Blue Button files, while VA patients who also complete an identity-proofing process can include both self-entered information and clinical information extracted from the VA EHR. Table 1 presents a comprehensive list of the types of information available to identified-proofed VA patients through VA Blue Button.

Veterans using VA Blue Button can choose to view and print their information from a Web browser window, or download their information in portable document format (PDF), as a plain text file, or as a Blue Button text file intended to support use with other electronic applications. Veterans can tailor the Blue Button file by selecting specific date ranges and/or specifying the types of information that they wish to include. Figure 1 shows the VA Blue Button download results screen within the My Health***e***Vet PHR portal; the inset shows the format of a Blue Button file.

Expansions of the clinical information available through VA Blue Button have been released incrementally. Some information is accessible after a brief delay to allow time for health care providers to communicate directly with patients, for example to discuss abnormal test results. In January 2013, the VA joined the OpenNotes Initiative, sponsored by the Robert Wood Johnson foundation [37], and now offers patients open access to their clinical progress notes authored from January 1, 2013 forward. The VA also introduced patient access to a Continuity of Care Document through Blue Button; a standards-based health summary available in extensible markup language (XML) and PDF file formats. All of these efforts build on the success of the My Health***e***Vet Pilot Program [35], align with specifications for Meaningful Use, and reflect the VA’s commitment to patient-centered care.

Table 1. Personal health information, including clinical information available through VA Blue Button.

