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Capitalizing on the Teachable Moment: Osteoarthritis Physical Activity and Exercise Net for Improving Physical Activity in Early Knee Osteoarthritis

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Abstract

Background: Practice guidelines emphasize the use of exercise and weight reduction as the first line of management for knee osteoarthritis (OA). However, less than half of the people with mild OA participate in moderate intensity physical activity. Given that physical activities have been shown to reduce pain, improve quality of life, and have the potential to reduce the progression of joint damage, many people with OA are missing the benefits of this inexpensive intervention.

Objective: The objectives of this study are (1) to develop a behavioral theory-informed Internet intervention called Osteoarthritis Physical Activity & Exercise Net (OPEN) for people with previously undiagnosed knee OA, and (2) to assess the efficacy of the OPEN website for improving physical activity participation through a proof-of-concept study.

Methods: OPEN was developed based on the theory of planned behavior. Efficacy of this online intervention is being assessed by an ongoing proof-of-concept, single-blind randomized controlled trial in British Columbia, Canada. We are currently recruiting participants and plan to recruit a total of 252 sedentary people with previously undiagnosed knee OA using a set of validated criteria. Half of the participants will be randomized to use OPEN and receive an OA education pamphlet. The other half only will receive the pamphlet. Participants will complete an online questionnaire at baseline, 3 months, and 6 months about their participation in physical activities, health-related quality of life, and motivational outcomes. In addition, we will perform an aerobic fitness test in a sub-sample of participants (n=20 per study arm). In the primary analysis, we will use logistic regression to compare the proportion of participants reporting being physically active at or above the recommended level in the 2 groups, adjusting for baseline measurement, age, and sex.

Results: This study evaluates a theory-informed behavioral intervention at a time when people affected with OA tend to be more motivated to adopt an active lifestyle (ie, at the early stage of OA). Our approach, which consisted of the identification of early knee OA followed immediately by an online intervention that directly targets physical inactivity, can be easily implemented across communities.

Conclusions: Our online intervention directly targets physical inactivity at a time when the joint damage tends to be mild. If OPEN is found to be effective in changing long-term physical activity behaviors, it opens further opportunities to promote early diagnosis and to implement lifestyle interventions.

Trial Registration: Clinicaltrial.gov: NCT01608282; http://clinicaltrials.gov/ct2/show/NCT01608282 (Archived by WebCite at http://www.webcitation.org/6G7sBBayI)

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KEYWORDS

osteoarthritis physical activity; Internet; lifestyle intervention; theory of planned behavior

Introduction

Background

Arthritis is the most common cause of severe chronic pain and disability [1,2], affecting about 4.6 million Canadians (aged 15 or older) and projected to affect 7 million by 2031 [2]. It is estimated that the majority of these people are affected by osteoarthritis (OA) [3]. Being physically active has been shown to reduce pain, improve quality of life [4-6], and have the potential to slow the progression of joint damage [7]. However, the gap between the *knowledge* about OA management and the *action* of being physically active is extremely large.

Sedentary lifestyle and obesity are predictors of poor health outcomes in people with OA [8-10]. Recent guidelines by the OA Research Society International (OARSI) specifically recommend the use of aerobic, muscle strengthening, and water-based exercises, as well as weight reduction as first line management of knee OA [11], but the majority of people with OA are physically inactive. In 2002, the Arthritis Foundation developed 22 indicators to assess the quality of care in OA [12-14]. When the indicators were applied to a community-based sample in Ontario, 40.1% of people with OA who had no contraindication to exercise had tried exercise [15]. A survey of 1713 people with OA in British Columbia, Canada found that although 79% reported spending time “walking for exercise in the past week”, the majority walked less than one hour per week [16].

Several factors are associated with low participation in physical activities in people with arthritis, some of which are related to the disease (eg, higher levels of pain and fatigue [17-19]), sociodemographics (eg, lower education [20] and income [21]), the person (eg, other commitments, lack of time and motivation [17], doubts about the effectiveness of exercise [19]), and other enabling factors (eg, access to transportation [18], weather [17,18]). People who are newly diagnosed with knee OA tend to have mild pain, stiffness, and functional disability [22]. For these patients, disease-related factors may be a less important barrier to engaging in physical activities. It should be noted that factors associated with physical activity participation were often studied without an overall explanatory framework, making it challenging to develop interventions that work equally well for people with different needs.

Adapting Knowledge to the User’s Context: Theory-Informed Lifestyle Interventions

In health promotion, the Theory of Planned Behavior (TPB) has been used extensively to understand and predict health-related/lifestyle change behavior [23]. TPB posits that the adoption of a health *behavior* is driven by the person’s *intention* and *perceived behavioral control (PBC)* [24]. The latter represents the perceived skills/ability, resources, and opportunities of performing the behavior [25]. Furthermore, the strength of *intention* is determined by PBC, the *attitudes* toward the behavior (ie, affective attitude—enjoyment, pleasure evaluations about the behavior; and instrumental attitude—benefit, utility evaluations about performing the behavior) and *subjective norm* (eg, the perception of how others view the behavior and the importance of these views to the person). In a metaanalysis, Hagger et al [26] reported that intention and PBC accounted for about 30% of the variance in physical activity *behaviors*, while attitude and PBC accounted for about 40% of the variance in *intention*. A 2009 metaanalysis by Rhodes found that interventions targeting affective judgement constructs such as affective attitude (eg, enjoyment, pleasure) were effective for predicting intention and physical activity behaviors above the instrumental attitude construct [27].

Although the TPB has not yet been used in the study of physical activity in people with early OA, it has been applied in comparable populations, including older adults [28], those with painful intermittent claudication [29], and those who are obese [30], to inform the development of interventions for improving physical activity. For example, Godin observed that in people with a body mass index (BMI) ≥30, PBC, past behavior, and anticipated regret (ie, the perceived feeling of regret if the behavior is not performed) substantially improved the predictive power of intention, explaining 59% of the variance [30]. Another study examining social cognitive constructs in people awaiting joint replacement surgery for end-stage OA found that pain was a predictor of pre-operative physical activity [31]. Hence, proper monitoring and control of symptoms may be important for people with knee OA during physical activity.

There is no consensus on the timing to offer physical activity interventions, but sociopsychological research suggested that after a major life experience (eg, having a child) or a health event (eg, a new diagnosis), people tend to be more amenable to adopting healthy behaviors [32,33]. This “teachable moment” [34] is thought to be the ideal time for lifestyle interventions because people are more motivated. Systematic reviews of chronic diseases such as cancer suggest that people who are

newly diagnosed are more likely to respond to interventions aimed at smoking cessation and healthy eating [34-36]. A recent study in people with previously undiagnosed knee OA also found that about 40% started exercising within the first month after receiving a pamphlet on OA and completing a volunteer-led self-management program [37]. Although, the mechanism of this behavior change was unclear, the diagnosis of OA appeared to present a "teachable moment" for engaging people who have been sedentary to become physically active.

Why Use Internet-Based Physical Activity Interventions?

In recent years, computerized programs have gained popularity as tools for promoting healthy lifestyles because of their potential to improve the delivery and presentation of information. Evidence suggested that computerized health information programs could improve disease knowledge and clinical outcomes in people with rheumatoid arthritis, diabetes, asthma, and hypertension [38], as well as self-care behaviors and patient satisfaction in those with chronic conditions [39]. A 2008 systematic review suggested that mediated interventions such as telephone prompts, emails, and websites can increase duration of walking in healthy participants, with the added advantage of saving time for busy individuals because none of these interventions require a visit to an exercise professional [40]. They also have the benefit of reaching patients outside of urban centers who are often marginalized with respect to health care.

To capitalize on this "teachable moment", our goal was to develop a Web-based tool, Osteoarthritis Physical Activity and Exercise Net (OPEN), and evaluate its ability to improve physical activity participation in people with early knee OA. OPEN has interactive modules that allow users to prioritize their daily activities, set goals, and find venues where they can participate in different types of activities according to their preferences and the local availability. We have begun the participant recruitment phase of this study, with the following objectives and goals:

1. To develop a behavioral theory-informed Internet intervention for people with early knee OA.
2. To assess the efficacy of OPEN through a proof-of-concept randomized controlled trial (RCT). The *primary goal* of this ongoing RCT was to determine if OPEN could increase participation in physical activity in people with previously undiagnosed, early knee OA at 6 months. We hypothesized that the Internet intervention plus an information pamphlet about OA would improve participation in physical activities in persons with early OA, compared to those who would receive only the pamphlet (ie, controls). Our *secondary goals* were to assess: (1) whether the intervention has an effect on knee pain, stiffness, and physical function at 6 months, (2) whether differences between groups could be explained through a mediation model based on a behavioral theory (ie, the TPB), and (3) in a subsample of participants, the agreement between self-reported exercise behaviors and a performance-based measure of physical activity.

Guided by Graham's Knowledge-to-Action process [41], this study will directly address a key recommendation from the 2005 Summit on Standards for Arthritis Prevention and Care:

> *Every Canadian must be informed about the importance of achieving and maintaining a healthy body weight, and actively encouraged to engage in physical activity to prevent the onset and worsening of arthritis. [42]*

Methods

Overview

Our research plan was guided by the 8-phase Action Cycle of Graham's Knowledge-to-Action Process [41]. Co-developed with the Centre for Digital Media and hosted by the Arthritis Research Centre (ARC) of Canada, OPEN was designed to mainly target *perceived behavioral control* (ie, the person's skills/knowledge, resources, and opportunities to be physically active) and *affective attitude* (ie, enjoyment)[27]. The website consists of 4 main components: (1) information on OA, benefits of physical activity in OA, and the association between sedentary lifestyle and poor outcomes (to target knowledge), (2) tips about how to be physically active (to target skills and opportunities), (3) an interactive calendar for goal setting (to target resources), (4) local resources (walking trails, parks, shopping malls for indoor walking) and community fitness facilities using Google Maps (to target resources and enjoyment).

To populate OPEN with these local resources, the team (researchers, patient/consumer, and health professional collaborators) first defined the breadth of resources to be included. Next, the geographic locations of these resources were determined (through Web searches and strategic calling) for all BC communities with populations of 5000 or greater and geocoded (ie, a postal code or street address was recorded). Following this, local resources were compiled onto a Google Map that was embedded within the OPEN website. Tags were added to each resource to provide information such as operating hours and contact information.

Randomized Controlled Trial

The efficacy of OPEN is currently being assessed by a proof-of-concept, single-blinded RCT. Individuals with early OA will be identified using validated criteria developed by Marra at al [22]. Eligible participants are those who:

1. have had pain/discomfort in or around the knee during the previous year lasting over 28 separate or consecutive days,
2. are age 50 years or older,
3. have no previous physician diagnosis of OA, rheumatoid arthritis, psoriatic arthritis, gout, ankylosing spondylitis, polymyalgia rheumatica, connective tissue diseases, or fibromyalgia,
4. have no history of using disease-modifying anti-rheumatic drugs or gout medications,
5. have no prior knee arthroplasty,
6. have not had knee surgery within 4 months prior to enrolling in the study,

7. have no history of acute injury to the knee in the past 6 months,
8. have been physically inactive (defined as participation in moderate intensity activities less than 150 minutes a week) within 6 months prior to study,
9. are not using medication that may impair physical activity tolerance (eg, beta blockers), and
10. have Internet access and used their email accounts.

People who may be at risk by exercising, as identified by the Physical Activity Readiness Questionnaire (PAR-Q) [43], will be asked to obtain permission from their physicians before enrolling in the study.

Individuals will be mainly recruited from the following sources: (1) community health centers across Metro Vancouver, (2) the ARC website, newsletters, and Facebook site, (3) social networking websites (eg, Craigslist, Kijiji), (4) local television network (community event posting), and (5) local newspapers.

The research coordinator will contact eligible individuals and obtain consent via password-protected email documents. After completing the baseline measures, they will be randomly assigned to the Internet intervention group or the control group in 1:1 allocation ratio. Randomization will be performed using computer-generated random numbers in unequal blocks, which is necessary to ensure adequate allocation concealment.

The intervention group will receive an emailed password. Participants will receive an automatically generated email prompt to access the website every 2 weeks, with a short newsletter about the ongoing projects at ARC, for the first 3 months. The website will remain accessible throughout the study, but no further prompting emails will be sent after 3 months. In addition, they will receive, by email, an education pamphlet. It will contain information about OA, physical activity, and other treatments.

The control group will receive the same pamphlet by email. For the first 3 months, participants will also receive the same newsletter about the ongoing projects at ARC every 2 weeks by email. During the intervention period, both groups will be able to contact a physical therapist for a consultation via email if they experience increased discomfort after activities.

Outcome measures will be administered online at baseline, 3 months, and 6 months. The primary outcome will be the proportion of participants to meet the American College of Sports Medicine physical activity recommendation of 150 minutes or more of weekly physical activity (moderate or heavy intensity) at 6 months, as measured using the modified Minnesota Leisure Time Physical Activity Questionnaire (MLTPAQ). The MLTPAQ assesses the frequency and amount of time spent on 63 activities in 8 categories: walking, conditioning exercise, water activities, winter activities, sports, garden activities, home repair activities, fishing, and hunting. The average time spent on moderate and heavy physical activity and average weekly energy expenditure (kilocalories/week) will be calculated using the standardized intensity code associated with each activity [44]. It has shown test-retest reliability in both men and women (r=.79-.82) [45] and has been validated against caloric intake and treadmill tests [46-48].

Secondary outcomes will be measured with the Knee Injury & OA Outcome Score (KOOS) [49,50]. The KOOS consists of 5 subscales: knee pain, stiffness, daily activity, sports/recreation, and quality of life. It was originally developed for people recovering from injuries such as anterior cruciate ligament and meniscus injury, and has been validated in people with OA [49,50]. KOOS includes all items of the Western Ontario MacMaster OA Index (WOMAC) in its original format [51] and has a normalized aggregate score ranging from 0 (worst outcome) to 100 (best outcome). Motivation for physical activity will be measured with Rhodes's 7-point Likert-type TPB questionnaire [52-54]. It consists of 16 items measuring all components of the TPB model, including behavioral, normative, and control beliefs. Previous studies using this measure have shown good predictive validity and internal consistency in adult populations [52-54]. Demographic variables and comorbid conditions will also be collected at baseline. Website statistics (frequency and duration of use, intervention group only) and adverse events (falls, cardiovascular, and musculoskeletal events) [55] will be tracked monthly.

Finally, in a convenient subsample of participants (n=20 per arm), we will perform an aerobic fitness test at baseline, 3 months, and 6 months. Aerobic fitness tests (VO_{2Peak}) will be conducted by an assessor who is blinded to the group assignment. Heart rate, blood pressure, and VO_2 will be recorded at rest, during each exercise stage, and in recovery.

Sample Size and Data Analysis

Based on the Pharmacist Identification of New, Diagnostically Confirmed OA (PhIND-OA) study [22,37], 40% of residents from British Columbia in Canada (N=194, mean age=62 years) started to exercise after receiving an OA diagnosis and minimal intervention (ie, a pamphlet and the self-management program). We expect that, if OPEN is efficacious, 60% of the intervention group will meet or exceed the recommended level of physical activity at follow-up. Taking into account a 15% loss to attrition over 6 months, 80% power to detect a difference of 20% in physical activity rates between groups and alpha level of .05, a total of 252 participants (126 per group) will be needed. To validate the self-reported physical activity measure, the MLTPAQ, a subsample of 40 participants will be recruited. Assuming we observe a Pearson correlation of .5 for MLTPAQ and VO_{2Peak}, a 95% confidence interval around the estimate would range from 0.26 to 0.74.

As the aim of a proof-of-concept study is to demonstrate evidence of efficacy, a per-protocol analysis will be performed. For the primary outcome, dichotomized physical activity participation (ie, yes/no to meeting the American College of Sports Medicine recommendation) from baseline to 3 and 6 months will be analyzed in a logistic regression model after adjusting for the baseline measurement, age, and sex. Intention-to-treat analysis will assess the robustness of the findings. Analysis of covariance (ANCOVA) will analyze the difference in KOOS scores (overall and subscales) between the groups over time. No adjustment will be made for multiple comparisons because Type II error is a greater concern than Type I error in proof-of-concept studies [56,57].

We will examine the mechanisms of OPEN on physical activity participation by conducting mediation analysis using the bootstrapped sampling distribution model by Preacher and Hayes [58,59]. Changes in TPB variables over the intervention period (ie, between baseline and 3 months) will be examined as potential mediators on physical activity behavior at 3 months. In addition, changes in TPB variables over the entire study period (ie, baseline to 6 months) will be examined as potential mediators on physical activity participation at 6 months. Finally, an exploratory analysis using Pearson's correlations will examine the association between MLTPAQ (ie, energy expenditure) and the VO_{2Peak}.

Timeline

Development and usability testing of OPEN were completed in November 2012 and RCT recruitment commenced in December 2012. Final follow-up assessment is expected to conclude in January 2014. The study protocol has been approved by the University of British Columbia Clinical Research Ethics Board (certificate number: H12-00493).

Discussion

The proposed study will be one of the first to evaluate a theory-informed behavioral intervention at a time when people tend to be more motivated to adopt an active lifestyle (ie, at the "teachable moment"). Our approach, consisting of identifying people with early knee OA using a set of validated criteria [22] followed immediately by an online intervention that directly targets physical inactivity, can be easily implemented across communities. This proof-of-concept study will provide a foundation to further study and implement lifestyle interventions in managing chronic musculoskeletal conditions. If the intervention is found to be effective in changing physical activity behaviors, it will open further opportunities to promote early diagnosis and to implement lifestyle interventions. Conversely, if the intervention shows no difference in improving physical activity behavior compared to the control, this study will still offer the opportunity to examine relationships between the TPB constructs and physical activity participation.

The OPEN project also has potential to improve primary and community-based care in people with arthritis. The value of this project is summed up by our Knowledge User Co-Investigator and a primary care physician, Dr. James Pencharz:

> *I see the impact of physical inactivity on my patients daily. Even though I work within an interdisciplinary team environment specifically designed to manage chronic disease, we still struggle to consistently motivate and educate our patients about how to increase their physical activity…I see the innovative approach of OPEN as an excellent initiative to educate patients about osteoarthritis, but more importantly customize and realize their physical activity goals. Simply, we need this type of tool in our clinical practice.*

The partnership with Centre for Digital Media allows for the development of OPEN using the latest digital media technologies and provides training to digital media students in health research. Once the research is completed, OPEN will be available free of charge for public use.

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Conflicts of Interest

None declared.

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Abbreviations

ANCOVA: analysis of covariance
ARC: Arthritis Research Centre of Canada
BMI: body mass index
KOOS: Knee Injury & Osteoarthritis Outcome Score
MLTPAQ: Minnesota Leisure Time Physical Activity Questionnaire
OA: osteoarthritis
OARSI: Osteoarthritis Research Society International
OPEN: Osteoarthritis Physical Activity and Exercise Net
PAR-Q: Physical Activity Readiness Questionnaire
PBC: perceived behavioral control
PhIND Study: Pharmacist Identification of New, Diagnostically Confirmed OA Study
RCT: randomized controlled trial
TPB: Theory of Planned Behavior
VO_{2Peak}: maximum aerobic capacity
WOMAC: Western Ontario MacMaster OA Index

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Proposal

InsuOnline, a Serious Game to Teach Insulin Therapy to Primary Care Physicians: Design of the Game and a Randomized Controlled Trial for Educational Validation

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Abstract

Background: Physicians´ lack of knowledge contributes to underuse of insulin and poor glycemic control in adults with diabetes mellitus (DM). Traditional continuing medical education have limited efficacy, and new approaches are required.

Objective: We report the design of a trial to assess the educational efficacy of InsuOnline, a game for education of primary care physicians (PCPs). The goal of InsuOnline was to improve appropriate initiation and adjustment of insulin for the treatment of DM. InsuOnline was designed to be educationally adequate, self-motivating, and attractive.

Methods: A multidisciplinary team of endocrinologists, experts in medical education, and programmers, was assembled for the design and development of InsuOnline. Currently, we are conducting usability and playability tests, with PCPs and medical students playing the game on a desktop computer. Adjustments will be made based on these results. An unblinded randomized controlled trial with PCPs who work in the city of Londrina, Brazil, will be conducted to assess the educational validity of InsuOnline on the Web. In this trial, 64 PCPs will play InsuOnline, and 64 PCPs will undergo traditional instructional activities (lecture and group discussion). Knowledge on how to initiate and adjust insulin will be assessed by a Web-based multiple choice questionnaire, and attitudes regarding diabetes/insulin will be assessed by Diabetes Attitude Scale 3 at 3 time points—before, immediately after, and 6 months after the intervention. Subjects´ general impressions on the interventions will be assessed by a questionnaire. Software logs will be reviewed.

Results: To our knowledge, this is the first research with the aim of assessing the educational efficacy of a computer game for teaching PCPs about insulin therapy in DM. We describe the development criteria used for creating InsuOnline. Evaluation of the game using a randomized controlled trial design will be done in future studies.

Conclusions: We demonstrated that the design and development of a game for PCPs education on insulin is possible with a multidisciplinary team. InsuOnline can be an attractive option for large-scale continuous medical education to help improving PCPs´ knowledge on insulin therapy and potentially improving DM patients´ care.

Trial Registration: Clinicaltrials.gov: NCT01759953; http://clinicaltrials.gov/show/NCT01759953 (Archived by WebCite at http://www.webcitation.org/6Dq8Vc7a6).

(JMIR Res Protoc 2013;2(1):e5) doi:10.2196/resprot.2431

KEYWORDS

Diabetes Mellitus; Insulin; Video Games; Medical Education; Educational Technology; Continuing Medical Education

Introduction

Achieving and maintaining good glycemic control is the mainstay of treatment of diabetes mellitus (DM) [1]. Unfortunately, only 24-56% of patients with DM are within the goal of the glycated hemoglobin A1c <7%, in most countries [2,3].

Worldwide, according with public health trends, most diabetics are treated by primary care physicians (PCPs) [4], but these professionals lack knowledge and confidence on several aspects of DM management [5], specially regarding insulin use [6]. This contributes to the common problem known as clinical inertia, "the failure to advance therapy when indicated" [7], underuse of insulin [8], and poor glycemic control.

Continuing medical education (CME) on DM and insulin is often advocated as a solution to optimize the knowledge and the practice of PCPs [9]; however, traditional CME activities (such as lectures and group discussions) have small and short-lasting efficacy [10]. Thus, new educational methods are urgently required.

Digital games are currently one of the six greatest trends in higher education [11], since they are able to "create a tight marriage among content, game play, and valued ways of thinking and acting" [12]. One of the reasons for increasing interest in games for higher and professional education is the huge familiarity of most college students with the medium [13]. Most medical students, for instance, even those who do not play video games, have highly favorable views about the use of video games and new technologies in medical education [14]. However, the most compelling reason for adopting learning games, probably, is their pedagogical adequacy. Good learning games are usually built by the same rules that guide the design of effective learning activities, which include stimulus to players´ intrinsic motivation, practice and repetition, effective feedback, arousal of positive feelings, intensity of the experience, and learner choice/involvement [15]. In the medical area particularly, the use of games and simulators for learning clinical skills has the additional advantage of increasing the safety of real patients [16].

In the field of diabetes, some games for education of patients [17-19], and a few technology-based initiatives for education of health professionals [10,19-25] have been described, but to our knowledge, no game have been reported for education of health professionals on diabetes or insulin.

In this paper, we report the design and development of a serious personal computer game for teaching PCPs about initiation and adjustment of insulin in the treatment of DM, and describe the design of a randomized controlled trial to assess if the game can be educationally effective.

Methods

Game Design

A multidisciplinary team was assembled, consisting of clinical endocrinologists (LAD, RZE), experts in medical education (PAG, MLSGJ, ICMC) and software developers/game designers (JBA, RMS). The endocrinologists compiled a list of main topics on insulin initiation and adjustment for treatment of adults with DM, in the context of a primary health care setting, outlining the minimum curriculum of the game (Textbox 1).

Periodic team meetings were scheduled during the design and development phases, to review each step, correct problems, and make decisions for the following stages, in an iterative process. The group agreed that the game should be developed in a way to satisfy 2 basic conditions: (1) to be educationally adequate, and (2) to be self-motivating and attractive to the final users.

Textbox 1. The minimum curriculum describing teaching topics on insulin therapy selected for inclusion in the game.

1. Goals of glycemic control in adults with DM
2. When to start insulin in type 2 DM
3. How to start insulin in type 2 DM (bedtime scheme)
4. Recommendations on insulin use (storing, injection technique, and devices)
5. Hypoglycemia: prevention, recognition, and treatment
6. Self-monitoring of blood glucose
7. Types of insulin: when to use which (NPH, regular)
8. Oral antidiabetic drugs associated with insulin
9. How to adjust insulin dosage
10. How to intensify insulin therapy in type 2 DM (basal-plus scheme)
11. How to start insulin in recent-onset severe type 2 DM (basal-bolus scheme)
12. Type 1 DM: how to recognize it and how to start treatment
13. How to recognize and manage diabetic ketoacidosis

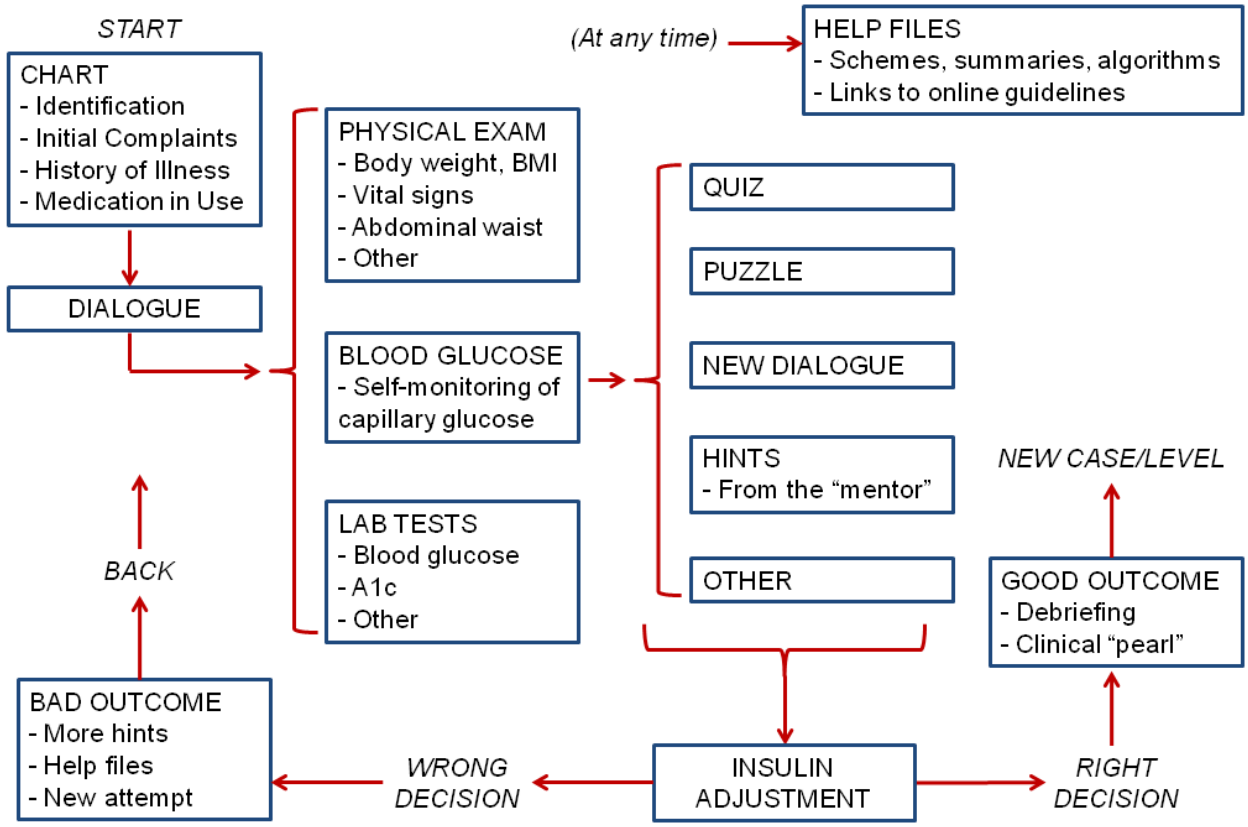
Storyline

The authors (LAD, RMS) developed the story of InsuOnline based on Joseph Campbell´s classical description of the myth cycle [26]. The story begins in a primary health care clinic, where an experienced medical doctor (the mentor) wants to go on vacation, but he cannot leave without getting a substitute physician to take care of his diabetic patients. So, he randomly chooses a younger doctor to replace him (ie, the player´s avatar). The player proceeds to see a series of diabetic patients who usually require insulin initiation or adjustment in order to obtain a better glycemic control. If the player successfully reaches the end of the game, the mentor character is finally able to go on vacation, and the player´s character is thanked by the mentor, obtains the respect of the nurse and the patients, and a brand new office. The main objective of the game is to have each player correctly initiate or adjust insulin for each patient case.

Level Design

We created 16 diabetic patients, reflecting common clinical scenarios in actual primary health care clinical practice, each one corresponding to at least one of the topics of game´s minimum curriculum. Each game level has a new patient presented to the player. The patients/levels are disposed in order of increasing complexity. The player´s avatar must make decisions on the best therapeutic option to improve each patient´s glycemic control at every level. Right decisions lead to progression to the next level, and incorrect choices lead to a new attempt at the same level. The basic structure of each level is shown in Figure 1.

Figure 1. Basic structure of an InsuOnline level.



Interactive Components and Game Elements

Several ways of interaction and game elements were included to create a pleasant experience and to maximize players´ intrinsic motivation. The player can read patients´ clinical charts, dialogue with them (be choosing among a few options of "talks"), see their lab tests and fingertip glucose readings, review their physical exam, answer quiz challenges, solve puzzles, get tips from the mentor and a nurse, and, prescribe insulin. Sound track, score, visual and sound effects, patients' mood (the patient gets angry if the player makes too many errors), and between-levels animation scenes (machinimas) were also included, to improve the gaming experience and players´ motivation.

Pedagogical Elements

Several pedagogical elements were included in the game, aiming for the best educational effects. These were based on the principles of adult learning and problem-based learning, including motivation, goal-orientation, relevancy-orientation, self-pacing, timely and appropriate feedback, reinforcement of learning, informal environment, contextualization, and practical (ie, hands-on) approach with active participation of the learner [27,28].

The game gives immediate feedback (presented by the mentor character), comparing player's decisions with recommendations from clinical guidelines [1,29-31]. Correct decisions lead to gaining points and progression in the game. At every step, the game offers additional learning resources: help files (eg, algorithms, summaries, and clinical pearls), orientation from the mentor, and links to bibliographic references.

Usability and Playability Evaluation

The next step will be the usability and playability assessments. For this, we will enroll 4 physicians who work in Londrina, Brazil (2 female and 2 male; 2 with gaming/computer previous experience and 2 without experience) and 4 undergraduate medical students from Universidade Estadual de Londrina (UEL) (2 female and 2 male, with and without gaming experience), who will play the game on a desktop computer, in a controlled environment, each participant alone in a single session. Usability data will be assessed using Web-based System Usability Scale (SUS), as previously described by Brooke [32], and playability will be assessed by Web-based Heuristic Evaluation for Playability, as described by Desurvire et al [33] The actions of the players will be recorded by the software for further analysis by the researchers (LAD, RMS). Further adjustments will be made in the game, according to responses obtained in this phase of the study.

Educational Efficacy Assessment

After final adjustments in the game, guided by usability and playability assessments, the efficacy of InsuOnline as an educational tool will be assessed in an unblinded randomized controlled trial [34]. We will send a letter of invitation to all primary care physicians (PCPs) who work in Londrina to participate in the study. If those PCPs do not fulfill our sample size, we will also invite PCPs from other cities in the state of Paraná (Brazil), such as Maringá, Curitiba, or São José dos

Pinhais. The PCPs who are willing to participate in the study will be included and randomized at study entry, using a random number generator, to 1 of 2 groups. We will exclude clinical endocrinologists or diabetologists.

Physicians enrolled in the Group A will be exposed to InsuOnline. They will be asked to play the game until its end, on the Web (with an individual login) in their own time and rhythm. Physicians enrolled in the Group B will undertake a traditional instructional session, during one afternoon, composed of a short lecture and a group discussion of clinical cases, which will be identical to the ones included in InsuOnline. This traditional instructional session will focus on the same teaching topics of the game, and it will be coordinated by a clinical endocrinologist not linked to the research team in order to avoid potential biases. This endocrinologist will be trained by the researcher endocrinologists, and he will use didactic material prepared by our team.

We will evaluate subjects´ knowledge on insulin therapy using a Web-based questionnaire, containing 10-20 multiple choice questions. The questions will be clinical vignettes of diabetic patients who require initiation and/or adjustment of insulin. For each question, the participant should choose the best option for achieving a better glycemic control, according to current guidelines [1,29-31. Questions regarding insulin therapy will be selected from the American Diabetes Association Self-Assessment Program, Module 2 (Pharmacological Treatment of Hyperglycemia) [35], translated to Portuguese, and adapted to be compatible with the game´s clinical scenarios and learning objectives. Participants´ attitudes regarding diabetes will also be assessed, by the application of Web-based Diabetes Attitudes Scale, version 3 (DAS-3) [36]. The questionnaire and the DAS-3 will be answered by the participants at 3 time points: before the intervention (pre-test), immediately after the intervention (after-test), and 6 months after the intervention (late-test). The average number of right answers will be presented and compared in the different time points within each group (intragroup) using analysis of variance (ANOVA), and between the 2 groups at each time point (intergroup) using Student´s *t* test. A bicaudal significance level of 0.05 will be adopted. Data analysis will be done by intention-to-treat, with last observation carried forward, which means that all randomized participants´ data will be included in the final analysis.

The participants will be asked a few Likert-scale and free text questions at the end of each intervention to assess their general impressions about the intervention (mostly to assess if it was pleasant or enjoyable). Software-recorded data on player´s usage of the game will be analyzed to assess the number of logins, time spent on the game, etc. For the participants in Group A that do not finish the game, the reasons for early withdrawal will be collected by an online questionnaire. We will contact (by phone or email) the participants who do not eventually fulfill the questionnaires at least twice.

In order to detect a minimum standard deviation of 0.5 on the average of right answers with 80% of statistical power at 5% of significance level, we will need to include 128 subjects in our study (64 in each group). We will enroll 160 subjects (80 in each group), in order to compensate for an expected 25% dropout rate.

Ethical Considerations

Participation will be anonymous and voluntary, and all subjects will be asked to provide written informed consent, according to Brazilian Health Ministry´s regulations (Multimedia Appendix 1). The study protocol was approved by our local Research Ethics Committee (UEL, #051/2011 and #051/2012), and registered by UEL research board (Research Project #07471).

Results

InsuOnline is currently at the final stages of development and programming of its alpha version. The research team is currently playing and testing this version of the software, in order to detect and correct occasional bugs or problems.

The adventure genre was chosen, since it allows the learner to explore and try to solve consecutive problems, a design most compatible with adult education principles [11]. The game is represented in 3D, with third-person vision, representing the behavior of the character at scene. The characters were designed to present a visual appearance that slightly resembles those in the classic game "The Sims" [37], in that they were not too serious/realistic or cartoon-like. A few screenshots of the game can be seen in the Figures 2 to 5.

The programming was done using the game engine Unity, and the 3D-Suite Blender was used for the character modeling and animation. Players´ interaction with the game is made via mouse.

Figure 2. The main characters: the young doctor (player´s avatar), the nurse, and the older doctor (mentor).

Figure 3. InsuOnline main menu.

Figure 4. Panel for insulin prescription.

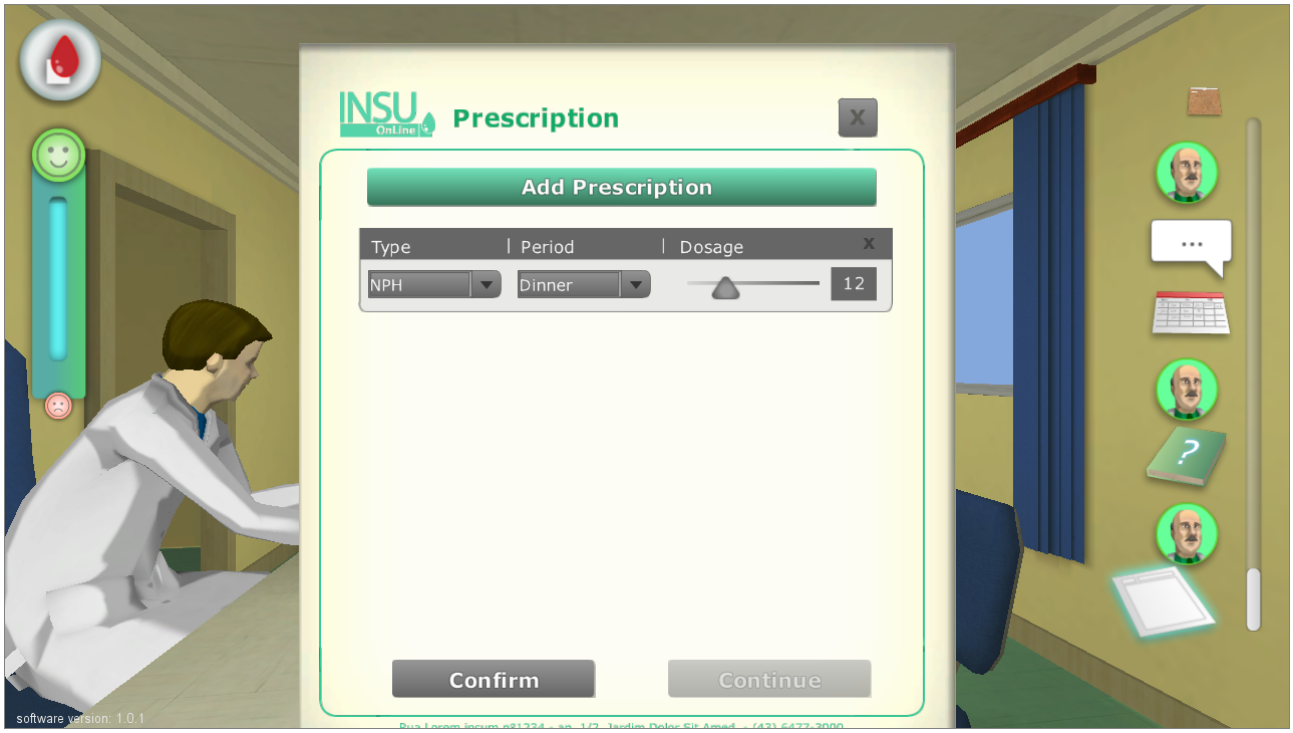
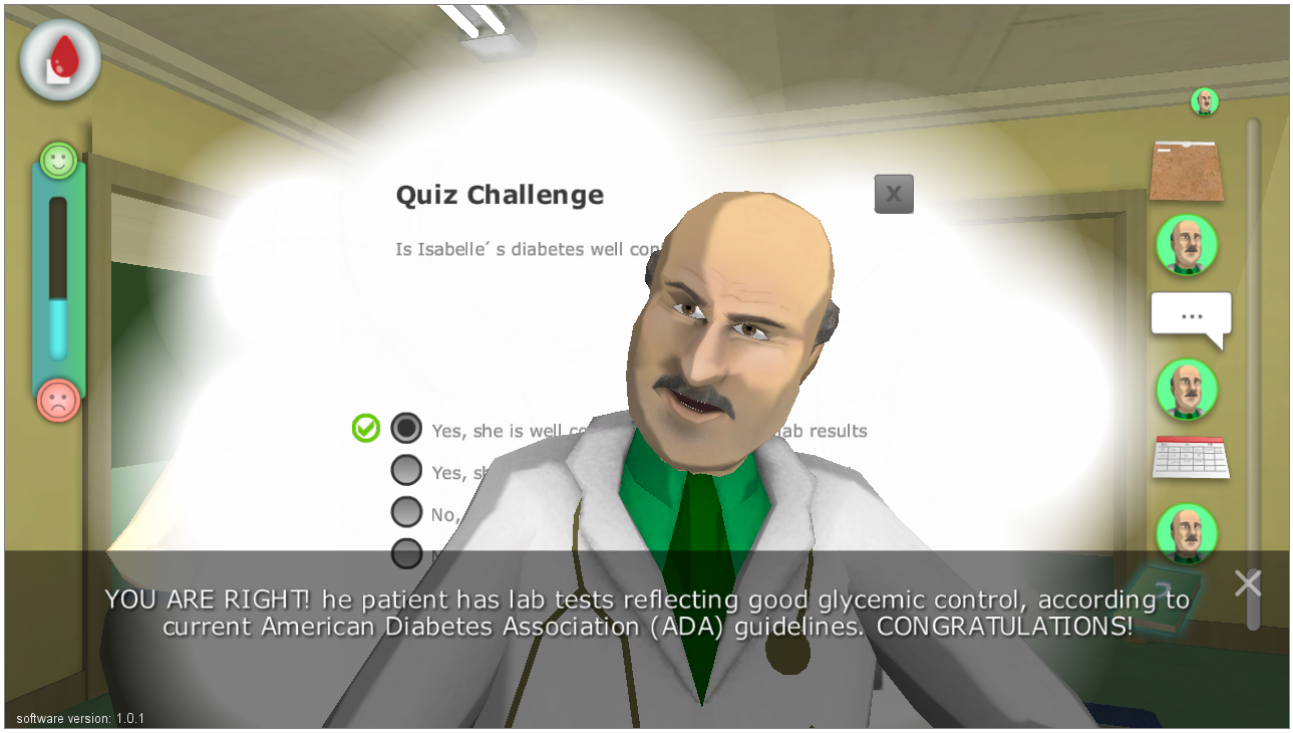


Figure 5. Feedback from the mentor after a player´s action.



Discussion

Games and simulators are useful for health care professionals´ education on various fields [38]. Specifically regarding diabetes education, a few simulators are available for clinicians to learn and practice insulin prescribing. These have been well accepted by the target audience, but lack an objective measurement of their educational efficacy [22-25]. However in our opinion, these tools have few ways of interaction and are excessively text-based. As a result, the existing simulators are not very attractive and probably unsuccessful for arousing the intrinsic motivation of their audience, who will often need some external stimuli in order to play them.

In order to fulfill learning purposes, any intervention must incorporate the main principles of adult education**:** individualized, self-pacing, contextualized learning, with active experimentation and appreciation of previous knowledge [12,27,39]. The inclusion of game elements adds entertainment to the learning experience, increasing the intrinsical motivation

of the learner to practice and to learn, making the learning experience more enjoyable and potentially more effective [39]. For these reasons, games can be a more interesting and successful approach to CME than simulators and other forms of distance education, such as virtual world interventions [40] or telemedicine consultations [41].

Many games have been developed for education of diabetic patients showing good results, including reducing the rates of urgent hospitalization of diabetic children, for example [42]. However to our knowledge, there were no reported games for education of medical doctors on insulin or DM, and this is the first report of a game oriented to education of primary care physicians on insulin prescription (initiation, adjustment, and problem solving). The need of a new approach for education of health professionals regarding insulin therapy is justified by their difficulties in this field. In Londrina, 87% of PCPs directly involved in the treatment of diabetic patients reported at least one difficulty or insecurity with insulin use, and 38% admitted that they would not initiate insulin for a hypothetical patient with type 2 diabetes who was clearly in need of insulin initiation [43].

Also, this is the first known research trial studying the educational efficacy of a computer game in teaching PCPs about insulin therapy for DM. This is important, as most games for health care have not been validated as tools for education or health outcomes improvement, and there is a great need of good quality studies which can provide good scientific evidences to support the fast-growing field of games for health. Therefore, our study was designed to follow the rigorous guidelines for research on games´ effectiveness proposed by Kato [44].

We hope to demonstrate that a game can be an attractive and effective option for CME on insulin and diabetes. If we can do that, it would give more support to the idea that games can be very good options for large-scale CME, since they can be published on the Web to reach more health professionals compared to traditional learning activities, such as conferences or symposia, which cost substantial amount of time and money. A well-designed Web-based learning game can be used by the learners in their own time and rhythm, at possibly smaller costs, and have a number of significant potential advantages.