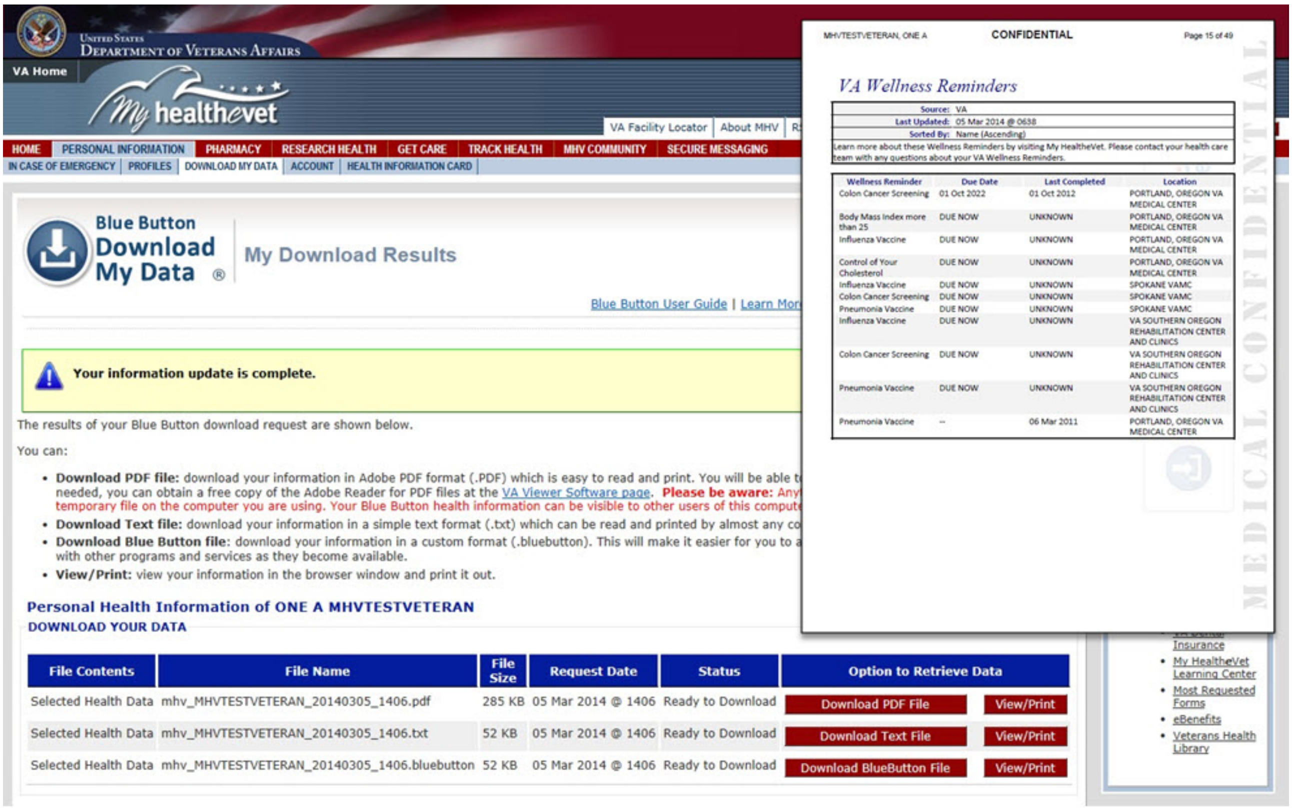
Type of information	Description	When available	Date range
Patient self-reported information			
Activity journal	Daily exercise and activity log	Immediately	User selected
Allergies	History of allergies including severity, reaction, diagnosis, and comments	Immediately	All
Demographics	Personal information entered during account registration or profile updates, emergency contacts	Immediately	All
Family health history	Family member’s health history and events that may affect health	Immediately	All
Food journal	Daily food intake to monitor diet or control weight	Immediately	User selected
Health care providers	Information pertaining to caregivers and health care providers	Immediately	All
Health insurance	Information about health insurance coverage and policies	Immediately	All
Immunizations	Immunization date, method used, and any reactions	Immediately	All
Labs and tests	Information about lab tests performed and test results	Immediately	User selected
Medical events	History of illnesses, accidents, or other events	Immediately	All
Medications and supplements	Medications, over-the-counter drugs, herbals, and supplements	Immediately	All
Military health history	Military health history, potential exposures, and treatments	Immediately	All
My goals (current goals and completed goals)	Set individualized, personally relevant recovery goals and track progress toward achieving these goals	Immediately	Current goals: all completed goals: user selected
Treatment facilities	Medical treatment facilities and locations	Immediately	All
Vitals and readings	Common health measures (eg, blood pressure, blood sugar, pain, etc.)	Immediately	User selected
VA EHR [a] information			
VA allergies[b]	Recorded allergies and adverse reactions	Immediately	All
VA admissions and discharges[b]	Admissions and discharges including comprehensive discharge summaries	Discharge Summary only: 3 days after completed	User selected
VA appointments[b]	Two years past and all future VA appointment details	Immediately	All
VA demographics[b]	Demographic information from VA treating facilities in the last 3 years	Immediately	All
VA electrocardiogram (EKG) reports[b]	A list of EKG studies performed at VA treating facilities	Immediately	User selected
VA immunizations[b]	History of recorded immunizations along with any reactions	Immediately	All
VA laboratory results[b]	Results of chemistry, hematology, and microbiology lab tests	3 days after results verified	User selected
VA medication history	History of VA medication refills	Immediately	User selected
VA notes[b]	All completed progress notes from January 1, 2013 forward	3 days after Note completed	User selected
VA pathology reports[b]	Surgical pathology, cytology, and electron microscopy study results	14 days after report completed	User selected
VA problem list[b]	List of active health issues and conditions	3 days after entry	All
VA radiology reports[b]	Results of radiology and other imaging studies	3 days after report verified	User selected
VA vitals and readings[b]	Blood pressure, pulse, body temperature, weight, etc.	Immediately	User selected
VA wellness reminders[b]	Patient friendly clinical reminders for preventive services	Immediately	All

Type of information	Description	When available	Date range
Department of defense information			
Military service information[b]	Historical record of military service including position and rank codes	Immediately	All

[a] Electronic health record

[b] Requires My Health*e*Vet account authentication

Figure 1. VA Blue Button download results screen and blue button file.



My Download Results

Your information update is complete.

The results of your Blue Button download request are shown below.

You can:

- **Download PDF file:** download your information in Adobe PDF format (.PDF) which is easy to read and print. You will be able t needed, you can obtain a free copy of the Adobe Reader for PDF files at the VA Viewer Software page. **Please be aware:** Any temporary file on the computer you are using. Your Blue Button health information can be visible to other users of this compute
- **Download Text file:** download your information in a simple text format (.txt) which can be read and printed by almost any co
- **Download Blue Button file:** download your information in a custom format (.bluebutton). This will make it easier for you to a with other programs and services as they become available.
- **View/Print:** view your information in the browser window and print it out.