In conclusion, we demonstrated that the design and development of a game for education of PCPs on insulin management is possible with the collaboration of a multidisciplinary team. Although its efficacy still needs further evaluation, we think that InsuOnline can be a valuable tool for large-scale CME on DM, in view of its easy dissemination on the Web, customizable content, and accordance with adult learning principles. We hope it can contribute to improving PCPs´ knowledge and optimize DM control in primary care.

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Conflicts of Interest

InsuOnline is a copyrighted game. Its design and development was entirely founded by personal resources from the authors LAD and PAG, and from Oniria Software Industry, who are copyright holders. All authors contribute to design and evaluation of the game.

Multimedia Appendix 1

Informed Consent Form [in Portuguese].

[PDF File (Adobe PDF File), 375KB - resprot_v2i1e5_app1.pdf]

Multimedia Appendix 2

CONSORT EHEALTH Checklist V1.6.2 [34].

[PDF File (Adobe PDF File), 990KB - resprot_v2i1e5_app2.pdf]

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Abbreviations

A1c: glycated hemoglobin A1c
BMI: body mass index
CME: continuing medical education
DM: diabetes mellitus
PCP: primary care physicians
UEL: Universidade Estadual de Londrina

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Original Paper

Evaluation Design for Community-Based Physical Activity Programs for Socially Disadvantaged Groups: Communities on the Move

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Abstract

Background: As interventions are not yet successful in substantially improving physical activity levels of low socioeconomic status groups in the Netherlands, it is a challenge to undertake more effective interventions. Participatory community-based physical activity interventions such as Communities on the Move (CoM) seem promising. Evaluating their effectiveness, however, calls for appropriate evaluation approaches.

Objective: This paper provides the conceptual model for the development of a context-sensitive monitoring and evaluation approach in order to (1) measure the effectiveness and cost-effectiveness of CoM, and (2) develop an evaluation design enabling the identification of underlying mechanisms which explain what works and why in community-based physical activity programs.

Methods: A cohort design is proposed, based on multiple cases, measuring impact, processes, and changes at each of the distinguished levels. The methods described in this paper will evaluate both short- and long-term effects, costs, and benefits of CoM.

Results: Testing of the proposed model began in October 2012 and is on-going.

Conclusions: The design offers a valid research strategy for evaluating the effectiveness of community-based physical activity programs. Internal validity is guaranteed by the use of several verification techniques such as triangulation. The multiple case studies at the program and community levels enhance external validity.

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KEYWORDS

community-based physical activity program; cost-effectiveness; low socioeconomic status groups; health promotion; evaluation design

Introduction

Background

Physical inactivity is one of the four core risk factors for non-communicable diseases such as diabetes type 2 and cardiovascular diseases. It has been identified by the World Health Organization (WHO) as the fourth leading risk factor for global mortality in 2012, causing an estimated 3.2 million deaths globally [1].

In the Netherlands, the Dutch Healthy Physical Activity Guidelines (NNGB) have been in use as a standard for monitoring physical activity behavior at population level since 1998. These guidelines set the norm for healthy daily physical activity for adults at a minimum of 30 minutes of moderate activity at least 5 days a week [2]. Research shows that physical activity levels of the Dutch adult population are rising, from 44% in 2000 to 62% in 2009 meeting the guidelines for healthy physical activity [3]. Adults spend on average 178 minutes per day in physical activity. Work, school, and domestic activities are the most important sources of physical activity.

Not all population strata, however, show this upward trend. The engagement of low socioeconomic status (SES) groups in sports and physical activity in the Netherlands remains lower than in high SES groups [4], despite various policies promoting community-based health and physical activity programs at the national, regional, and local level [5]. The neighbourhood is recognized as a setting in which to promote health and physical activity and to strengthen people's responsibility for their own health and social participation [5-7].

As interventions have not yet been successful in substantially improving physical activity levels of low SES groups, it is a challenge to undertake more effective interventions [8]. In line with national policy objectives, the Netherlands Institute for Sports and Physical Activity (NISB) developed and disseminated a community-based program enhancing physical activity in inactive low SES target groups: the Communities on the Move (CoM) approach. The aim of CoM is to enhance physical activity levels of low SES groups, in order to contribute to social participation, quality of life, and life satisfaction of individual participants. Since 2003, CoM has been carried out by a variety of user organizations in 37 municipalities, reaching over 100 groups. Preliminary results of the program are promising. An expert panel of the Dutch Centre of Healthy Living has approved CoM as theoretically underpinned [9], but its effectiveness and cost-effectiveness have not yet been researched comprehensively.

Community-based interventions like CoM are grounded in both individual and community level theories [9,10], calling for appropriate designs to evaluate them at different impact levels [11]. To our knowledge, community-based physical activity programs have not yet been assessed comprehensively on both process and indicators for effectiveness at multiple levels. The aim of this paper is to provide the conceptual model for the development of a context-sensitive monitoring and evaluation approach in order to (1) measure the effectiveness, including the cost-effectiveness, of CoM, and (2) develop an evaluation design enabling the identification of underlying mechanisms that explain what works and why in community-based physical activity programs. The proposed research design is based on insights derived from the authors' experiences in community-based health promotion programs [12-14].

The Communities on the Move Approach

CoM targets inactive, low SES groups. CoM is a principle-based approach, enabling community-based physical activity interventions to be tailored to the needs and demands of target groups within specific local contexts. The objective is to identify, assess, and mobilize available resources for physical activity within the target group and their community. This requires a participatory approach in program development and implementation, involving different stakeholders including the target population in all stages of program planning, implementation, and evaluation [15,16]. CoM is linked to the *assets for health* concept [17]—a health asset being any factor that enhances the ability of individuals, communities, populations, and/or social systems to improve or maintain health and well-being. The concept includes a salutogenic perspective on health, focusing on positive health outcomes [18,19].

The key principles of CoM, identified and used in a 4-year pilot phase (2003–2007), at the program and community levels are: intersectoral collaboration, coordinated action for sustainability, and active participation of local stakeholders (organizations and community representatives). The key principles at the group and individual levels are: a social network approach, active participation of participants in program development, enjoyment, group bonding, and creating supportive environments. Phase 1 of a CoM program starts with *problem definition*, based on community assessments identifying stakeholders, physical activity needs, and assets. Phase 2 is *planning and development* of program activities with local stakeholders, setting goals, and defining actions within contextual boundaries. Phase 3, the actual *implementation* phase, is a stepwise approach, starting with activities for *recruitment*. First, the participants are recruited by accessing community groups and mobilizing their social networks, where a community group may be women visiting a mosque, for instance. The second step is defining and implementing the *action* program using group members' input to tailor physical activities to their needs. The third step is consolidation. Group members practice what they have learned and actively involve their social and physical environments in order to sustain their behavior change. Phase 4 of CoM is program *evaluation* to document impact and lessons learned for further dissemination. Table 1 is a schematic representation of a local CoM program.

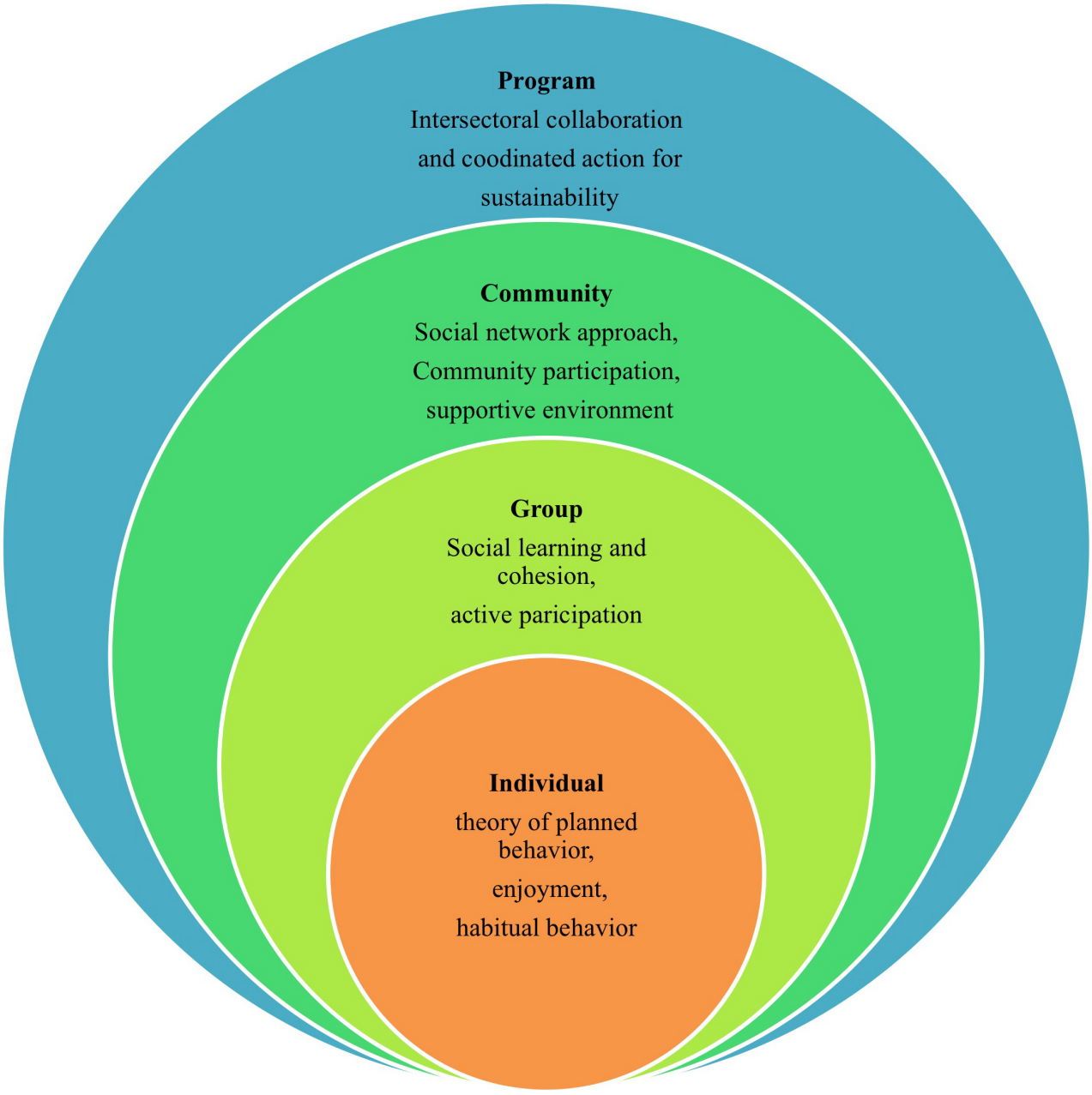
Theories to develop and implement CoM use an ecological perspective on human health. The ecological perspective emphasizes the interaction between factors within and across the different levels [20]. To address the reciprocity of human interactions with their social and physical environment, CoM advocates actions at multiple levels, whereas each level builds on different theoretical frameworks (Figure 1). At the *individual* level, CoM aims to initiate and sustain change in physical activity behavior, building on the concepts of the theory of planned behavior (TPB). These concepts include behavioral

intention, attitude, subjective norms and social influence, and self-efficacy [21]. CoM stimulates adherence to physical exercise and the development of habitual behavior through enjoyment [22-24]. At the *group* level, social learning processes and active participation, based on concepts of social cognitive theory (SCT), are used to support sustained behavioral change [20,25]. At the *community* level, CoM is based on the social network approach, community participation, and the notion of supportive environments. Social networks contribute to health [26] and effectively support physical activity behavior [27]. Community participation fosters higher levels of motivation and determines effectiveness [12]. At the *program* level, CoM is underpinned by theories on intersectoral collaboration and coordinated action [13], addressing stakeholder involvement and community ownership. Intersectoral collaboration strengthens the development and contextualization of the intervention by assessing assets and resources of various stakeholders and translates them into customised program activities. Intersectoral collaboration also contributes to the sustainable implementation of CoM.

Table 1. Principle-based CoM approach in local practice.

	Phase 1 Problem identification	Phase 2 Program development	Phase 3 Program implementation			Phase 4 Evaluation
			Recruitment	Action	Consolidation	
Program organization						
Intersectoral collaboration	assessment community needs and assets	setting goals	program coordination and monitoring	program coordination and monitoring	program coordination and monitoring	formation new groups
	stakeholder involvement	program development	communication	communication	communication	
Program sustainability	assessment policy goals	organizing resources	introduction activity program	physical activities program	physical activities program	
		capacity building	demonstration lessons	theme sessions		
Community						
Active participation	identification target groups	identification key persons				formation new groups
Social network			mobilizing participants			
Create supportive environments					involving social and physical environment	
Group						
Group bonding			getting acquainted	social learning	group cohesion	sustained group activities
Active participation			program attendance	program attendance	group initiatives	
Create supportive environments					involving social and physical environment	
Individual						
Social network			participants acquainted		involving social and physical environment	sustained physical activity behavior
Active participation			assessment physical activity needs and ambitions	competence development (attitude, knowledge, skills)	competence development	
Pleasure			exploring which physical activity are liked	learning to enjoy physical activity	competence and confidence development	

Figure 1. Theoretical underpinning of CoM.



Evaluation Objectives

CoM's evaluation approach aims to (1) assess the effectiveness of CoM at different impact levels (individual, group, program, and community), (2) identify underlying mechanisms to explain the context sensitivity of program development and implementation, and (3) assess the cost-effectiveness of CoM. This paper will address the following research questions:

1. Which effects can be documented with respect to physical activity behavior, health, quality of life, and life satisfaction?
2. Which mechanisms explain the successes and failures of CoM in low SES groups and how can these be addressed?
3. How can results be interpreted in terms of costs and benefits and what combination of economic evaluation methods and tools is most appropriate to evaluate a community-based program on cost-effectiveness?

Methods

Study Design

To measure the effectiveness and cost-effectiveness of CoM, our study combines a cohort analysis based on multiple cases, and a process evaluation and action research, measuring processes and changes at each of the 4 defined impact levels at multiple points in time (Figure 2). The study includes 16 groups of CoM programs in different municipalities, in 4 cohorts of 4 groups. Data will be collected through standardized questionnaires, open interviews, document analysis, interactive procedures, and focus groups. Four CoM programs (one case from each cohort) will be studied in depth. The advantage of a cohort analysis with cohorts starting successively over a course of 2.5 years is that multiple intermediate outcomes can be studied simultaneously over a period of time. It allows control for possible history and maturity effects, and as such it offers

a valid alternative for a randomized controlled trial (RCT) design. RCT designs are considered less appropriate to assess the cost and effectiveness of CoM at multiple levels and to identify underlying mechanisms explaining success and failures for the following reasons [14,28]:

1. RCT designs focus on behavior change at individual and community population level, not taking into consideration conditions for change related to social, cultural, and organizational factors [14,29].
2. Applying the RCT design is difficult because of the absence of appropriate ways to define control groups in real life settings. Community-based physical activity promotion settings are generally open to the public at large, and people living in the control areas have access to the activities as well, hence, participants cannot be assigned randomly. Initial physical activity motivations for members of the community may also be different, making randomization difficult [14,28].
3. There are limitations in the ability of RCT designs to grasp the importance of interactions between the individual and his or her social and physical environment [30,31].

A mixed method design is therefore required to gain insight into the effectiveness of CoM programs at all 4 defined impact levels and to understand the process, the interactions and the quality of interactions needed for success [14,30]. An action approach enables researchers and local CoM stakeholders, including CoM participants, to apply and benefit from loop learning [12,32]. Learning loops are applicable to the CoM programs and to the overall learning processes of CoM and this research project. For local CoM programs, single-loop learning results in an improved local program. Double-loop learning results in adaptation of the organization of the program. The learning outcomes in the first four CoM programs can be used in the next four CoM programs and so on. As a consequence, during the research, CoM quality will be improved.

Study Population

To assess outcomes at the *individual* and *group* levels, inclusion criteria for the study participants in CoM programs are inactivity, adults not meeting the NNGB, and low socioeconomic status (income, education, and employment conditions). In each CoM program, one or more groups will be included in the study for convenience sampling. During the study, 16 groups will be studied, each group consisting on average of 15 participants. Consequently, a total of 240 participants will be included. Data will be collected at 4 time-points: at the start of a local program (T_0), at 6 months (T_1), at 12 months (T_2), and at 18 months (T_3).

At *program* and *community* levels, on-going CoM programs will be included, based on existing partnerships between NISB and implementing organizations (purposive sampling). The study population consists of local stakeholders such as user organizations and networks in place, the disseminating organization (NISB), and community representatives.

Logic Model

Figure 3 illustrates the logic model for impact evaluation of CoM, based on the literature on community-based evaluation approaches [33] as well as dissemination studies of evidence-based interventions [34,35]. The hypothesis is that a community-based participatory approach to developing and implementing physical activity programs is effective in enhancing physical activity levels in low SES target groups and results in increases in quality of life, life satisfaction, and community participation.

The framework was developed based on the perspectives of the local program initiators and the community. Local program initiators seek the evidence base, developed in CoM and disseminated by NISB, whereas community-based approaches follow non-linear pathways of development and implementation [33]. This calls for process evaluation, addressing intersectoral collaboration, capacity building and network development, as well as identification of intermediate measures to be monitored at the different impact levels. *Short term output* is defined in terms of concrete activities, reach, and program satisfaction. *Short term outcome* indicators are defined in terms of measurable impact, such as increase in physical activity and knowledge, and the use of qualitative data (group learning) to understand outcomes. *Long term outcome* indicators are defined to measure broader outcomes and monitor local change.

Figure 2. Evaluation design of CoM.

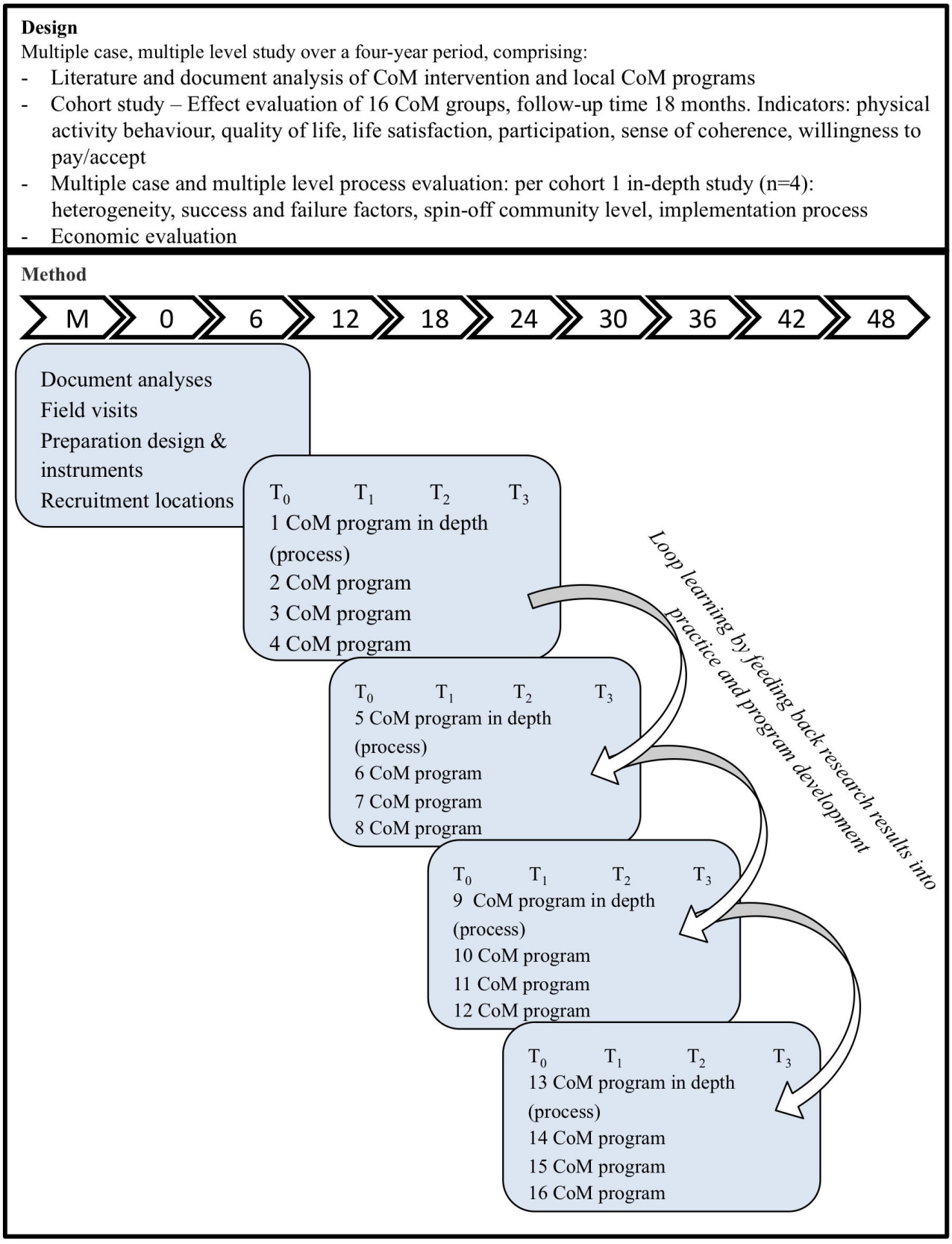
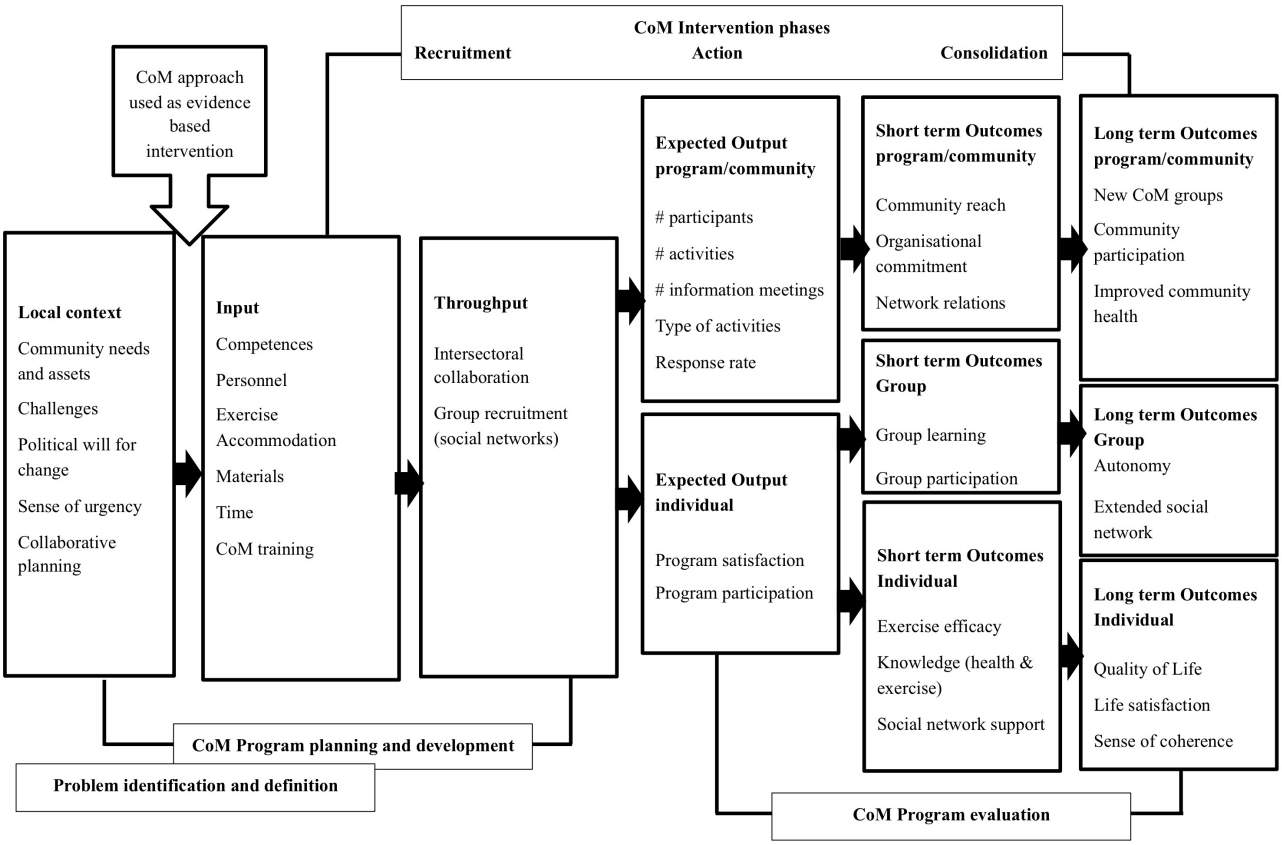


Figure 3. Logic model for evaluation effectiveness CoM.



Impact Assessment

To assess effects with respect to physical activity behavior, quality of life, and life satisfaction at the *individual* level, a standardized questionnaire will be used to measure quantitative short- and long-term outcomes (Table 2). The questionnaire has been developed using concepts from the underlying theories of TPB, in addition to questions related to sports and physical activity behavior. Data on socioeconomic indicators will be collected (ie, age, income, education, employment, living conditions), in accordance with standardized questions in the Local and National Monitor Public Health in the Netherlands [36].

To measure physical activity, the validated Short QUestionnaire to ASses Health enhancing physical activity (SQUASH) will be used [37]. Correlations for reproducibility of the separate questions vary between 0.44 and 0.96. Spearman's correlation coefficient between CSA readings and the total activity score was 0.45 (95% CI 0.17-0.66) [38]. The SQUASH questionnaire was used as it generates data that can be compared with national and regional data. The Dutch trend analyses for physical activity behavior over the past 2 decades were based on the SQUASH, offering a vast body of reference data for our study [3].

In this study we will explore the use of objective measures for physical activity, such as walking tests or accelerometers [39,40]. These objective measurements, however, generally require additional data such as generated by SQUASH, to be able to interpret outcomes on physical activity behaviors and the development of habitual physical activity behavior. Some challenges remain with the use of objective physical activity measures. First, validity and reliability can be questionable, for example, when these measures are used with user groups suffering from chronic diseases [41]. Second, organizational efforts and costs are practical issues related to implementation that must be considered [40].

To measure personal goals on health and physical activity behavior, a number of personal features will be documented (eg, demographics, BMI). To measure life satisfaction, Cantril's Self-Anchoring Ladder for Life Satisfaction will be used [42]. To measure the ability to cope with stressors, the validated 13-item Sense of Coherence (SOC) questionnaire will be used [43]. Cronbach alpha values in 127 studies using SOC-13 ranged from 0.70 to 0.92 [44]. To measure enjoyment, the 9-item short version of Physical Activity Enjoyment Scale (PACES) will be used [45,46].

To assess mechanisms explaining successes and failures of CoM in low SES groups and how these can be addressed, data will be collected at the *group* and *program* level through interviews, focus groups, and document analysis (Table 2). A combination of action research and realism evaluation will be used. Action research is important because it has both an action function, which supports the progress of the intervention, and an evaluation function, which seeks to monitor and ascertain processes and outcomes of interventions [47]. Realism evaluation facilitates the study of the interactions between context and program mechanisms determining the outcomes [48]. To assess CoM's context-based information, each of the CoM programs will include an interview with the program coordinator and the two focus groups—the local stakeholders and the CoM participants. To measure effectiveness at the

program level, we will incorporate the factors for achieving and sustaining participation and collaboration [49], the coordinated action checklist [50], and Pretty's participation ladder [25]. The RE-AIM dimensions (ie, reach, effectiveness-adoption, implementation, and maintenance) will serve as the framework to measure spin-offs and highlight areas that require special attention with respect to sustainability [51].

Table 2. Overview of variables and methods of data collection.

Level	Variables	Questionnaires				Document analysis	Interview	Focus group	Instruments
		T_0	T_1	T_2	T_3				
Individual									
	Age, gender, income, education, ethnic background	x							Questionnaire
	Quality of life	x	x	x	x				EQ-VAS
	Life satisfaction	x	x	x	x				Cantril's ladder
	Physical activity and health behavior	x	x	x	x			x	Questionnaire
	BMI	x	x	x	x				Questionnaire
	Sense of Coherence	x			x				SOC-13 scale
	Enjoyment	x	x	x	x			x	PACES scale
	Willingness to pay	x	x	x					Questionnaire
	Personal goals	x	x	x	x			x	Questionnaire
Group									
	Social support	x	x		x			x	Questionnaire
	Participation							x	Timeline Pretty's ladder
Program									
	Organization and collaboration					x	x	x	Coordinated action checklist
	Program participation	x	x				x	x	Pretty's ladder
	Support and training					x	x	x	
	Competences						x	x	
	Diffusion		x			x	x	x	
	Cost per QALY	x	x	x					
	Cost-effectiveness		x			x			QALY
Community									
	Spin-off: new programs and community participation			x	x	x	x	x	RE-AIM framework

Economic Evaluation of CoM

To assess how results can be interpreted in terms of costs and benefits and what combination of economic evaluation tools is most appropriate to evaluate a community-based program on cost effectiveness, results from the cohort analysis, process evaluation, and action research at all levels discerned will be used (Table 2). The study perspective in evaluating CoM's cost-effectiveness will be the societal perspective. Data will be collected about health-related quality of life in relation to the physical activity program and its program costs over a time frame of 18 months. To measure health-related quality of life, the Dutch EuroQoL (quality of life) scale (EQ-5D-3L) and the EQ visual analogue scale will be used. The EuroQoL scale is standardized, measuring non-disease specific health-related quality of life, in use for economic evaluation [52,53].

The methods used will include traditional measures such as cost utility, cost-benefit analysis, Quality Adjusted Life Year (QALY, expressed in euros per quality-adjusted life-year) gained, and willingness to pay or accept. We will also use instruments that measure changes in life satisfaction and sense of coherence (SoC).

At the *individual* level, the most usual means to measure changes in welfare are compensation tests. Compensation tests, such as willingness to pay, are measured based on monetary value [45].

Willingness to pay questions (for sport and physical activity) will be asked at distinctive points in time during the CoM program. To measure health gain, the QALY will be calculated by multiplying the amount of time in a particular health state by the quality of life during that time, summing over all time periods, standardized to a year [54].

A cost-effectiveness analysis at the *program* level will be performed by computing cost per QALY gained. At program level, costs such as salaries, training costs, and materials are summed up, and benefits are measured through the computation of QALY gained at various time-points, as described above. The outcomes of these computations will be compared with other relevant interventions. In all methods applied, assumptions used in the economic calculations and evaluation will be made explicit.

Analysis

Qualitative Analysis

Qualitative research data from interviews and focus group discussions will be audiotaped (with the interviewees' permission), transcribed (intelligent verbatim style), and analyzed using Atlas.ti (version 7.0) to manage the data and guarantee transparency. Top-down as well as bottom-up coding will be used to provide for the analysis of differences in perspective of CoM participants, professionals, and scientists [55,56]. Case study data will be used to describe general mechanisms of failures and successes of the CoM program for various low SES groups.

Quantitative Analysis

Quantitative data will be analyzed with multivariate analysis techniques using the SPSS program. The quantitative variables at the individual level (Table 2) are to be tested for 4 independent variables (gender, age, ethnicity, and SES) using a multiple regression analysis with a significance level of .05 and a power of 0.80 for a medium effect size. This requires 84 participants for the study [57]. If there are several different groups (eg, ethnicity, SES) each with eight independent variables, 107 participants will be needed. Targeting 240 COM participants would satisfy these conditions.

Power Calculation

As the study design lacks control groups and consequently limits randomization, the assumption made in the power calculation is, that the CoM principles used are the same in each location. Effect sizes, therefore, can be calculated based on the overall population included in CoM programs.

The power calculation of the effectiveness of the CoM program is based on the variable *physical activity*, as the prime aim of the CoM program is to enhance physical activity in inactive, socially disadvantaged groups. Measures for change to be considered include: increase in the average number of minutes people are physically active, in the number of people meeting the Dutch Healthy Physical Activity Guidelines (NNGB), and in the number of people indicating that they are more physically active after participation in a CoM program.

Estimation of the effect size is based on an American systematic review study [27]. This review showed that the average time spent on physical activity increased by 35.4% (range 16.7-83.3%), based on 17 studies involving middle-aged adults. Dutch studies reviewing physical activity interventions gave no numerical information about effect sizes [58,59]. One intervention report showed an increase of 38% on average in the physical activity pattern. Based in these data, the estimated effect size for our study is set at an increase in physical activity of 35% in each group, roughly equivalent to 500 minutes a week.

A limitation of the proposed cohort design is the ability to correct for history or maturity effects, as the timeframe for data collection per cohort is restricted to 18 months with measurement intervals of only 6 months. To control for these effects, a comparison of cohorts will be conducted. Furthermore, comparisons will be made with existing population statistics for physical activity.

Management and Governance

Research activities will be developed and implemented in close collaboration with NISB to stimulate active knowledge exchange and co-creation of new knowledge. In this way, so-called context-sensitive evidence will be generated, which by its nature is relevant for intended users [60].

For the research project, a steering group consisting of representatives from Wageningen University and NISB will meet regularly. In addition, advisors from national and international organizations (eg, the Dutch Centre of Healthy Living, other universities, and community programs) will be involved for specific purposes, such as to review the developed questionnaires, to critically assess results of the interviews and focus groups, and to comment on drafts of scientific articles.

Intended Outputs

This study will result in recommendations for improving the health of low SES groups through physical activity. Further research results include:

1. An elaborated monitoring and evaluation design for participatory community health and physical activity promotion.
2. Assessment of CoM effectiveness and cost-effectiveness at the *individual*, *program*, and *community* levels.
3. The facilitation of wider implementation of CoM at both national and local level.

Results

The study began in October 2012 with data collection at both the *individual* (T_0) and *program* levels. Baseline data was collected for the first cohort. At the *program* level, documentation is collected and interviews are conducted with local stakeholders. The study is on-going and funded by ZonMw, the Netherlands Organization for Health Research and Development (project number: 50-51505-98-103).

Discussion

Need for an Alternative Evaluation Approach

The need to elaborate an alternative evaluation approach to study the effectiveness and cost-effectiveness of a community-based physical activity program such as the CoM is evident. New indicators, methods, and tools are required in a real-world setting, comprising multiple levels. The design described in this paper offers a valid research strategy for effectiveness, combining cohort analysis, process evaluation, and action research within multiple cases (parallel investigations in different settings), addressing the different impact levels in a comprehensive way.

Credibility or internal validity is guaranteed by the use of several verification techniques such as triangulation, stakeholder checking, external auditing, and peer review [31,61]. Triangulation of data obtained by questionnaires, interviews, and focus groups elucidates why effects on physical activity behavior, health related quality of life and life satisfaction have occurred.

The multiple cases carried out at the program and community level (4 in-depth cases) will enhance external validity. The findings of the study will be context specific and specific to different low SES groups, but will also reveal generic mechanisms of change.

Value for Science, Practice, and Society

Conducting comparable studies in different situations will make it possible to draw conclusions about the quality of achievements and the processes and mechanisms in force in community-based projects, but also about the usefulness of (new) research techniques [31,47].

Practice will benefit from the research in various ways. Research activities will be part of the intervention, and stakeholders will participate in the development, implementation, and evaluation of research activities. Results will be fed back into the program immediately in order to undertake subsequent action. In addition, this research project will facilitate wider implementation of CoM.

Information on the effectiveness and cost-effectiveness of community health promotion is highly relevant for policy makers to decide on the implementation of community-based approaches. In view of the increasing number of programs expected as a result of Dutch health policies aiming at self-mobilization and organization in neighbourhoods, this study will address the need to contribute to insight into context-sensitive intervention development targeting low SES people who are physically inactive, and how to monitor and evaluate these in a comprehensive way.

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Authors' Contributions

MH was the first author of the manuscript and participated in the design of the study. AW, LV, JO, and MK designed the study. All authors have read and approved the final manuscript and contributed to the drafting and revision of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
CoM: Communites on the Move approach
EQ-VAS: standard visual analogue scale for rating health-related quality of life
NISB: Netherlands Institute for Sports and Physical Activity
NNGB: Dutch Healthy Physical Activity Guidelines
PACES: Physical Activity Enjoyment Scale
RE-AIM: reach, effectiveness-adoption, implementation, maintenance
RCT: randomized controlled trial
SES: socioeconomic status
QALY: Quality Adjusted Life Year
SOC: sense of coherence
TPB: theory of planned behavior
SCT: social cognitive theory
SQUASH: Short QUestionnaire to ASses Health enhancing physical activity
QoL: quality of life
WHO: World Health Organization
ZonMw: Netherlands Organization for Health Research and Development

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Original Paper

Feasibility of a Personal Health Technology-Based Psychological Intervention for Men with Stress and Mood Problems: Randomized Controlled Pilot Trial

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Abstract

Background: Work-related stress is a significant problem for both people and organizations. It may lead to mental illnesses such as anxiety and depression, resulting in increased work absences and disabilities. Scalable interventions to prevent and manage harmful stress can be delivered with the help of technology tools to support self-observations and skills training.

Objective: The aim of this study was to assess the feasibility of the P4Well intervention in treatment of stress-related psychological problems. P4Well is a novel intervention which combines modern psychotherapy (the cognitive behavioral therapy and the acceptance and commitment therapy) with personal health technologies to deliver the intervention via multiple channels, includinggroup meetings, Internet/Web portal, mobile phone applications, and personal monitoring devices.

Methods: This pilot study design was a small-scale randomized controlled trial that compared the P4Well intervention with a waiting list control group. In addition to personal health technologies for self-assessment, the intervention consisted of 3 psychologist-assisted group meetings. Self-assessed psychological measures through questionnaires were collected offline pre- and post-intervention, and 6 months after the intervention for the intervention group. Acceptance and usage of technology tools were measured with user experience questionnaires and usage logs.

Results: A total of 24 subjects were randomized: 11 participants were followed up in the intervention group (1 was lost to follow-up) and 12 participants did not receive any intervention (control group). Depressive and psychological symptoms decreased and self-rated health and working ability increased. All participants reported they had benefited from the intervention. All technology tools had active users and 10/11 participants used at least 1 tool actively. Physiological measurements with personal feedback were considered the most useful intervention component.

Conclusions: Our results confirm the feasibility of the intervention and suggest that it had positive effects on psychological symptoms, self-rated health, and self-rated working ability. The intervention seemed to have a positive impact on certain aspects of burnout and job strain, such as cynicism and over-commitment. Future studies need to investigate the effectiveness, benefits, and possible problems of psychological interventions which incorporate new technologies.

Trial Registration: The Finnish Funding Agency for Technology and Innovation (TEKES), Project number 40011/08

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KEYWORDS

stress; technology-supported mini-intervention; personal health technologies; cognitive behaviour therapy; acceptance and commitment therapy; mhealth; mobile health; smartphone; Internet

Introduction

Work-related stress is one of the biggest health challenges that the world faces at this moment. According to the 2009 European Risk Observatory Report, stress is the second most frequently reported work-related health problem and affects 22% of working Europeans [1]. Long-term exposure to work-related stress has been linked to an increased risk of psychological problems, such as depression, anxiety, emotional exhaustion, and may lead to long-term absenteeism, work disability, and early retirement [2].

Several studies have investigated work-related mental health [3,4]. Psychological interventions based on cognitive behavioral therapies (CBT) have a proven effectiveness for a range of common mental health disorders [5-7]. CBT is also an effective intervention for occupational stress [8-11]. Besides traditional CBT methods, research suggests that stress management interventions based on the acceptance and commitment therapy (ACT) have a positive impact on employees' psychological health, well-being, and stress management skills [12-19]. Research implicates that psychological acceptance promoted by ACT is associated with not only mental health variables but also with a performance-related variable.

Lifestyle-related chronic conditions are an increasing problem in the developed world. Most existing health services do not have sufficient resources to support long-term individual interventions. The delivery of current disease prevention and management models are not feasible due to their high cost and they do not always reach those who need them. Therefore, new models of prevention and treatment measures based on self-management are needed. Personal health systems including Web-based programs, mobile devices, and other health monitoring tools may be used for self-management of chronic conditions and behavioral change [20].

Internet-based and computer-aided treatments have been shown to be effective in treating a wide range of psychological problems, and have effect sizes (ES) comparable to those found for more traditional types of psychological treatments [21-32]. Seymour and Grove [33] have pointed out that accessibility and acceptability are key issues for further research in addition to effectiveness. To address these issues, Web-based treatment programs can be complemented by mobile and wearable technologies for self-monitoring to best suit the user's needs and preferences and also to potentially enhance the effect of the intervention. In addition, technology delivered interventions may be complemented by traditional intervention methods such as individual or group face-to-face meetings and phone counseling.

P4Well is a novel CBT- and ACT-based intervention which combines personal health technologies (mobile, Web, and self-monitoring technologies) to an intervention program which is based on group meetings [34,35]. In intervention design, our aim was to combine the cost-effectiveness of the group meetings to a personalized intervention enabled by technology tools. We designed the intervention program content and technology toolkit in parallel, matching them to each other. The P4Well intervention utilizes a variety of technology tools which allow personalization of the intervention methods and feedback. This may increase the acceptance and efficacy of the intervention by giving the users the possibility to choose appropriate self-management tools according to their personal interest.

The objective of this study was to study the feasibility and effectiveness of the developed P4Well intervention among working age males who experienced mild to moderate symptoms of stress and/or depression. We assessed the effects of the intervention using depression, psychological symptoms, and stress as primary outcome measures and compared these effects to a control group without intervention. Secondary outcome measures included quality of life, psychological flexibility, and job strain. Furthermore, we studied the acceptability and usage of the intervention and its components.