Personal Health Information of ONE A MHVTESTVETERAN

DOWNLOAD YOUR DATA

File Contents	File Name	File Size	Request Date	Status	Option to Retrieve Data	
Selected Health Data	mhv_MHVTESTVETERAN_20140305_1406.pdf	285 KB	05 Mar 2014 @ 1406	Ready to Download	Download PDF File	View/Print
Selected Health Data	mhv_MHVTESTVETERAN_20140305_1406.txt	52 KB	05 Mar 2014 @ 1406	Ready to Download	Download Text File	View/Print
Selected Health Data	mhv_MHVTESTVETERAN_20140305_1406.bluebutton	52 KB	05 Mar 2014 @ 1406	Ready to Download	Download BlueButton File	View/Print

MHVTESTVETERAN, ONE A CONFIDENTIAL Page 15 of 49

VA Wellness Reminders

Source: VA
Last Updated: 05 Mar 2014 @ 0638
Sorted By: Name (Ascending)

Learn more about these Wellness Reminders by visiting My HealtheVet. Please contact your health care team with any questions about your VA Wellness Reminders.

Wellness Reminder	Due Date	Last Completed	Location
Colon Cancer Screening	01 Oct 2022	01 Oct 2012	PORTLAND, OREGON VA MEDICAL CENTER
Body Mass Index more than 25	DUE NOW	UNKNOWN	PORTLAND, OREGON VA MEDICAL CENTER
Influenza Vaccine	DUE NOW	UNKNOWN	PORTLAND, OREGON VA MEDICAL CENTER
Control of Your Cholesterol	DUE NOW	UNKNOWN	PORTLAND, OREGON VA MEDICAL CENTER
Influenza Vaccine	DUE NOW	UNKNOWN	SPOKANE VAMC
Colon Cancer Screening	DUE NOW	UNKNOWN	SPOKANE VAMC
Pneumonia Vaccine	DUE NOW	UNKNOWN	SPOKANE VAMC
Influenza Vaccine	DUE NOW	UNKNOWN	VA SOUTHERN OREGON REHABILITATION CENTER AND CLINICS
Colon Cancer Screening	DUE NOW	UNKNOWN	VA SOUTHERN OREGON REHABILITATION CENTER AND CLINICS
Pneumonia Vaccine	DUE NOW	UNKNOWN	VA SOUTHERN OREGON REHABILITATION CENTER AND CLINICS
Pneumonia Vaccine	--	06 Mar 2011	PORTLAND, OREGON VA MEDICAL CENTER