Methods

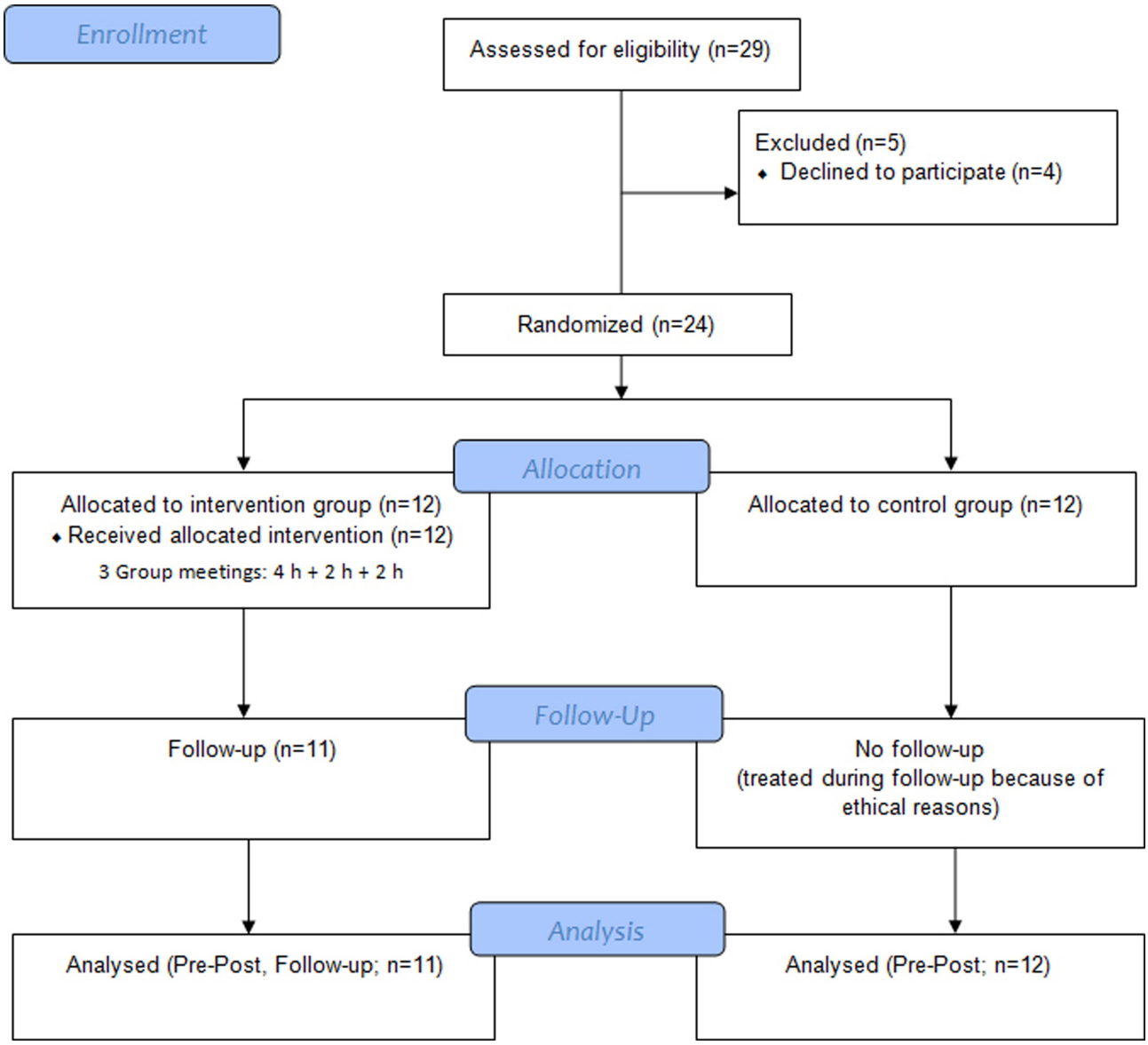
Recruitment and Allocation

Participants were recruited through an advertisement in a local newspaper, seeking males aged 25 to 45 years old with exhaustion, stress symptoms, or sleeping problems. Other inclusion criteria were full time employment, basic computer skills, and access to Internet. Exclusion criteria included diabetes and simultaneous attendance in other stress management programs. We focused this study on male adults because men have a lower tendency to seek treatment for psychological problems compared to females [36,37]. The psychotherapy clinic of the University of Jyväskylä was contacted by 29 respondents via telephone or email. Before randomization of subjects into the research groups, 4 men dropped out. Since fewer participants responded to the advertisement than expected, we also included respondents older than 45 years of age in the study. The adjusted age range was 28 to 58 years. Of the 25 male participants, we excluded one participant from analysis because he did not fulfill the inclusion criteria (because of age and retirement) and one participant who did not participate in the follow-up measurements. One participant in the intervention group was lost at follow-up (Figure 1). Thus, the total number of participants included in the study was 23. Dropout (n=1) was treated with an intention-to-treat-analysis using the data missing principle of last observation carried forward. We then randomly allocated participants either to the intervention or the waiting list control group (intervention group=11, control group=12). The sample was first divided into pairs based on participants with similar depression scores, measured by Beck's Depression Inventory (BDI) [38]. Second, the order of pairs was randomized. Third, participants within pairs were randomly

assigned either to intervention or control group. Thus, the groups were made equal on the basis of reported depressive symptoms and the researchers generated the randomization. Consent from participants was obtained offline in paper format at pre-measurement. Participants received detailed information about the study procedure and their rights.

The study took place at the psychotherapy clinic of the department of psychology at the University of Jyväskylä, Finland, from January 2009 to October 2009. The Research Ethics Committee of the University of Jyväskylä approved this study. The study was funded by the Finnish Funding Agency for Technology and Innovation (TEKES). The study was not registered in a public trials registry, because the study was a phase 1 small-scale pilot study including no participants with medical or psychiatric diagnosis. The study tested a psychological and technical intervention without any side effects. The funding of the project required that participants with diagnoses should not be included in the study.

Figure 1. Participant flow chart.



Participants

The mean age of the participants was 47.1 years (SD 4.72) in the intervention group and 39.4 (SD 7.96) in the control group (Table 1). The intervention group was older, t_{21}=2.78, P=.011, and had a lower BMI, t_{21}=2.42, P=.025, than the control group. The groups did not differ in regard to education, type of work, shift work, or reported depressive symptoms.

Table 1. Participant characteristics.

Background variable	Intervention (n=11)	Control (n=12)
Age	47.1 (4.7)	39.4 (8.0)[a]
Body Mass Index	24.4 (3.1)	28.1 (4.2)[a]
Education (yrs)	7.1	7.2
Married (%)	7 (63)	10 (83)
Permanent employment (%)	9 (82)	11 (92)
Fulltime work (%)	10 (91)	12 (100)
Shift work (%)	11 (100)	11 (92)
No physical work (%)	8 (73)	8 (67)
Depressive symptoms (%)[c]	7 (63)	6 (50)
Medication (%)[d]	4 (44)	1 (8)

[a]*P*=.011

[b]*P*=.025

[c] score is 10 or greater in Beck's Depression Inventory

[d] use of antidepressants and/or hypnotics

Intervention

The P4Well intervention integrated different personal health technologies, including a Web portal, mobile phone applications, personal monitoring devices, and analysis software, with a CBT- and ACT-based intervention program which was specifically designed to utilize personal health technologies (Figure 2). The main idea behind the intervention concept was to combine cost-efficiency of group meetings, personalization and self-monitoring capabilities provided by technologies, and, technology use between the group meetings to increase the continuity and impact of the intervention. The intervention program consisted of 3 group meetings held by a psychologist. The main CBT- and ACT-based methods used in the intervention included clarification of personal values, goal setting, self-monitoring, relaxation, mindfulness, and acceptance procedures. Furthermore, regular physical activity was encouraged and emphasized as means for stress reduction, mood elevation, and improved well-being.

Participants placed in the control group did not receive any technical tools or group meetings during the study period. Pre-measurement consisting of self-assessed questionnaires in paper format and heart rate variability recording was done for both the control and intervention groups before the first group meeting. Both groups had an individual assessment meeting during the pre-measurement phase where they received questionnaires and were given a wearable beat-to-beat heart rate (HR) recording device (Suunto Memory Belt, Suunto Ltd, Vantaa, Finland) with instructions to do a 3-day HR variability (HRV) recording. One week after the assessment meeting, the questionnaires and the heart rate belts were collected and analyzed. Feedback was given to both groups by an exercise physiologist. The intervention group received feedback for the HRV recording (1 hour individual discussion of topics concerning stress, sleep and relaxation, and exercise habits) after the first group meeting. Two weeks after the intervention group finished its third and last meeting (ie, after 3 months), both groups were measured for the second time (post-measurement). Follow-up questionnaires were sent to the intervention group 6 months after the intervention ended (intervention group follow-up, n=11). We offered the control group 1 mini-intervention meeting after the post-measurement. Feedback of the recordings for the control group was given during the mini-intervention.

The first intervention group meeting was an informative and motivating session that consisted of: (1) measurements (background information questionnaire, technology literacy and attitude questionnaire, and psychological questionnaires), (2) general background information about the P4Well intervention and introduction to the wearable technologies, and (3) the psychological mini-intervention (90 minutes). Participants were provided with credentials to the Web portal, mobile phones (Nokia E51) with preinstalled mobile applications (Wellness diary, Fitness coach, and Relaxation assistant; Figure 3), pedometers, heart rate monitors, and actigraphs. The ACT value analysis method was used to initiate the intervention by motivating behavioral changes in the participants [39,40]. Participants were asked to define their valued directions and goals, as well as actions to accomplish these goals. Additionally, a mindfulness exercise was carried out and participants were instructed to practice mindfulness and relaxation by doing exercises in the Web portal and with a mobile phone application. A self-observation worksheet was presented to encourage participants to begin their self-observations. As a homework assignment, participants were asked to further clarify their personal values and select actions based on these values and to conduct mindfulness exercises. Participants were also asked to start monitoring their sleep with the actigraph. The participants were encouraged but not required to start using one or more mobile applications and begin their self-observations after the group meeting.

The second group meeting (2 hours) was given 4 weeks later. The psychological assessment Web tool in the portal including individual problem analysis was presented and participants were asked to reflect over their situation (eg, stressors in their daily life, sleep, exercise habits, and variables affecting these factors). Participants were encouraged to continue working with the assessment tool at home. The session was ended with a mindfulness exercise. Actigraphs were collected from the participants and analysis reports about sleep and activity were sent to them through the Web portal after the meeting. The participants were encouraged to continue their self-observations with the technology tools.

The third group meeting (2 hours) took place 4 weeks after the second group meeting. The theme of the meeting was acceptance, which involves a willingness to experience all psychological events (thoughts, feelings, and physiological sensations), especially negatively evaluated events, without avoiding, changing, or controlling them [39,40]. Experiential exercises, such as metaphors and exercises related to acceptance, were carried out and discussed. At the end of the group meeting, all of the provided technology tools were collected from the participants. After the meeting, the 3-day HRV recording was repeated, accompanied by an individual stress and recovery analysis. The participants completed the final psychological and user experience questionnaires (sent through mail) 2 weeks after the last group meeting (post-measurement).

Figure 2. P4well intervention process.

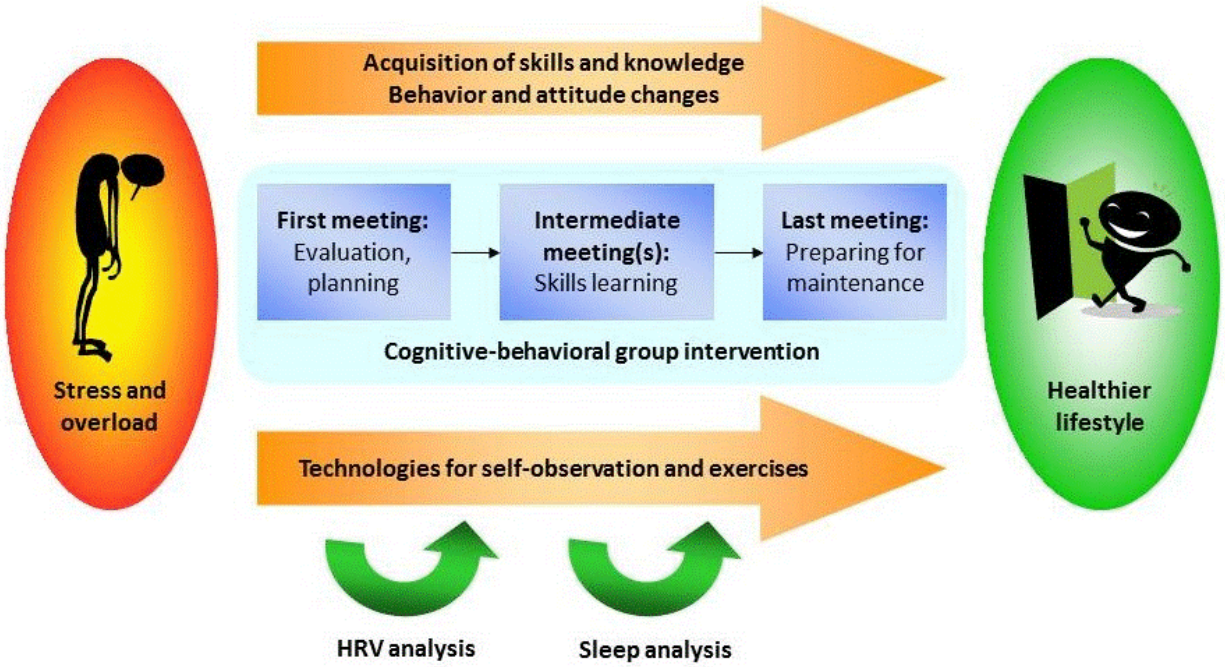


Figure 3. Screenshots of the 3 mobile applications.

Technology Tools

The personal health technologies that were provided to the participants formed a wellness toolkit from which the participants could choose the most appropriate ones for their needs and preferences. The toolkit included a Web portal, a mobile phone with 3 preinstalled applications, a pedometer and a heart rate monitor. Additionally, the participants wore heart rate belts (Suunto Memory Belt, Suunto Ltd, Vantaa, Finland) for 3 days before and after the intervention period to obtain HRV recordings and actigraphs (Vivago Personal Wellness Manager, Vivago Ltd, Helsinki, Finland) for 4 weeks during the intervention to obtain sleep recordings. Based on these recordings, individual feedback reports were given to the participants. Full details of the P4Well technology toolkit have been described elsewhere and so only a brief outline will be provided here [34,35,41].

The secured Web portal (Figure 4) provided the participants access to information, exercises, self-assessment and self-reflection tools, Web-based wellness services, peer support, and expert consultation. The content of the portal was divided into modules focusing on different areas of well-being—sleep, exercise, mood, stress and recovery, and good life. The modules consisted of 5 phases: information, evaluation of personal status, planning of lifestyle changes, putting the plans into action, and follow-up. In addition, the portal included a discussion forum and a messaging client for expert consultation. Mobile wellness diary entries were made available through portal interface (Nokia Wellness Diary Connected, Nokia Corp, Espoo, Finland) and access to an adaptive Web-based fitness training program was also included (Firstbeat WebTrainer, Firstbeat Technologies Ltd, Jyväskylä, Finland). Finally, the participants could utilize a library of evidence-based health-related information through the portal (Duodecim Health Library, Duodecim Medical Publications Ltd, Helsinki, Finland).

The purpose of the 3 mobile phone applications (Figure 3) was to better integrate wellness management and self-monitoring into the participants' daily lives. The first application was a mobile wellness diary (Nokia Wellness Diary (WD), Nokia, Espoo, Finland) that could be used to make daily self-observations on wellness related parameters. The second application was a mobile phone version of the fitness training program (Firstbeat Mobile Coach, Firstbeat Technologies Ltd, Jyväskylä, Finland), and the third one was a mobile phone

relaxation assistant which included personalized relaxation programs (SelfRelax, Relaxline, France).

The participants were encouraged to monitor their physical activity with a heart rate monitor (Suunto Ltd, Vantaa, Finland) or a pedometer (Omron, Kyoto, Japan). Heart rate monitors were primarily meant for participants who were interested in fitness training, whereas pedometers were used to measure and encourage everyday activity. Participants could enter step counts and other exercise parameters manually as daily self-observations into WD.

Figure 4. The main screen of the P4Well web portal.

Measures

Primary Outcome Measures

We measured symptoms of depression using BDI, a widely used 21-item self-report measure of depression [38].

Psychological symptoms were measured using the general symptom index (GSI), which is based on the 90-item symptom checklist (SCL-90). The SCL-90 has been validated for the Finnish population. In a Finnish community sample (n=337) [42], the mean GSI was 0.60 (SD=0.44).

The primary stress measure was the Finnish 15-item version of the Bergen Burnout Indicator (BBI-15) [43], based on the original 25-item Bergen Burnout Indicator [44]. The BBI-15 measures 3 aspects of professional burnout: exhaustion, cynicism, and sense of inadequacy.

Secondary Outcome Measures

Quality of life included 5 items: mood, self-rated health, life satisfaction, self-confidence, and working ability. Participants' perceptions of each item were measured using a visual analogue scale (VAS) from 0 to 100 [45-47].

We measured psychological flexibility and experimental avoidance using the Acceptance and Action Questionnaire-2 (AAQ-2), a 10-item questionnaire that involves both the ability to accept difficult thoughts and feelings as well as to engage in valued activity in their presence (a 7-point Likert-type scale). High scores indicate high psychological flexibility (range 0-70). The AAQ-2 is a revised version of the original AAQ [48].

We measured job strain and over-commitment using the effort-reward imbalance (ERI) questionnaire, which measures extrinsic effort with six items and reward with 11 items. The ratio of effort to reward (ER-ratio) expresses the amount of effort-reward imbalance. High scores indicate high job strain. The ERI questionnaire also includes 6 items that measure over-commitment [49].

User Experiences and Usage

User experiences were measured post-intervention with a questionnaire about perceived utility and acceptance of each individual technology tool, and the perceived usefulness of different intervention components. The perceived utility of the intervention as a whole was assessed with questions about perceived benefits from participation in the study. Usage logs were collected from the portal and the mobile applications after the end of the intervention. For pedometers and heart rate monitors, usage frequency was assessed through the post-intervention questionnaire. Participants were defined as active users of a given tool if they had used it during at least half of the study weeks (based on log data) or reported having used it at least weekly (questionnaire data).

Statistical Analyses

We performed statistical analyses using SPSS 15.0 for Windows (SPSS, Inc, Chicago, IL). A repeated-measures ANOVA evaluated the intervention effect with group (intervention vs control) as the between-subjects factor, and pre- and post-measurements as the within-subject factor. When analyzing pre-, post-, and follow-up measurements of the intervention group, a repeated-measures ANOVA was used. The level of

statistical significance was set at $P<.05$; however, due to the small sample size, we took into account interactions where $P<.10$. The ES, measured by Cohen's d, were calculated to measure clinically significant between group differences and within group changes. We calculated the post-treatment between-group ES by dividing the difference between the treatment mean and the control mean with the pooled standard deviation of the two conditions. The within-group ES was calculated by dividing the mean change from pre- to post- with the pre-treatment SD and the mean change from pre- to follow-up with the pre-treatment SD [50,51]. Between-group ESs of 0.2, 0.5, and 0.8 were considered small, medium, and large, respectively. Within-group ESs of 0.5, 0.8, and 1.1 were treated likewise [7,52].

Results

Acceptance and Usage

All participants in the intervention group stated that their well-being had improved as a result of the intervention. The most common benefits the participants reported included increased willingness to improve personal well-being (8/11, 73%), decreased level of stress (6/11, 55%), and increased amount of exercise (5/11, 45%). The most useful intervention components were considered to be measurements and feedback (10/11, 91%), personal monitoring devices (9/11, 82%), group meetings (8/11, 73%,), and mobile applications (6/11, 55%).

All participants tried at least 3 out of 6 available tools (mean 4.7, range 3-6) and 10/11 participants used at least 1 of the tools (mean 1.9, range 1-4) actively. Each tool had at least 1 active user (Table 2). The mobile relaxation application had the highest number of active users. Pedometer was ranked as the easiest and most personally suitable. Heart rate monitor was rated as the most useful and difficult to use.

Table 2. Usage and user experiences of technology tools.

	Web portal	Wellness diary	Exercise coaching	Relaxation application	Pedometer	Heart rate monitor
Active users (n)	3	1	4	5	4	4
Easy to use[a]	6	5	5	8	11	0
Useful[a]	5	5	7	6	7	8
Personally suitable[a]	5	3	7	6	8	7
Motivating[a]	3	5	6	7	6	6

[a]Values are the numbers of users who agreed or strongly agreed with the statement.

Efficacy

Depressive symptoms, as measured by BDI, decreased more in the intervention group compared to the control group (Table 3). There was a marginally significant group by time interaction effect for BDI ($P=.072$). The mean BDI value decreased with more than 8 scores (CI 4.92-11.99) in the treatment group compared to four scores (CI 0.62-7.38) in the control group. We found a medium ES (d=0.57) between groups in favor of the intervention group. Participants maintained positive changes at the 6-month follow-up. We found a significant within-group effect over time for the intervention group ($P=.001$): both post- and follow-up measurements were significantly lower compared to the BDI pre-measurement. Pre- to follow-up BDI measurements indicated a large within-group ES (d=1.11). An analysis of the number of the participants who reported depressive symptoms at pre-, post-, and follow-up measurements also suggested that the intervention had a positive effect on mood. At the beginning of the study, 64% (7/11) of the participants in the intervention group and 50% (6/12) in the control group reported at least mild depression (a BDI of at least 10). Only 9% (1/11) reported depressive symptoms in the intervention group after the intervention ended. In the control group, 50% (6/12) were still depressed at post-measurement. At follow-up, only 1 person (9%) in the intervention group reported BDI values greater than 10.

Psychological symptoms (SCL-90) decreased in the intervention group but remained at the same level in the control group (Table 3). We found a marginally significant group by time interaction effect in psychological symptoms ($P=.053$). The between-group ES was small (d=0.39). The within-group ES from pre- to follow-up measurement was medium (d=1.07). Again, we found a significant within-group effect for the intervention group—both the post- and follow-up measurements were significantly lower compared to pre-measurement scores. A significant group by time interaction effect was found for health ($P=.008$) and working ability ($P=.016$). The between- and within-group ESs were small for both health (d=0.38 and 0.56, respectively) and working ability (d=0.21 and 0.60, respectively). Furthermore, for these variables we found a significant within-group effect in the intervention group. Thus, health was rated higher after treatment, and participants estimated their working ability to be higher at follow-up compared to the beginning of the treatment. As we can see from Table 3, there was some indication that life satisfaction increased from pre-measurement to follow-up, as well.

Table 3. Psychological symptoms and life quality for the intervention and control group.

		Pre Mean (SD)	Post Mean (SD)	95% CI for the difference		Follow-up Mean (SD)	Pre-Post group x time	Intervention within effect
				Lower	Upper			
Depression BDI								
	Intervention	14.64	6.18	4.92	11.99	6.18	$F_{1,21}$=3.59	$F_{2,20}$=17.45
		(7.61)	(3.31)			(3.28)	*P*=.072	*P*=.001
	Control	13.33	9.33	0.62	7.38	-	d=0.57	d=1.11
		(9.24)	(7.10)					
Symptom SCL								
	Intervention	0.64	0.40	0.11	0.37	0.35	$F_{1,21}$=4.22	$F_{2,20}$=10.28
		(0.27)	(0.18)			(0.18)	*P*=.053	*P*=.001
	Control	0.57	0.51	-0.07	0.18	-	d=0.39	d=1.07
		(0.30)	(0.36)					
Psych Flex AAQ								
	Intervention	52.46	55.73	-7.95	1.40	55.45	$F_{1,21}$=1.74	$F_{2,20}$=0.93
		(10.00)	(6.25)			(7.26)	*P*=.201	*P*=.41
	Control	54.50	53.67	-3.64	5.31	-	d=0.25	d=0.30
		(7.82)	(9.60)					
Life Satisfaction								
	Intervention	59.91	66.09	-14.78	2.42	69.27	$F_{1,21}$=0.04	$F_{2,20}$=5.68
		(15.55)	(10.51)			(13.45)	*P*=.838	*P*=.01
	Control	59.92	64.92	-13.23	3.23	-	d=0.09	d=0.60
		(17.29)	(15.50)					
Self-rated Health								
	Intervention	63.27	74.91	-18.89	-4.38	71.09	$F_{1,21}$=8.57	$F_{2,20}$=5.18
		(13.86)	(11.64)			(15.41)	*P*=.008	*P*=.02
	Control	72.42	69.92	-4.44	9.44	-	d=0.38	D=0.56
		(10.26)	(14.49)					
Mood								
	Intervention	60.27	66.82	-14.38	1.29	66.09	$F_{1,21}$=0.08	$F_{2,20}$=1.50
		(17.35)	(8.34)			(13.32)	*P*=.783	*P*=.25
	Control	57.08	65.08	-15.50	-0.50	-	d=0.15	d=0.34
		(16.51)	(14.18)					
Self-Confidence								
	Intervention	63.55	70.27	-15.80	2.34	74.73	$F_{1,21}$=0.07	$F_{2,20}$=2.49
		(15.63)	(15.85)			(16.41)	*P*=.788	*P*=.11
	Control	69.58	74.67	-13.77	3.6	-	d=0.34	d=0.72
		(13.76)	(9.21)					
Working Ability								
	Intervention	64.36	74.00	-16.93	-2.34	75.45	$F_{1,21}$=6.86	$F_{2,20}$=5.48
		(20.25)	(15.93)			(13.48)	*P*=.016	*P*=.01

		Pre Mean (SD)	Post Mean (SD)	95% CI for the difference		Follow-up Mean (SD)	Pre-Post group x time	Intervention within effect
				Lower	Upper			
	Control	74.00 (7.79)	70.92 (12.91)	-3.9	10.07	-	d=0.21	d=0.60

We did not observe a significant group by time interaction for burnout (Table 4). However, the burnout scores decreased from pre-measurement to follow-up and showed a medium ES (d=0.91). In the intervention group we found a significant within-group effect on cynicism, although there was no significant group by time interaction. However, we obtained a medium (between group) ES for cynicism. There were marginally significant interaction effects on effort (*P*=.07) and over-commitment (*P*=.08). The scores for over-commitment were lower at follow-up compared to the beginning of treatment. The within-group ES from pre-measurement to follow-up was small for over-commitment (d=0.61).

Table 4. Burnout and stress for the intervention and control group.

		Pre Mean (SD)	Post Mean (SD)	95% CI for the difference		Follow-up Mean (SD)	Pre-Post group x time	Intervention within effect
				Lower	Upper			
Burnout								
	Intervention	3.52	3.03	0.16	0.82	2.88	$F_{1,21}$=1.02	$F_{2,20}$=6.67
		(0.70)	(0.83)			(0.73)	*P*=.32	*P*=.006
	Control	3.64	3.38	-0.5	0.59	-	d=0.47	d=0.91
		(0.70)	(0.64)					
Exhaustion								
	Intervention	3.96	3.67	-0.09	0.67	3.42	$F_{1,21}$=0.01	$F_{2,20}$=3.08
		(1.10)	(1.15)			(1.06)	*P*=.93	*P*=.07
	Control	4.13	3.87	-0.10	0.63	-	d=0.20	d=0.49
		(0.67)	(0.84)					
Cynicism								
	Intervention	3.15	2.42	0.32	1.14	2.22	$F_{1,21}$=2.63	$F_{2,20}$=10.94
		(0.93)	(0.96)			(0.75)	*P*=.12	*P*=.001
	Control	3.22	2.93	-0.11	0.68	-	d=0.60	d=1.00
		(0.78)	(0.73)					
Sense of Inadequancy								
	Intervention	3.46	3.00	-0.1	0.92	3.00	$F_{1,21}$=0.44	$F_{2,20}$=2.04
		(1.10)	(0.96)			(1.02)	*P*=.51	*P*=.16
	Control	3.58	3.33	-0.19	0.69	-	d=0.35	d=0.41
		(1.04)	(0.95)					
Effort								
	Intervention	3.39	3.21	-0.9	0.45	3.04	$F_{1,21}$=3.74	$F_{2,18}$=2.08
		(0.82)	(0.95)			(0.90)	*P*=.07	*P*=.15
	Control	3.26	3.43	-0.43	0.09	-	d=0.36	d=0.41
		(0.66)	(0.40)					
Reward								
	Intervention	3.69	3.88	-0.56	0.18	4.18	$F_{1,21}$=0.59	$F_{2,18}$=2.21
		(0.68)	(0.95)			(0.48)	*P*=.45	*P*=.14
	Control	3.64	4.02	-0.73	-0.03	-	d=0.04	d=0.62
		(0.89)	(0.72)					
Effort-reward imbalance								
	Intervention	0.96	0.91	-0.10	0.19	0.74	$F_{1,21}$=0.02	$F_{2,18}$=2.43
		(0.29)	(0.43)			(0.25)	*P*=.89	*P*=.12
	Control	0.94	0.89	-0.08	0.19	-	d=0.13	d=0.69
		(0.27)	(0.23)					
Over commitment								
	Intervention	2.92	2.64	0.05	0.53	2.48	$F_{1,20}$=3.53	$F_{2,18}$=4.03

		Pre Mean (SD)	Post Mean (SD)	95% CI for the difference		Follow-up Mean (SD)	Pre-Post group x time	Intervention within effect
				Lower	Upper			
		(0.64)	(0.61)			(0.57)	*P*=.08	*P*=.04
	Control	2.79	2.80	-0.25	0.22	-	d=0.44	d=0.61
		(0.53)	(0.44)					

In the group intervention, the amount of therapist face-to-face contact time was 8 hours (4 + 2 + 2), totalling 480 minutes (including measurements). Thus, the therapist contact time used for each participant during the intervention was 44 minutes.

Discussion

The objective of this study was to assess the feasibility of the P4Well intervention in the target population of working-age adults who experience mild psychological and stress-related symptoms. Our results confirm that the intervention was acceptable and personal health technologies were actively used by the participants. The results also suggest that the intervention had a positive effect on our primary outcome measures (depressive and psychological symptoms) as well as on self-rated health and working ability. The intervention was also cost-effective. The total professional time used during the active intervention period was less than 1 hour per person.

Before the intervention, the majority of participants reported symptoms of depression; after the intervention only 1 reported symptoms of depression. The intervention group's within-group ES (measuring clinical significance) from pre-measurement to the follow-up was large and the between-group post-treatment ES was medium. These effects are in line with other studies investigating the effects of cognitive-behavioral methods. Meta-analysis from Gloaguen et al [53] found that the between-group ES between CBT and controls was typically d=0.82. In our study, the ES was somewhat smaller (d=0.57), however the ES was at least the same or larger compared to groups taking anti-depressant medications. Our data also indicated that the intervention might have positive effects on burnout symptoms: participants' BBI-15 scores were lower at the 6-month follow-up compared to the beginning of the treatment. Moreover, the results suggest that there were positive effects on cynicism and over-commitment related to recovery from stress and burnout.

Participants perceived the intervention as beneficial and useful, and reported reduced amount of stress, increased physical activity, and greater motivation to improve their well-being. Almost everyone took some of the technology tools into active use and each tool was considered useful, motivating, and personally suitable by several participants. These results suggest that offering several tools and techniques to support changes in multiple behaviors may be a promising approach in interventions that address psychological problems. Most interventions to this date have tailored their content to individual needs, but few have used multiple applications or delivery channels that could be freely chosen by participants based on their preferences. There is a wealth of applications and devices available for self-monitoring of stress, mood, physical activity and sleep, and for relaxation and mindfulness skills training. Nevertheless, individuals struggling with psychological problems and stress may not be aware of the existence or usefulness of these tools. Based on the wide variety of reasons and behavioral treatment options for psychological problems, intervention outcomes and adherence may be improved by matching and recommending specific applications and/or devices to different needs and preferences of participants [54]. An intervention program should be designed with careful consideration of appropriate technology tools that best serve the purposes of the intervention.

Even though personal monitoring devices and mobile applications were received favorably and used actively, human contact was still highly valued. Personal feedback and advice based on physiological measurements was considered the most useful component of the intervention, and group meetings were also appreciated. Peer and counselor support may be crucial factors that increase participant engagement and motivation in technology-based interventions [55]. Interestingly, measurements and personal monitoring devices were evaluated as useful as group meetings. Technology can facilitate remote consultation regardless of time and place, hence reducing the costs and widening the reach and accessibility of interventions. Furthermore, leveraging technology tools in intervention delivery optimizes the use of professionals' time, since it allows participants to complete routine exercises and tasks independently with automated and personalized guidance.

There is an acute need to improve people's psychological well-being, especially depression and various stress-related problems. These problems are widespread and can lead to long-term absenteeism and work disability, which include a significant economic burden [4,56]. Our data suggest that it is possible to positively affect psychological well-being by using interventions that combine face-to-face meetings and technology. Our intervention may be a noteworthy tool for self-management, health-related prevention and general well-being in health care settings. Prevention and early intervention based on self-management are especially important given that healthcare resources are limited. In addition, our intervention offers considerable flexibility, and requires only little professional guidance. In accordance with earlier studies that have investigated the combination of technology and multimodal intervention methods to promote health, our results suggest that interventions using technologies can extend the reach of preventive care to many people at a relatively low cost [57-61]. Our findings are also in line with other studies that

show positive effects using Web-based stress management approaches [11, 62].

This study had several limitations. First of all, the number of participants was small and therefore the statistical power of the study is weak. This lack of power affects our ability to detect differences between the intervention and control group as well as our ability to generalize the results. Also, most participants reported a small number of psychological problems at the beginning of the study. Thus, the possibility for improvement was small (eg, for AAQ, BDI and SCL-90) suggesting that other measurements may have been more appropriate for observing the changes. The control group showed also some improvement that was possibly due to assessment procedures at the beginning. The effectiveness and the acceptability of this intervention need also to be investigated in other populations reporting more severe problems. Furthermore, longer follow-up periods may be needed to ensure the sustainability of the effect. Overall, because all the participants in this study were male, our results can be generalized to only middle-aged men who seek help for stress-related problems and mild to moderate depression. Additionally, participants were provided several technology tools within a short period of time, which caused cognitive load that may have hindered participants' capability and motivation to discover personally suitable tools. Some tools also had usability problems, data entered in one application was not synchronized to others, and most of self-monitoring was done manually. Since the time the study was conducted, there have been considerable advances especially in smartphone technology, which would allow a more integrated and usable technology toolkit.

In conclusion, this study supports the idea that personal health technologies, when combined with a brief psychological group intervention program, may have a positive impact on mild psychological problems and stress-related symptoms. Our intervention provides a potential solution to the demand for accessible and affordable empirically-supported psychological treatments [63]. Our approach is potentially cost-efficient, flexible and accessible, and may help people to prevent and manage stress-related problems and to adopt a healthier lifestyle. However, due to the limitations in the design and procedure, our results may be spurious, and must be interpreted with caution. Furthermore, because the intervention included several components and it was not possible to control all of them within our design, we cannot rule out that these effects were caused by the group sessions alone. Although there are several limitations in this study, this intervention nevertheless shows promising effects. Future studies need to investigate the effectiveness, benefits, and possible problems of psychological interventions which incorporate new technologies. Our aim is to enhance and simplify the presented concept, and evaluate it in a larger, more comprehensive research study using mobile technology. A fully powered RCT using partly the same concept is under way. In the ongoing study, a brief group ACT-based intervention is compared with an ACT-based mobile intervention.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-eHealth Checklist V1.6.1 [64].

[PDF File (Adobe PDF File), 881KB - resprot_v2i1e1_app1.pdf]

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Abbreviations

AAQ-2: acceptance and action questionnaire
ACT: acceptance and commitment therapy
BBI-15: Bergen Burnout Indicator
BMI: body mass index
CBT: cognitive behavorial therapies
ER-ratio: effort to reward ratio
ERI: effort-reward imbalance
ES: effect sizes
GSI: general symptom index
HR: heart rate
HRV: heart rate variability
SCL-90: 90-item symptom checklist
TEKES: Finnish Funding Agency for Technology and Innovation
VAS: visual analogue scale
WD: wellness diary

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Original Paper

The SADI Personal Health Lens: A Web Browser-Based System for Identifying Personally Relevant Drug Interactions

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Abstract

Background: The Web provides widespread access to vast quantities of health-related information that can improve quality-of-life through better understanding of personal symptoms, medical conditions, and available treatments. Unfortunately, identifying a credible and personally relevant subset of information can be a time-consuming and challenging task for users without a medical background.

Objective: The objective of the Personal Health Lens system is to aid users when reading health-related webpages by providing warnings about personally relevant drug interactions. More broadly, we wish to present a prototype for a novel, generalizable approach to facilitating interactions between a patient, their practitioner(s), and the Web.

Methods: We utilized a distributed, Semantic Web-based architecture for recognizing personally dangerous drugs consisting of: (1) a private, local triple store of personal health information, (2) Semantic Web services, following the Semantic Automated Discovery and Integration (SADI) design pattern, for text mining and identifying substance interactions, (3) a bookmarklet to trigger analysis of a webpage and annotate it with personalized warnings, and (4) a semantic query that acts as an abstract template of the analytical workflow to be enacted by the system.

Results: A prototype implementation of the system is provided in the form of a Java standalone executable JAR file. The JAR file bundles all components of the system: the personal health database, locally-running versions of the SADI services, and a javascript bookmarklet that triggers analysis of a webpage. In addition, the demonstration includes a hypothetical personal health profile, allowing the system to be used immediately without configuration. Usage instructions are provided.

Conclusions: The main strength of the Personal Health Lens system is its ability to organize medical information and to present it to the user in a personalized and contextually relevant manner. While this prototype was limited to a single knowledge domain (drug/drug interactions), the proposed architecture is generalizable, and could act as the foundation for much richer personalized-health-Web clients, while importantly providing a novel and personalizable mechanism for clinical experts to inject their expertise into the browsing experience of their patients in the form of customized semantic queries and ontologies.

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KEYWORDS

drug interactions; telemedicine; Web-based services; Web-based interaction; semantic Web; SADI; SHARE

Introduction

For the lay-person, free health information on the Web is a potentially valuable resource for better understanding personal symptoms, medical conditions, drugs, and nutrition. However, while sites such as WebMD [1] provide accredited sources of information, a multitude of other sources such as blogs, Wikipedia articles, and news articles exist that provide no guarantees about their completeness, accuracy, or objectivity. Thus, distinguishing between reliable and unreliable information is a central issue. However, even when restricted to verified sources, the sheer quantity of available material often makes meaningful interpretation a challenging task for readers without a medical background. For example, a study published by White and Horvitz in 2009 demonstrated a phenomenon known as "cyberchondria", wherein a person experiences a heightened anxiety about medical conditions after reviewing search results and online literature relating to common symptoms (eg, headache [2]). Finally, the issue of "information quality" is both personal and subjective—information that is relevant for one individual might not be relevant to another, based on personal factors such as overall health, drug-regimen or other interventions, lifestyle, gender, or even personal interest. As observed by Burgess et al, "due to the unique nature of every individual, a single…method that assumes all people are the same will fail to meet every person's information needs" [3]. It would be highly desirable, therefore, to assist Web users by filtering and/or annotating the information they encounter on the Web in a personalized way, thereby increasing its relevance and utility to that individual. Moreover, given that a patient may be at any point in their continuum-of-care, it would be particularly desirable to provide the patient's clinical-care team an opportunity to include their "voice" into that annotation and filtering mechanism, such that the clinician's plan for that patient enhances the personalization of the page even further.

We recently published a novel framework for automatically synthesizing contextually-sensitive data retrieval and analysis workflows composed of dynamically-selected Semantic Web Services [4]. The system used a semantic template describing the abstract "intent" of the workflow, combined with the specific details in a given dataset, to concretize an appropriate workflow capable of evaluating that data. In this work we intend to demonstrate, using a straightforward prototype application called the Semantic Automated Discovery and Integration (SADI) Personal Health Lens, that these components—the data, the semantic model, and the derived analytical workflow—map directly onto the various facets of the Health Web personalization problem described above. The Personal Health Lens application utilizes the patient's individual medical history and data, the clinician's plan for that patient (in the form of a semantic query), and publicly available tools that can be automatically selected and appropriately chained-together to analyze and contextually interpret the content of a webpage. The output is an annotated page containing new information specifically relevant to that patient, which is loaded into their browser as usual.

Personalization of Web information necessitates the use of the individual's personal medical profile, since this information can be used to identify both relevant and inappropriate advice within a webpage. There has been considerable work in the area of semantic representation of electronic patient records, both institutional [5] and personal [6], and a variety of different standards exist for the content and structure of these records. Here, we do not intend to prescribe or proscribe any particular standard. This work simply assumes that such health records exist, are accessible to the local browser, and are (or can be) expressed in standard Semantic Web syntaxes. As the various models for electronic health records begin to consolidate, the prototype system could be easily re-written to conform to that standard. For the purposes of this prototype, we created a simple model of the drug-regime portion of the patient's health record, along with several other clinical and personal features.

Much of the prior work in "personalization" of a patient's Web experience has been in the domain of facilitated search, particularly through the use of semantically-backed personal health portals (eg, [3,7]) where the role of semantics in the portal is either for search-expansion to discover additional relevant pages, and/or to simplify medical terminology for the patient while still providing access to complex literature. While portals allow a much higher degree of potential curation by experts, thus (presumably) improving information quality, they also require a much higher level of buy-in from the patient, who must choose to exclusively visit the portal for their health information in lieu of more typical forms of Web exploration such as search engines and browsing. Moreover, though a portal may provide access to a curated or filtered set of pages, the pages themselves are generally untouched; we were unable to identify any personal health portal in which the source pages were, themselves, contextually marked-up. We believe that context is an important part of the personalization experience, as is the freedom to explore the Web in any manner the patient chooses. The Personal Health Lens, therefore, was designed to operate over any page, at any time, discovered in any manner, and places its patient-oriented annotations directly into the page-context. This is achieved by utilizing the semantics—both in the patient's data, as well as in a semantic template query—to generate a contextually-relevant Semantic Web Service-based annotation workflow at the moment the Health Lens is invoked. This workflow may differ depending on the patient's medical information and the content of the page they are viewing, thus providing the flexibility necessary to operate on the open Web, rather than through a curated portal.

We now describe in detail our prototype system that attempts to identify drugs within the online literature that are potentially dangerous to the user based on their personal health record. We begin by giving an overview of the system and a description of the prototype implementation in the Methods section. In the Results section, we demonstrate use of the prototype in the context of a sample health profile. Finally, we discuss some high-level design issues and provide closing remarks in the Discussion section.

Methods

Use of Semantic Web Standards and Technologies

RDF, OWL, SADI, and SHARE

Overview

All data within the Health Lens system were represented using the Resource Description Framework (RDF) model [8], which provides significant advantages over other formats such as Extensible Markup Language XML and ad hoc text formats when integrating data across multiple sources. In particular, RDF allows the assignment of globally unique identifiers (URIs) to all entities within the data, making it possible to match entities across distributed data sets in a reliable manner. Further, RDF supports an automated procedure called RDF-Merge [9] for merging data sets into a single file or database, regardless of the actual content of the data sets involved. This significantly reduced the cost of developing a database for the system, and will also reduce the cost of maintenance when adding new data sources in the future. Finally, in contrast to other data models, RDF data sets are not constrained to a fixed schema. This property of RDF allows any type of statement to be added to an existing data set without adversely affecting clients or servers that use that data set. For instance, in Health Lens, the use of RDF to represent the personal health profile will allow any new type of health data to be added to the profile in the future without requiring an update to the database schema or the interfaces of the various system components.

The Web Ontology Language (OWL) [10] also played a central role in the design of the Health Lens system, providing a general framework for describing and processing logical constraints about RDF data. The chief advantage of using OWL in the context of the Health Lens project is that data matchmaking and validation tasks can be performed by a reusable tool called an OWL reasoner (eg, [11]), rather than by custom, application-specific software.

The Health Lens system utilizes 2 Semantic Web projects that have been built on top of the RDF and OWL standards—Semantic Automated Discovery and Integration, and Semantic Health and Research Environment.

Semantic Automated Discovery and Integration (SADI)

SADI is a set of design patterns for producing stateless Web services that natively consume and produce RDF data. The structure of the input and output data for SADI services are formally described by an input OWL class and an output OWL class, respectively. Further details about SADI are described in [12].

Semantic Health and Research Environment (SHARE)

SHARE is a proof-of-concept Semantic Web query engine that resolves SPARQL Protocol and RDF Query Language (SPARQL, [13]) queries by building and executing workflows of SADI services. SHARE is also capable of discovering instances of a given OWL class by building an appropriate SADI workflow. Further details about SHARE are described in [14].

A Note About Opaque URIs in RDF Data

Many of the URIs in the example RDF data of this paper are opaque, making human interpretation of the data considerably more difficult than if human-readable identifiers had been used. For example, the URI of the “has attribute” predicate of the Semanticscience Integrated Ontology (SIO) ontology [15] is http://semanticscience.org/resource/SIO_000008. The use of opaque URIs is a best practice when the uniqueness of a label for an entity cannot be guaranteed, due to the existence of synonymous labels or labels in multiple languages. By convention, human-readable labels are indicated via the *rdfs:label* predicate. This allows multiple labels to be assigned to the same entity, and also permits changes to the labels without adversely affecting other RDF data sets on the Web that refer to the entity in question. To aid the reader, comments are provided within the example data that provide translations from opaque URIs to human-readable labels.