MEDICAL CONFIDENTIAL

VA Blue Button Usage to Date

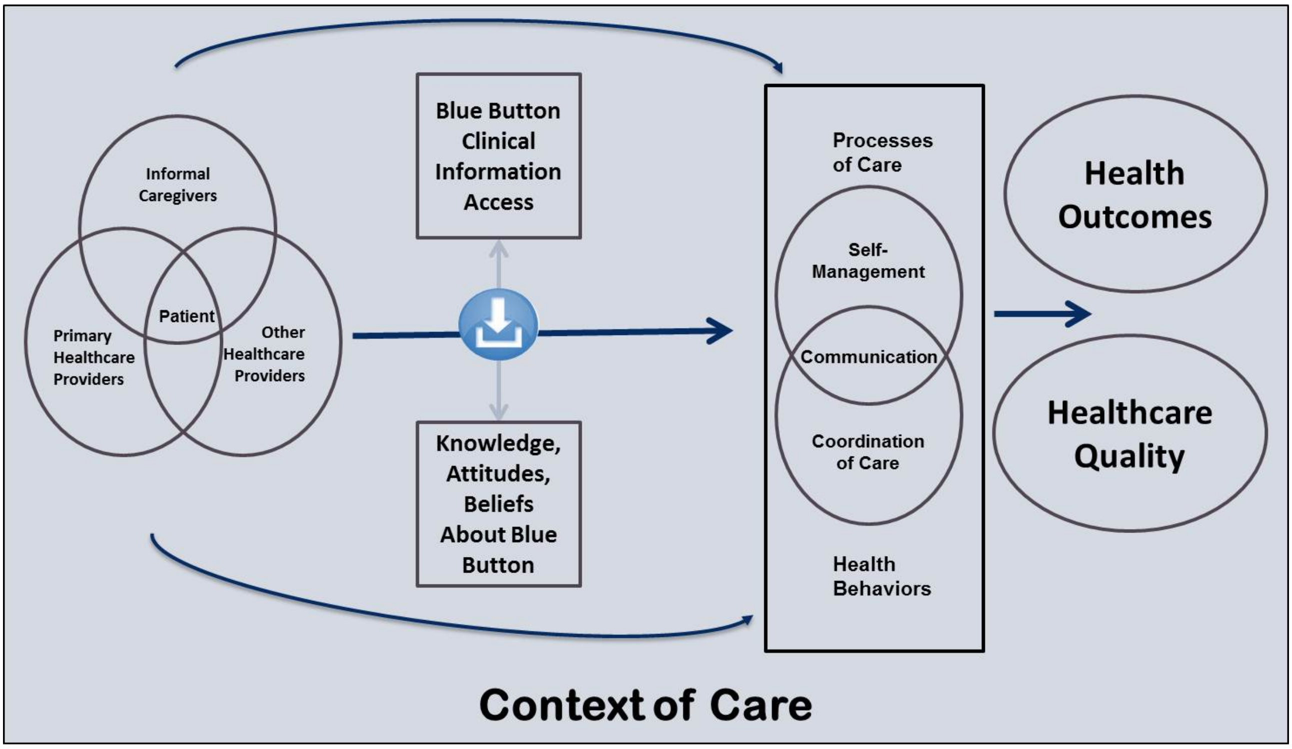
Through January, 2014, there were 2,127,462 VA patient registrants with the My Health*e*Vet PHR portal (a 37.57% penetration rate among all VA patients in fiscal year 2013), and 1,456,807 VA patients who had completed the identity proofing process for the portal (a 25.73% penetration rate among all VA patients in fiscal year 2013). Over 955,800 unique registered users had submitted download requests through VA Blue Button, downloading over 5.7 million files [39]. As we describe below, it is important to recognize that Blue Button is one of many technologies that the VA and other health care organizations are now implementing to make clinical information more available to patients, and that framing the use of Blue Button separate from those other technologies may be problematic. Further, along with these advances has been discussion about the potential of Blue Button to fuel improvements in health care quality; however, evidence to support these assertions is currently limited.

Results

An Evaluation Framework for Blue Button

Building on existing models used to inform the evaluation of quality and that emphasize structures, processes, and outcomes at different levels of analysis [40,41], we propose an evaluation framework that examines patient-accessible clinical information technologies (exemplified by Blue Button) not just in terms of a health care organization's goals, but also focusing on anticipated outcomes for patients and other key stakeholders. Figure 2 presents a framework that depicts how the use of Blue Button can influence processes of care and related behaviors, and ultimately improve outcomes. We describe the framework components below.

Figure 2. An evaluation framework for Blue Button.



Framework Component 1: Key Stakeholders

A central component of personal health information management is “exchanging” or sharing information in an effort to support health-related tasks, a practice that commonly involves a patient’s informal caregivers (eg, spouses/partners, family members, and others) and their health care providers (eg, primary care doctors, specialists, nurses, and other professionals across health care systems). Previous research has shown that personal health information is often accessed and managed with sharing in mind, and that the exchange of information is performed through multiple means, including paper-based systems and electronic tools [42].

Stakeholders encompass those who use and/or are affected by the clinical information accessed through Blue Button. The proposed framework focuses on patients and three additional stakeholder groups: informal caregivers, health care providers from a patient’s primary health care organization, and other health care providers that a patient may see. As depicted in Figure 2, the patient is at the center of a social system that involves a variety of existing relationships with the other stakeholders who may interact directly with the patient as well as with each other.

Framework Component 2: Clinical Information Accessible Through Blue Button

Patients can use Blue Button to access different kinds of clinical information either alone or in collaboration with others. They may also share that information with their informal caregivers and health care providers to support various processes of care and associated health behaviors. The knowledge, attitudes, and beliefs that all stakeholders have about Blue Button influence how, why, and if, it is used initially, as well as whether it is adopted and used more routinely.

In the case of the VA, the types of clinical information available through Blue Button were summarized in Table 1. While some evaluation efforts may focus on particular types of information, others may focus on the effects of increased access to clinical information overall.