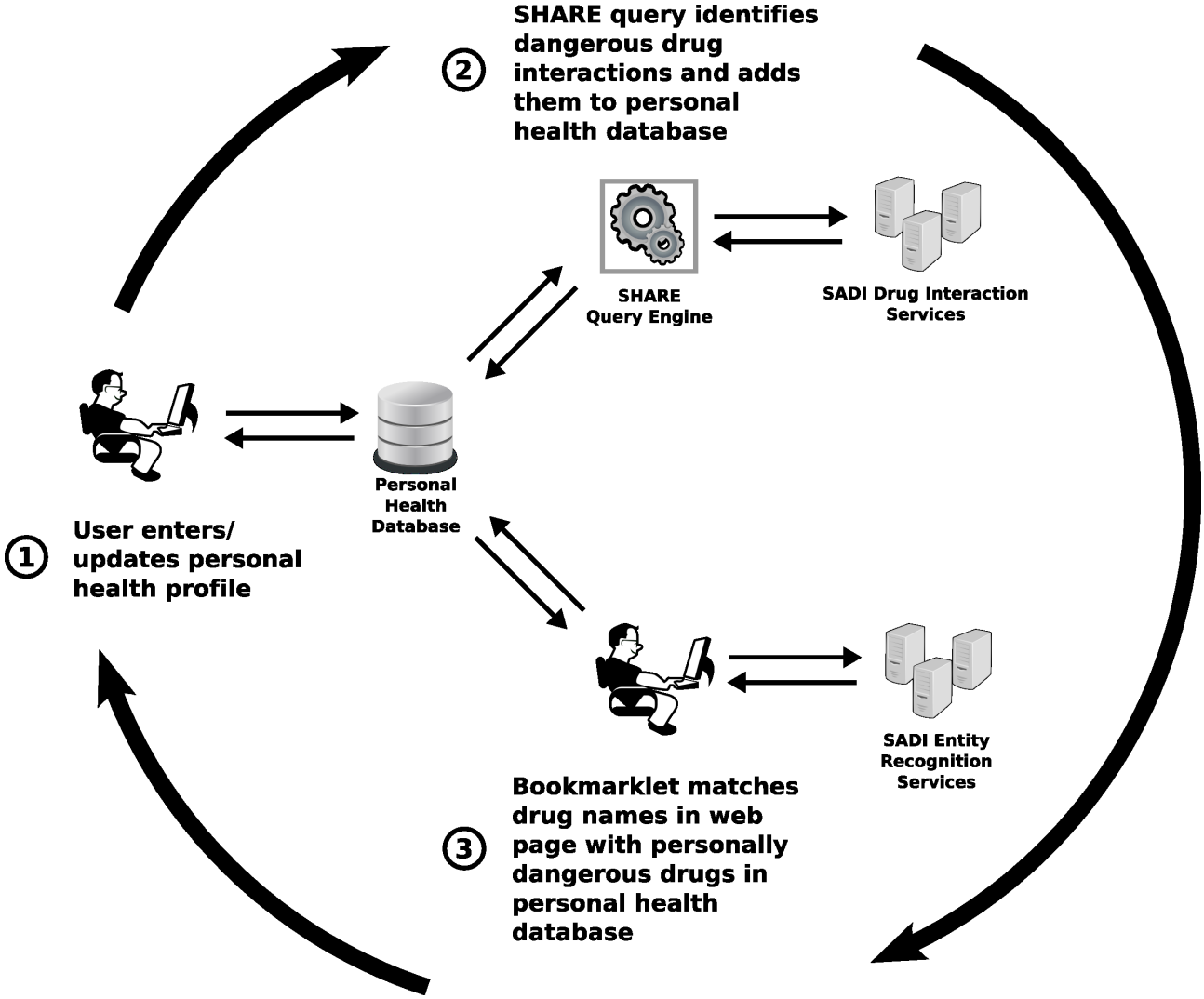
System Overview

The Health Lens system operates in a cycle of 3 steps, as depicted in Figure 1:

1. The user creates or updates his/her *personal health profile*, which is stored locally in the *personal health database*.
2. The system executes a SHARE query to identify dangerous interactions between the user's personal health profile and any known drug. All discovered interactions are aggregated and stored in the personal health database for use in Step 3.
3. From within a Web browser, the user clicks the Health Lens bookmarklet to identify mentions of drugs in the current webpage that may be personally dangerous. The bookmarklet accomplishes this by (a) identifying drug mentions within the text using one or more SADI entity recognition services, and (b) comparing the identified drugs against the list of drugs that have interactions with the personal health profile, as computed in Step 2.

The circular arrows of Figure 1 indicate that Steps 1-3 occur in a repeating cycle; each time the user changes his/her profile (eg, adding a new prescription), Step 2 must be rerun to rebuild the full set of known interactions with the profile.

Figure 1. An overview of the SADI Personal Health Lens system. In Step 1, the user enters or updates his/her personal health profile, which contains information such as sex, age, and current prescriptions. In Step 2, a SHARE query is used to aggregate interactions of any known drug with the user's personal health profile. This query may be time-intensive and is performed as a separate step prior to interactive use of the system. In Step 3, the user browses the Web and clicks the Health Lens bookmarklet when reading a health-related webpage. The bookmarklet identifies drugs mentioned within the webpage using one or more SADI services for entity recognition, and compares those drugs with drugs in the personal health database that are known to be personally dangerous. Finally, the bookmarklet annotates the webpage with appropriate warnings.



Step 1: Creating/Updating the Personal Health Profile

Our prototype implementation of the Health Lens system includes a sample personal health profile (Multimedia Appendix 1). The profile is provided as an RDF/N3 file, and describes a 37-year-old female named Jane Doe who is on a prescription for Alprazolam (Xanax), a member of the benzodiazepine class of psychoactive drugs that is commonly used to treat anxiety disorders.

While the current focus of the profile is drug prescriptions, the use of RDF will allow future extension of the profile to include personal data such as allergies, medical conditions, diet, clinical test results, and genotyping.

Currently, changes to the health profile must be made by editing the RDF/N3 file by hand; however, any future versions of the system will provide a user interface for this task. The schema for the sample health profile uses a combination of Friend of a Friend (FOAF) [16], an ontology for describing people and their relationships, and the SIO [15], an upper level ontology for representing scientific data. The main subject of the profile, Jane Doe, is represented by a blank node ("[ ]") with an *rdf:type* of *foaf:Person*, and this node has a combination of FOAF and DBPedia [17] properties indicating first name, last name, gender, and date of birth. A prescription node is attached to the Jane Doe node by the *med:prescription* property, and this node has attached attributes indicating the prescribed drug, quantity, dosage, and date of prescription.

Step 2: Precomputing Dangerous Drug Interactions

In order to access dangerous drug interactions, we developed a drug-drug interaction (DDI) discovery SADI service. For the backend data, a small data set of approximately 40 known drug interactions with St. John's Wort, a herbal treatment for depression, was constructed manually from the literature. The authors chose to use a hand-constructed data set for the initial version of the project because they were unsuccessful in finding a curated public resource with all of the required details of the interactions, namely directionality, supporting citations, and coded clinical effects. The databases that came closest to

meeting the requirements were DrugBank [18], which describes clinical effects in natural language, the Twosides [19] PharmGKB database, which provides only computationally-predicted interactions, NDF-RT [20], which does not provide access to supporting citations, and the Drug Interaction Knowledge Base (DIKB) [21], which does not describe clinical effects. In future work, the authors may be able to replace the hand-curated St. John's Wort data set with some combination of these resources.

Example input and output data from the DDI service are provided in Multimedia Appendix 2 and Multimedia Appendix 3, respectively. Using the terminology of this example input/output data, the DDI discovery service takes as input a "chemical entity" (Alprazolam) that "has attribute" some "chemical identifier" and outputs an "annotated chemical entity" that "is participant in" some "drug-drug interaction". The provided output data describes a directed drug-drug interaction between St. John's Wort and the input drug Alprazolam, where the direction of the interaction is indicated by assigning the roles of "actor" and "target" to St. John's Wort and Alprazolam, respectively. A citation providing evidence for the interaction is attached via the SIO "has source" property, and the clinical effect of the interaction is attached via the SIO "results in" property. The effect of the interaction itself is represented using a controlled vocabulary term for "decreased efficacy of drug". For clarity of exposition, many long auto-generated URIs (UUIDs) in the real service output data have been replaced by blank nodes in Multimedia Appendix 3, however, the resulting RDF is semantically equivalent.

The Health Lens system invokes the drug interaction service via a SPARQL query (Multimedia Appendix 4) to a local instance of SHARE. The result of this query is the collection of all known interactions between the user's prescribed drugs and any other drug. Using the SHARE system as the client for the drug interaction service had several advantages over implementing application-specific client code. One advantage is that new sources for interaction data can be added to the system in the future simply by adding entries to SHARE's registry of SADI services. Another advantage is that the nature of the conflicts that are discovered by the system can be changed by modifying the SHARE query, rather than modifying the application code. For example, while the current version of the system searches for interactions with prescribed drugs, future versions might also take into account interactions with allergies or specific genotypes.

One caveat of using SHARE system for invoking the DDI service is that running the query can be time intensive. Resolving a SHARE query involves several potentially expensive operations such as downloading ontologies, performing OWL reasoning to match local data to available services, and invoking SADI services over the Web. The Health Lens system therefore runs the SHARE query "offline"; whenever the user creates or updates his/her personal health profile, the query is re-executed and the retrieved interactions are cached in the personal health database. This approach enables the user to scan a webpage and view any resulting warnings in a reasonably short amount of time.

Step 3: Identifying Dangerous Drugs in Webpages

The Health Lens system was integrated with the user's Web browser via a javascript bookmarklet [22]. Whenever the user is reading a health-related webpage, he/she can click the bookmarklet to scan the page for drugs that are potentially dangerous with respect to his/her health profile. The bookmarklet performs the following actions when activated. First, the text of the <*body*> element of the webpage is extracted using jQuery's *text()* function. This text is then substituted into an input RDF template for the entity recognition service (described below) and the service is invoked with an AJAX request. When the service invocation completes, the URIs of the identified drugs are extracted from the output RDF. Next, the URIs of all personally dangerous drugs are obtained by issuing a SPARQL query (Multimedia Appendix 5) against the local personal health database. Finally, the URIs of all personally dangerous drugs are compared with the URIs of drugs returned by the entity recognition service, and any drugs in both of these sets are marked up with appropriate warnings in the page.

As part of the Health Lens prototype, a SADI entity recognition service was created that identifies drug names within plain text. Example input and output RDF data for the service are provided in Multimedia Appendices 6 and 7, respectively. The input data for the service was modeled using a combination of the Bibliographic Ontotology (BIBO) [23] and the Dublin Core (DC) [24] ontology, while the output data was modeled using the FOAF and SIO ontologies. A valid input is an instance of the *bibo:Document* class, with the text content attached via the *bibo:content* predicate and a MIME type of "text/plain" attached via the *dc:format* predicate. The resulting output attaches instances of SIO "chemical entity" to the input document URI via the *foaf:topic* predicate, where each "chemical entity" has attributes indicating the DrugBank [18] identifier and any synonymous drug names. The semantics of *foaf:topic* are slightly stronger than is required in the context of the entity recognition task; however, since we failed to find a more suitable predicate, we followed a weaker interpretation where any object mentioned in the text was considered a topic of the document.

For the business logic of the entity recognition service, we implemented our own drug extraction algorithm based on a dictionary lookup. The dictionary was extracted from the DrugBank database and contains 58,708 entries, where each entry consists of the name of a drug, its DrugBank ID, and its canonical name in DrugBank. Drugs are recognized using the GATE ANNIE Gazetteer lookup tool [25], which loads the dictionary and annotates the text with DrugBank IDs and canonical names. At the final step, annotations of names with length less than 4 characters were filtered from results. The entity recognition service is a prototype and has not yet been evaluated in terms of precision and recall. Although it follows a basic lookup-based approach with naive filtering of candidates, it has shown qualitatively acceptable performance during testing of the Health Lens system.

Results

The authors have provided a downloadable demonstration of the Health Lens system as a standalone executable jar file

(Multimedia Appendix 8). This jar file bundles all components of the prototype system, including the sample personal health profile, the SHARE query engine, the bookmarklet, and the SADI services for drug interactions and entity recognition. Please note that running the prototype requires a Java Runtime Environment (JRE) to be installed on your system.

To start the system the user must execute the jar file, which can be done on most systems by double-clicking the file. Alternatively, the user may run the jar by typing the following at a Linux/Windows/OSX command line prompt: *java -Xmx1g -jar personal-health-lens.jar*. Executing the jar file brings up a console that allows the user to start and stop the system on port 8080. (Please note that the current version of the system will only work correctly on port 8080.) Clicking "Start" starts up the local SADI services and the Joseki server that hosts the personal health database.

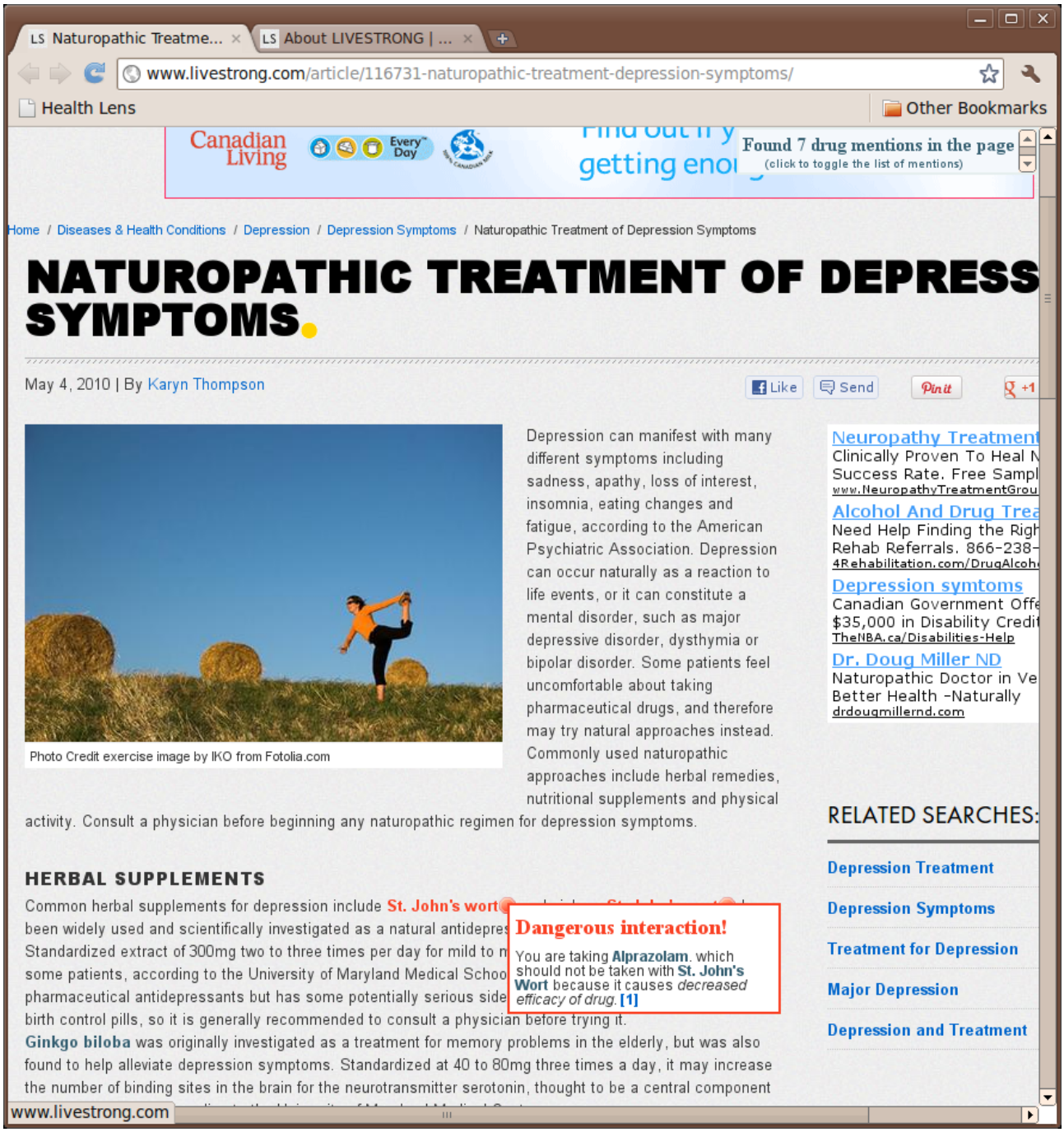
In most environments, the *Start* button will open the installation/testing page for the Health Lens bookmarklet in the user's default Web browser. If this does not happen automatically, the user must instead manually visit *http://localhost:8080/* in a Web browser. The Health Lens bookmarklet can then be installed by dragging one of the two "Personal Health Lens" links near the top of the page onto the browser's bookmarks toolbar.

The webpage at *http://localhost:8080/* can be used to test correct operation of the system. As the content of the test page is under the control of the authors, it provides a reliable means to separate issues with the system components from issues that are specific to the content of particular webpages. To run the bookmarklet against the test page, the user must click the Personal Health Lens bookmarklet in the toolbar, which will activate scanning of the page for dangerous substances. During scanning, an animated SADI logo appears in the top right hand corner of the page. When scanning is complete, the words "St. John's Wort" are colored in red and annotated with a stop sign symbol indicating a dangerous interaction. Clicking on "St. John's Wort" displays a dialog box with the details of the interaction between "St. John's Wort" and the personal health profile, as shown in Figure 2. The warning indicates that St. John's Wort may decrease the efficacy of Alprazolam, a prescribed drug in the user's personal health profile. As evidence, it provides a link to a publication that describes the interaction, which is believed to due to the induction of the CYP3A4 enzyme.

Any webpage may be scanned for personally dangerous drugs by clicking the Health Lens bookmarklet. For example, Figure 3 shows the St. John's Wort warnings in the context of an online article regarding naturopathic treatments for depression [26].

Figure 2. The test page for the Health Lens system, after being scanned with the bookmarklet. St. John's Wort is annotated with a warning due to a conflict with Alprazolam, a prescribed drug in the sample personal health profile. The test page provides a mechanism to verify that all components of the system are working correctly, independently of the varying structure and content of real webpages.

Figure 3. A screenshot of the Health Lens bookmarklet operating on a real webpage. The subject page correctly advises its readers to consult a physician before taking St. John's Wort and mentions a possible interaction with birth control pills. Health Lens augments this information with a warning about an interaction between St. John's Wort and the user's current prescription for Alprazolam.



Discussion

The Personal Health Lens is only one of many tools that have been developed in recent years to leverage personal health data. For example, profile-oriented smartphone applications are now available for identifying allergy-safe foods [27,28], monitoring sleep patterns [29,30], and sharing medical information across physicians and caregivers [31,32]. The use of such personalized tools is likely to continue increasing as new forms of personal health data, such as genotyping and whole genome sequencing, become more readily available to the general public. What makes the Personal Health Lens architecture distinct from other personalization tools is that, in addition to the patient's data and the set of analytical tools, there is a third component—the semantic model/query—which guides the selection of which tool to use given which set of data. Though in this prototype the semantic model was quite simplistic, taking the form of a SPARQL query relating to drug-drug interactions, the SHARE resolution engine is capable of interpreting significantly more complex models, for example, the clinician's treatment trajectory for any given patient. As such, we believe this is the first personal health tool which has the potential for clinician-initiated personalized medical advice to be injected into the patient's own health research browsing activities. Moreover, since the SADI Personal Health Lens has a flexible underlying infrastructure, we believe it can be easily adapted to operate in

combination with many of these existing health-information-support tools to enhance the relevance, detail, or quality of their personalization.

The Personal Health Lens project was intended only as a prototype of a novel framework for patient/practitioner/Web interaction, and was not intended to be used by genuine patients. There are some important factors of the personal profile that are not yet taken into account when detecting relevant interactions, such as sex, age, drug dosages, and drug routes (eg, pills, creams, inhalers), to name a few. Beyond these issues, it is useful to point some general concerns with our approach to health browsing personalization, and possible solutions.

Unlike earlier efforts [7], the Health Lens makes no attempt to evaluate the quality of the information on any given page; "hazardous" pages containing overtly incorrect information are not automatically weeded-out, as they are in other portal-based approaches. If there were a public registry of evaluated webpages, this limitation could be partially overcome by adding that registry's evaluation as part of the annotation pipeline; however, it could not be guaranteed that any page the reader had accessed would exist in that registry. Thus, by ensuring that our systems scales to the Web, we become limited in our ability to filter hazardous or fallacious information. Conversely, the Health Lens system, by not adopting a portal-like structure, becomes a more natural part of the patient's Web exploration, and one that is under their control. Rather than appearing as a centralized "paternalistic" [5] information source, the Personal Health Lens prototype allows the patient to choose when to bring the expert evaluation framework into their Web experience.

Although Health Lens does not attempt to evaluate the quality of information on webpages, information quality is still a relevant issue with respect to the underlying sources of drug interaction data. In this sense, much of the previous work and lessons learned from designing and maintaining portal-based sites such as MedlinePlus [33] could be usefully applied to Health Lens to build a more transparent and trustworthy system. For example, many metrics ("instruments") have been developed for systematically evaluating information quality on webpages that might also be used to evaluate the quality of the drug interaction services. Existing information quality metrics are based on factors such as provision of article metadata (eg, authors, date of last update, supporting citations), accuracy of information, completeness of information, and balanced presentation of evidence [34]; there also exist various composite scoring systems, such as DISCERN [35], that employ weighted combinations of these factors. The criteria of completeness is particularly relevant to the drug interaction data sets, as there exists a potential danger that users will assume a substance is safe in the absence of any warnings about interactions. Building a perfectly comprehensive and up-to-date corpus of drug interaction data is obviously not a feasible goal, especially given the distributed nature of the system. This caveat must be made clear to the end users, and they must be reminded to consult a physician before making changes to their medication regimes, regardless of any warnings that the system does or does not report.

Another area where the system can potentially be improved is in catering to the user's personal level of health literacy. While Health Lens makes no attempt to filter the webpages themselves by literacy level, the user's literacy is still relevant for the appropriate presentation of warnings. Although we have intentionally described interactions in terms of high-level clinical effects (eg, "decreased efficacy of drug"), the supporting citations provided with the interactions are scientific publications and thus require a high level of medical knowledge to understand. In future work, providing references to trusted secondary sources such as MedLine Plus would probably be more appropriate for most users. As with the issues of information quality described above, our approach to accommodating the user's literacy level could likely be informed by previous work. For instance, several ontology-based systems have been developed for automatically mapping expert medical terminology to equivalent consumer-friendly terminology (eg, [36,37]), and these might be employed within Health Lens to generate more accessible warning messages. In addition, many sociological studies have employed metrics based on word complexity and sentence length (eg, the Fry Readability Formula) to gauge readability levels of health-related webpages in a systematic manner [34]. These metrics might likewise be employed within the Health Lens framework to help present supporting documents for interaction warnings at an appropriate level of literacy.