Framework Component 3: Blue Button-Sensitive Processes of Care and Associated Health Behaviors

We propose three broad processes of care and associated health behaviors that can be influenced by Blue Button: (1) communication, (2) self-management, and (3) coordination of care. Communication refers to the strategies used to inform and influence individual and community decisions that affect health [43]. Effective communication can increase knowledge and awareness of health issues, shape perceptions, beliefs, and attitudes, reduce barriers, and prompt and sustain behaviors [44]. Clinical information accessed through Blue Button may spur communication, be exchanged through communication, and shape communication in myriad ways. Self-management, in the simplest sense, refers to a patient’s participation in health promotion and/or disease prevention efforts. In many situations, particularly in the context of long-term chronic diseases, the responsibility of managing symptoms, treatment, and other consequences of a condition falls upon the patient, and they must rely on their problem-solving and decision-making skills, their ability to find and use resources, and their relationships with others [45]. Access to and use of clinical information through Blue Button may support a variety of self-management tasks, from monitoring one’s vital signs and related readings to supporting effective management of medications. Finally, coordination of care refers to the usage of services and synchronization of activities among multiple participants in order to facilitate care delivery. Coordination may (or may not) occur among multiple stakeholders in the health care experience, including patients, health care providers, informal caregivers, and others [46]. Ultimately, coordination of care hinges on the effective sharing of clinical information across settings (eg, clinic to clinic, home to clinic) and stakeholders. Returning again to Figure 2, the two overarching arrows convey that stakeholders are confronted with these processes of care and associated health behaviors irrespective of Blue Button; access to clinical information through Blue Button has important potential to influence stakeholder engagement in those processes and behaviors.

Framework Component 4: Health Care Quality and Health Outcomes

The processes of care described above can influence both health care quality and health outcomes. The Institute of Medicine previously identified six aims for health care improvement, which have since been framed as domains of quality in patient care [5]. They include safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. Health outcomes pertain to the condition of a patient following some intervention or process, including their degree of wellness and any corresponding needs for care, treatment, or support.

Patient and Health Services Constructs

The authors of this paper engaged in a structured exercise to identify a thorough set of patient and health services constructs, based on the types of information available through VA Blue Button, which could be used in evaluation efforts. A spreadsheet was distributed that included a list of all VA Blue Button information types (spreadsheet rows) as well as the stakeholder groups of patients, health care providers, and informal caregivers (spreadsheet columns) along with these instructions: “Think of ways that patients, health care providers, and informal caregivers could use the following types of information available through VA Blue Button and in so doing, also reflect on the information required to understand the potential impact of each use.” Each author documented their ideas in their own copy of the spreadsheet, all of which were then collected, reviewed, and deduplicated. The resulting constructs are listed in Table 2 along with a mapping to associated stakeholders. By design, the constructs in the list are untied from the processes of care, associated health behaviors, and outcomes represented in Figure 2, thus providing a high degree of flexibility. Researchers and evaluators can select constructs from this list and combine them in various ways to address the focus of a particular evaluation effort (eg, self-management, communication, coordination of care). In addition, evaluations of Blue Button must use carefully selected measures appropriate for the construct(s) under investigation. Existing measures may be identified in the published literature or novel measures could be designed and validated for a given evaluation.

Framework Component 5: Context of Care

By context of care, we mean the environment or setting in which patients seek and receive health care services [47]. To the extent that access to and sharing of clinical information through Blue Button is intertwined and contemporaneous with other patient behaviors (eg, use of other PHR features or other information management strategies), other health care services (eg, treatment changes based on clinical care), and other aspects of complexity (eg, socioeconomic issues, personal life changes), teasing out the independent impact of Blue Button will require large studies of considerable power with careful assessment of covariates. Returning to the VA experience, in contrast to other types of organizational delivery models such as fee for service, the VA is structured as a capitated system enabling investments and strategies, which focus on improving the long-term health of patients. The VA also has specialized care systems to meet the needs of Veterans living with prevalent and costly conditions like polytrauma and spinal cord injury. Across these models and systems, the VA also invests in a variety of patient-facing technologies (eg, the My Health*e*Vet PHR portal, mobile applications, telehealth, and kiosks) to facilitate care delivery and address varying Veteran preferences for accessing and receiving services. All of these contextual variables have implications for the ways that Blue Button may be accessed and used. Similarly, the eight million Veterans enrolled for VA services tend to be more complex to manage compared with the general population. Veterans often have less education and lower annual income [48,49], and many have multiple chronic health conditions, a situation that is associated with higher mortality [50]. A substantial number of veterans also use multiple health care systems [51]; and because the VA is a national system, the geographic dispersion of Veterans can create challenges related to access and coordination [52]. Finally, many veterans are faced with unique health care needs that are associated with their military experiences [53-55]. Understanding how such patient population characteristics shape adoption and use of Blue Button is critical.

Table 2. Constructs relevant to processes of care and outcomes.

Constructs	Stakeholder		
	Patient	Informal caregiver	Health care provider
Adverse drug interactions	X		X
Allergic events	X		X
Appointment attendance	X		X
Appropriateness of prescriptions	X		X
Caregiver burden		X	
Caregiver capacity to support patient	X	X	
Cholesterol management	X		X
Cross-system information sharing			X
Cross-system medication reconciliation			X
Duplicate services	X		X
Duration/frequency of appointments	X		X
Extent of physical activity	X		
Glucose management	X		X
Medical record accuracy	X		X
Medical record comprehensiveness	X		X
Nutrition management	X		X
Patient activation	X		
Patient attrition	X		X
Patient–caregiver collaboration	X	X	
Patient health perceptions	X		X
Patient–provider communication	X		X
Patient self-monitoring	X		
Patient self-understanding	X		
Preventative self-care practices	X		
Provider time management			X
Provider workload management			X
Quality of care plans	X	X	X
Satisfaction with health care system	X	X	X
Satisfaction with provider–patient interaction	X		X
Service usage (emergency, telephone, urgent care)	X		X
Shared decision-making	X		X
Shared goal setting	X		X
Timeliness of medication refills	X		X
Weight management	X		X

Discussion

Principal Findings

Enhancing patient access to clinical information represents a paradigm shift for health care; yet, despite the potential implications of this transformation, there has been little discussion regarding how to systematically evaluate these changes. At present, only isolated reports suggest that patient portals can enhance patients' access to information, and, in so doing, extend their ability to communicate with providers, support their self-management efforts, and improve coordination of services [16,56-58]. We have provided a framework for the evaluation of patient-accessible clinical information through technology based on VA's experiences implementing Blue Button. We conclude with a set of seven recommendations relevant across health care organizations and related to future policies and technologies exemplified by Blue Button.

Policy and Technology Recommendations

Blue Button is Best Framed as Part of an Ensemble of Evolving Patient-Facing Technologies

Although seemingly novel at present, Blue Button fits within an expanding array of patient-facing technologies that are now being implemented across health care organizations. Beyond those that are already available, the years ahead will see the proliferation of other patient portal features, mobile applications, and other technologies; all designed to support access to, sharing, and management of clinical information. It is unlikely that patients would choose to use Blue Button to the exclusion of other available technologies; on the contrary, it is more likely that they would use Blue Button in concert with them. In the case of VA, for example, one can easily envision how increased access to clinical information through Blue Button could spur increases in the number of messages exchanged between patients and health care providers using the secure messaging feature of the My Health***e***Vet PHR portal. In this way, use of one technology enhances or “begets” use of another. From this perspective, it may not only be counterproductive to try to untangle and separate use of Blue Button from other technologies, it may also be misleading. As described elsewhere [56], adopting a more complementary vision that situates Blue Button within the milieu of other technologies may more accurately reflect the experiences of patients.

Raising Awareness and Educating Stakeholders About Blue Button is a Necessary First Step

In order to rigorously assess the influence of Blue Button on processes of care and outcomes, health care organizations must establish a critical mass of stakeholders who use it. As described earlier, analyzing the independent impact of Blue Button will likely require large, well-powered studies. For this reason, steps must be taken to ensure that patients, their informal caregivers, and their health care providers are using Blue Button to its fullest. We suggest an early investment in research to identify best practices for raising awareness about Blue Button, educating stakeholders about its potential to improve aspects of care, and determining effective strategies for promoting its adoption and sustained use. Later research could then address how best to expand reach of Blue Button to other segments of a patient population, including those with limited Internet access and/or computer skills.

Health Care Organizations Must Invest in Data Resources to Support Evaluations of Blue Button

If rigorous evaluations are to be conducted, health care organizations must gather data on use of Blue Button and make those data available for evaluation purposes. Although revisions have recently been made, the policies and terms of use for VA’s My Health***e***Vet PHR portal, for example, historically made data about VA Blue Button use unavailable for research purposes. To fully leverage the data resources that a health care organization has in efforts to understand the effects of Blue Button, appropriate access to individual-level, linkable data is necessary. This includes data regarding when patients have used Blue Button and the types of clinical information accessed, as well as data documenting activities that they have performed using other technologies.

Initial Blue Button Evaluations Should Focus on Processes of Care and Associated Health Behaviors

Although the tendency is to evaluate the impact of a novel intervention on outcomes, focusing initial evaluations of Blue Button on processes of care will further our understanding of the role of context and other intervening factors, and reduce the likelihood of producing inaccurate or misleading findings. With this foundation, evaluations can move further along the causal pathway toward outcomes of interest. To that end, we suggest that early evaluations focus on two areas: (1) changes in efficiencies of care, and (2) patient–provider communication during in-person, “brick-and-mortar” clinic visits. For example, reductions in duplicate testing represent a firm example of potential increased efficiencies gained through Blue Button use. Similarly, patients who share clinical information accessed through Blue Button with their health care providers may experience improvements in the accuracy and meaningfulness of their communication.

Evaluations of Blue Button Must Account for Unintended Consequences

Also important to acknowledge is that implementation of innovative tools like Blue Button can have unintended consequences. One can speculate, for example, how the interpretation of a prescribed medication list accessed through Blue Button could be difficult for patients and health care providers who do not have access to the various clinical notes that contextualize the medications within the patient trajectory. There may be information missing from a Blue Button report due to the information or timeframe selected by the patient, or because of technical constraints. Exchanging clinical information accessed through Blue Button could potentially result in longer visits as patients present their information and expect health care providers to review it. Moreover, some patients may perceive that they have less privacy and control in light of the ready information access and sharing that Blue Button facilitates. Early evaluations can shed light on such potential unintended consequences and suggest ways to address them through system redesign efforts or targeted interventions

Evaluations of Blue Button Must Account for the Complex and Collaborative Nature of Managing Personal Health Information

Implementation of Blue Button represents an early step by health care organizations to support patient access to and exchange of clinical information. A growing body of evidence indicates that the management of personal health information is, in many cases, a collaborative process that involves not only patients, but a variety of other stakeholders [59-61]. Similarly, the ability to move clinical information across organizational boundaries is likely to become an even more pressing need as the complexity of the US health care system increases and consumers seek services across fragmented settings. For these reasons, finding ways to promote effective access to and exchanging of clinical information will be of tremendous importance in the years ahead. There may be considerable value in viewing future evaluations of Blue Button through the lens of collaborative information management, framing it as a kind of social system intervention.

Subsequent Research Should Examine Ways to Support Stakeholder Use of Blue Button

As different stakeholders use Blue Button, it is likely that other changes in experience and practice will transpire. Evaluating this cascade of change will be critical. As noted earlier, some patients may find clinical information confusing, and realizing the positive benefits of Blue Button may require additional supportive technologies, translating clinical text into patient terms, providing links to tailored patient education information, and supporting shared decision-making based on the clinical information provided. Thus, in addition to the evaluations we suggest here, considerable basic health informatics research is needed.

Conclusions

We are just now realizing what was articulated in the medical literature nearly four decades ago [23], “Give the Patient His Medical Record.” Since the release of the pivotal “Crossing the Quality Chasm” report [5], policymakers, clinical administrators, and other stakeholders have envisioned how care could be improved along multiple indicators. The current emphasis on patient engagement coupled with the increase in consumer use of technology [62-64] provides the essential ingredients for ready access to clinical information to support personal health information management and by extension, processes of care and associated health behaviors. However, the evidence base to support Blue Button and related technologies is not yet established. The framework for Blue Button evaluation presented in this paper represents the VA’s early steps along a trajectory of research in this area and will serve as a roadmap to inform the VA’s subsequent evaluation efforts related to this new and important technology.

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Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health records
EKG: electrocardiogram
PDF: portable document format
PHR: personal health records
VA: United States Department of Veterans Affairs
XML: extensible markup language

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