Finally, it is important to note that there is a potential privacy concern relating to the use of a public drug interaction service—the system must send the URIs of the user's prescribed drugs out over the Internet in order to retrieve the relevant interactions. In general, there is a trade-off between the degree of privacy the user wants to maintain and the ability to utilize all possible sources of data for identifying conflicts. In future work, this issue can be addressed by allowing the user to indicate which types of data are safe to send over the Web. In addition, the user might also choose to restrict the system to services that support HTTPS. With respect to privacy, the prototype implementation errs on the side of caution by using a locally hosted drug interaction service.

We believe the SADI Personal Health Lens demonstrates that dynamically-generated, context-sensitive pipelines of data and analytical Semantic Web Services can be usefully applied to the personalization of health information on the Web. Moreover, this approach provides the unique ability to fine-tune these workflows through the utilization of expert knowledge within semantically-encoded guidelines. Thus, for the first time, the Personal Health Lens establishes a framework within which clinicians can provide on-demand guidance during their patient's personal health explorations.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

A sample personal health profile for the Health Lens system.

[Notation3 File, 1KB - resprot_v2i1e14_app1.n3]

Multimedia Appendix 2

Sample input RDF for the SADI drug interaction service.

[Notation3 File, 610B - resprot_v2i1e14_app2.n3]

Multimedia Appendix 3

Sample output RDF for the SADI drug interaction service.

[Notation3 File, 3KB - resprot_v2i1e14_app3.n3]

Multimedia Appendix 4

The SPARQL query issued to the SHARE system, in order to precompute all known drug interactions with the personal health profile.

[SPARQL Protocol and RDF Query Language File, 277B - resprot_v2i1e14_app4.sparql]

Multimedia Appendix 5

The SPARQL query issued by the bookmarklet, in order to obtain personally dangerous drugs from personal health database.

[SPARQL Protocol and RDF Query Language File, 2KB - resprot_v2i1e14_app5.sparql]

Multimedia Appendix 6

Sample input RDF for the SADI entity recognition service.

[Notation3 File, 529B - resprot_v2i1e14_app6.n3]

Multimedia Appendix 7

Sample output RDF for the SADI entity recognition service.

[Notation3 File, 1KB - resprot_v2i1e14_app7.n3]

Multimedia Appendix 8

SADI Personal Health Lens Prototype Java ARchive File [38].

[Java ARchive File, 59MB - resprot_v2i1e14_app8.jar]

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Abbreviations

AJAX: Asynchronous Javascript and XML
BIBO: Bibliographic Ontotology
DC: Dublin Core
DDI: drug-drug interaction
FOAF: Friend of a Friend
JRE: Java Runtime Environment
OWL: Web Ontology Language
RDF: Resource Description Framework
SADI: Semantic Automated Discovery and Integration
SHARE: Semantic Health and Research Environment
SIO: Semanticscience Integrated Ontology
SPARQL: SPARQL Protocol and RDF Query Language
URI: Uniform Resource Identifier
UUID: Universally Unique Identifier
XML: Extensible Markup Language

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Original Paper

Web-Based eHealth to Support Counseling in Routine Well-Child Care: Pilot Study of E-health4Uth Home Safety

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Abstract

Background: Providing safety education to parents of young children is important in the prevention of unintentional injuries in or around the home. We developed a Web-based, tailored safety advice module to support face-to-face counseling in the setting of preventive youth health care (E-health4Uth home safety) in order to improve the provision of safety information for parents of young children.

Objective: This pilot study evaluated a Web-based, tailored safety advice module (E-health4Uth home safety) and evaluated the use of E-health4Uth home safety to support counseling in routine well-child care visits.

Methods: From a preventive youth health care center, 312 parents with a child aged 10-31 months were assigned to the E-health4Uth home safety condition or to the care-as-usual condition (provision of a generic safety information leaflet). All parents completed a questionnaire either via the Internet or paper-and-pencil, and parents in the E-health4Uth condition received tailored home safety advice either online or by a print that was mailed to their home. This tailored home safety advice was used to discuss the safety of their home during the next scheduled well-child visit. Parents in the care-as-usual condition received a generic safety information leaflet during the well-child visit.

Results: Mean age of the parents was 32.5 years (SD 5.4), 87.8% (274/312) of participants were mothers; mean age of the children was 16.9 months (SD 5.1). In the E-health4Uth condition, 38.4% (61/159) completed the online version of the questionnaire (allowing Web-based tailored safety advice), 61.6% (98/159) preferred to complete the questionnaire via paper (allowing only a hardcopy of the advice to be sent by regular mail). Parents in the E-health4Uth condition evaluated the Web-based, tailored safety advice (n=61) as easy to use (mean 4.5, SD 0.7), pleasant (mean 4.0, SD 0.9), reliable (mean 4.6, SD 0.6), understandable (mean 4.6, SD 0.5), relevant (mean 4.2, SD 0.9), and useful (mean 4.3, SD 0.8). After the well-child visit, no significant differences were found between the E-health4Uth condition and care-as-usual condition with regard to the satisfaction with the information received (n=61, *P*=.51). Health care professionals (n=43) rated the tailored safety advice as adequate (mean 4.0, SD 0.4) and useful (mean 3.9, SD 0.4).

Conclusions: Less than half of the parents accepted the invitation to complete a Web-based questionnaire to receive online tailored safety advice prior to a face-to-face consultation. Despite wide access to the Internet, most parents preferred to complete questionnaires using paper-and-pencil. In the subgroup that completed E-health4Uth home safety online, evaluations of E-health4Uth home safety were positive. However, satisfaction scores with regard to tailored safety advice were not different from those with regard to generic safety information leaflets.

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KEYWORDS

child health services; eHealth; counseling; health care evaluation mechanisms; health promotion; Internet

Introduction

Unintentional injury is a major cause of death among young children in Europe and the United States [1,2]. It is also a major source of morbidity and loss of quality of life [3,4]. The most common causes of child mortality and morbidity by injury in and around the home are drowning, poisoning, burns, and falls [1]. Parents can reduce the risk of injuries by applying various safety behaviors. However, necessary safety behaviors are still not taken by a large number of parents, causing unnecessary risk of injury of young children [5-7].

Many countries have installed preventive youth health care, which refers to various activities to improve and protect the health, growth, and development of young people, and also to prevent illness and disability in early life. These activities include a system of maternal and child health care, which serves children from birth to 18 years of age [8]. In the Netherlands, all parents are invited to attend regularly scheduled well-child visits at the preventive youth health care center, free of charge. During these well-child visits growth and development of the children is monitored and relevant health information and vaccinations are provided. In the Netherlands, around 93% of parents attend one or more well-child visits with their child under 4 years of age. The attendance rates may vary from circa 50% to 93% between the specific child-age related scheduled visits [9]. Parents receive health information on several topics, including information about nutrition, growth, and child home safety [10]. Currently this health information is provided to parents by using generic information leaflets that parents receive at regular well-child visits.

With the current strain on health care, greater efficiency is required. Providing health information through the Internet, as an additional source of information, might be beneficial in various ways. For example, tailored safety information can be provided to parents prior to a preventive youth health care visit, and the information gathered by the eHealth module regarding specific safety behaviors can be provided to the physician/nurse to enhance the efficiency of face-to-face counseling, as is done with regard to other health topics, such as nutrition and physical activity [11-14]. However the use of eHealth modules has not yet been evaluated in providing home safety information in the setting of day-to-day preventive youth health care. The application of eHealth in preventive youth health care provides the opportunity of giving individual, tailored information.

eHealth is a "broad, emerging field in the intersection of medical informatics, public health, and business, referring to health services and information delivered or enhanced through the Internet and related technologies" [15]. It is the use of information and communications, especially the Internet, to improve or enable health and health care [16]. eHealth could be used for providing information for parents on several health topics, including information to promote home safety. Because tailored information combined with counseling, which can be provided by using eHealth, is based on the personal situation, parents could find the information more useful than general information materials [17]. Furthermore parents could be inclined to change their behavior, when the information they receive is perceived as personally relevant [18,19].

However, eHealth is currently not extensively applied in preventive youth health care. We developed a Web-based, tailored safety advice module to support face-to-face counseling at preventive youth health care centers (E-health4Uth home safety) to provide safety information for parents of young children [7,20]. By using this eHealth module, parents can prepare for the next well-child visit at the preventive youth health care center, with regard to issues concerning the safety of the child at home [20]. In addition, the health care professional can evaluate the results of the E-health4Uth home safety module prior to or during each visit in order to improve communication with the parents [20]. It is unknown whether such Web-based, tailored information can be fitted within current daily practice, existing organizational goals, and parent-health care professional interactions, which is known to be important for such an eHealth approach to be successful [21].

This pilot study evaluates a Web-based, tailored safety advice module (E-health4Uth home safety) and evaluates the use of E-health4Uth home safety to support counseling in routine well-child care.

Methods

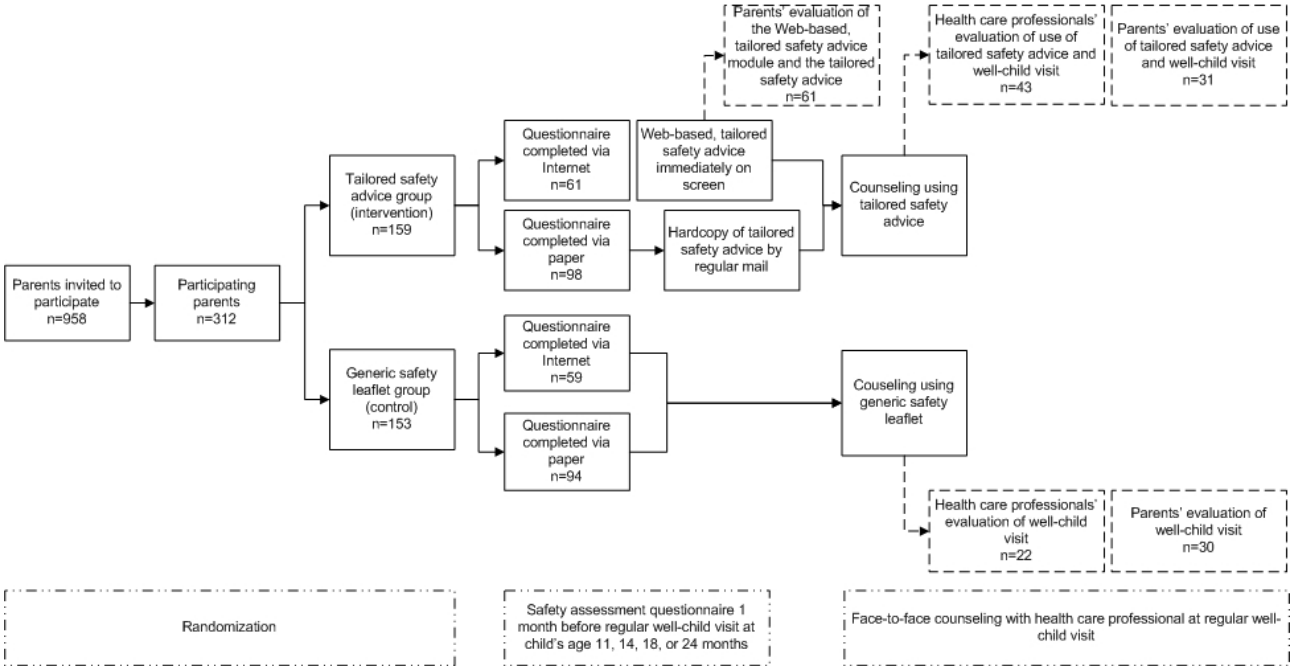
Sample and Setting

Physicians and nurses of 4 preventive youth health care centers situated in the Rotterdam area in the Netherlands participated in this study. These preventive youth health care centers were chosen because of their ongoing collaboration with the Erasmus University Medical Center in Rotterdam. In 2006 and 2007, parents (N=958) were invited to participate in the study one month before their regular well-child visit at the preventive youth health care center at child's age 11, 14, 18, or 24 months. Parents received written information about the study and provided written or online informed consent (checkbox). The Medical Ethics Committee of the Erasmus Medical Center gave a "declaration of no objection" for this study (MEC-2004-256).

Study Design

Parents within each participating preventive youth health care center were randomly assigned to a Web-based, tailored safety advice and counseling group (ie, the E-health4Uth condition), or to a group receiving the generic safety information (ie, the care-as-usual condition, Figure 1).

Figure 1. Study design, participant flow and evaluations.



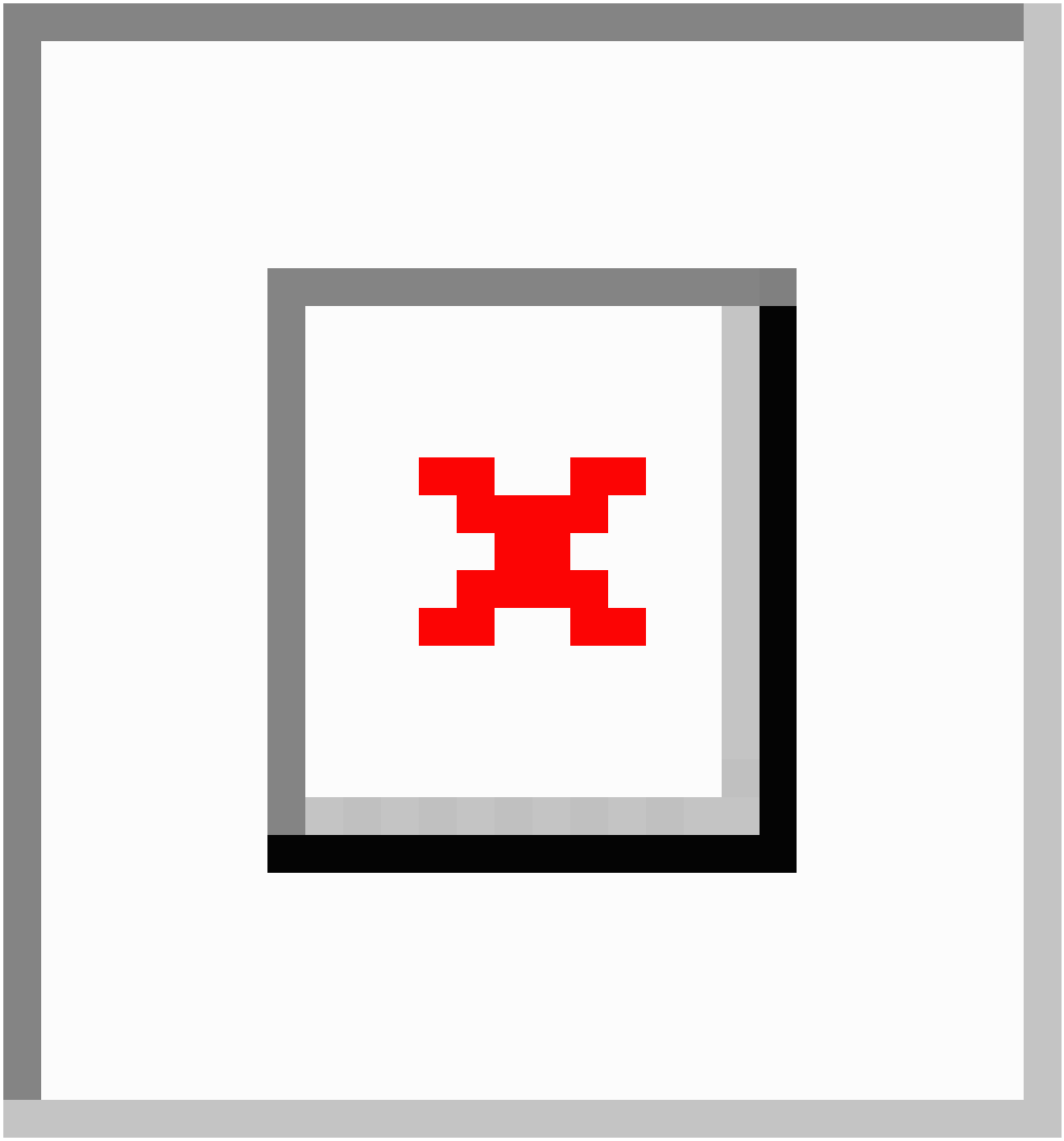
E-health4Uth Home Safety Condition

A Web-based, tailored safety advice module (E-health4Uth home safety) was developed. Parents completed a self-report questionnaire (via the Internet or paper-and-pencil) to assess safety behaviors on the following safety topics: falls, poisoning, drowning, and burns [7]. When a situation was not applicable (eg, when parents did not have stairs in their house), they did not receive any more questions about that subject. After completing this safety assessment questionnaire parents received a tailored safety advice immediately on the screen when completed via Internet. The parents mailed the completed paper-and-pencil questionnaires back to the research center. The responses were entered into the database and a hardcopy of the resulting tailored safety advice was printed and sent to the parents via mail.

When parents failed to practice a particular safety behavior ("unsafe behavior"), they received a tailored message on how they can improve their safety behavior (Figure 2). When parents successfully showed a specific safety behavior ("safe behavior") they received positive reinforcement and no safety advice on that item. The tailored safety messages were based on the guidelines of the Consumer Safety Institute [22]. Table 1 presents the contents and application of the tailored safety advices used in this study.

After completing the safety assessment questionnaire, parents were invited to visit the health care professional of their preventive health care center for their regular well-child visit. All the advice given to parents about safety were copied to the relevant health care professional, in order to enable the discussion of the advice with the parent during the visit. Parents and health care professionals could prepare for the well-child visit by formulating specific questions about the safety situation at home.

Figure 2. Sample page of tailored safety advice.



Care-as-Usual Condition

Parents of the care-as-usual condition completed the same self-administered questionnaire assessing parents' child safety behaviors, either by using the Internet or paper-and-pencil. However they did not receive any tailored safety advice after completing the questionnaire. After completing the safety assessment questionnaire, parents visited the health care professional of their preventive health care center for a regular well-child visit. Parents received a generic safety information leaflet from their health care professional during their regular well-child visit (care-as-usual) [23,24]. This generic safety information leaflet was developed by the Consumer Safety Institute [22]. Each age group was provided with a different information leaflet, divided into 0-6 months, 6-12 months, 1-2 years, and 2-4 years of age. The safety information leaflets contained information on the prevention of injuries in and around the home, divided into general information about the development and environment of the child, and safety advice about the prevention of falls, poisoning, drowning, and burns.

Table 1. Contents and application of the tailored safety advice in the prevention of falls, poisoning, drowning, and burns.

	Applicable if:	Reinforcement with no tailored safety advice, when:	Tailored safety advice when:
Prevention of falls			
Stair gate	The house has a staircase which the child can reach	A stair gate is present and is closed at all times	No stair gate is present A stair gate is present but is not closed at all times
Balcony	The house has a balcony	The child is never left alone on the balcony	The child is left alone on the balcony
Prevention of poisoning			
Cleaning products	Always		
Medicines	Always	Stored above adult chest-height or in a locked cupboard	Stored below adult chest height or in an unlocked cupboard
Prevention of drowning			
Bath tub	The child takes a bath	Child is never left alone in the bath tub	Child is left alone in the bath tub
Swimming pool	The child swims in the swimming pool	Never left alone in the swimming pool	Child is left alone in the swimming pool
Pond	There is a pond in the garden	Always the advice is to fill up the pond	A pond is present
Prevention of burns			
Thermostat-controlled tap	Always	Thermostat-controlled tap present in the bathroom	Thermostat-controlled tap not present in the bathroom
Hot drinks	Always	Child is never on parent's lap when drinking hot liquids	Child on parent's lap when drinking hot liquids
Kitchen	Always	Child is never in the kitchen when the parent is cooking Parent cooks on the back griddle Handles of pans are turned to the back during cooking	Child is in the kitchen when the parent is cooking Parent does not cook on the back griddle Handles of pans are not turned to the back during cooking

Measures

Socio-demographic data and parents' safety behaviors were collected through a self-administered assessment questionnaire completed by the parents. Immediately after receiving the tailored safety advice, the parents (only those in the E-health4Uth condition who used the Internet to complete the questionnaire) were invited to complete a Web-based evaluation form about the tailored safety advice received and the use of the tailored safety advice module.

When parents attended the scheduled well-child visit, they were invited to complete an evaluation form about the well-child visit. Parents in the E-health4Uth condition were specifically asked about the use of tailored information during the face-to-face counseling. The youth health care professionals were also invited to complete evaluation forms regarding the well-child visit, and, if applicable, the use of the tailored information during the face-to-face counseling.

Evaluation items of the tailored safety advice, the Web-based tailored safety advice module, and the well-child visit, were measured on 5-point Likert scales ranging from 1 (most negative evaluation) to 5 (most positive evaluation), unless stated otherwise.

Evaluation of the Web-Based Tailored Safety Advice Module (Immediately After Receiving the Tailored Safety Advice)

Parents of the E-health4Uth condition who completed the Internet version of E-health4Uth home safety, were invited to complete a Web-based questionnaire after having read the tailored safety advice. The questions were: (1) reading of the safety advice (ie, having read the advice completely, partly or not at all), (2) the reliability, understandability, relevance, and usefulness of the tailored safety advice, (3) the ease of use of the module, and (4) the pleasantness of the information source.

Table 2. Characteristics of all parents and by E-health4Uth condition and care-as-usual condition (n=312).

	Total participants n (%)	E-health4Uth condition n (%)	Care-as-usual condition n (%)	*P* value
Family characteristics				
Mean age of respondent in years (range, SD)	32.5 (20-48, SD 5.4)	32.3 (20-48, SD 5.7)	32.8 (20-44, SD 5.1)	.41[a]
Mother is respondent	274/312 (87.8)	139/159 (87.4)	135/153 (88.2)	.83
Non-Dutch mother	83/312 (26.6)	43/159 (27.0)	40/153 (26.1)	.83
Non-Dutch father	82/312 (26.3)	45/159 (28.3)	37/153 (24.2)	.53
Educational level of the respondent is low[b]	54/312 (17.3)	32/159 (20.1)	22/153 (14.4)	.14
Single parent	30/312 (9.6)	15/159 (9.4)	15/153 (9.8)	.82
One child in family	158/312 (50.6)	84/159 (52.8)	74/153 (48.4)	.71
Child characteristics				
Mean age of child in months (range, SD)	16.9 (10-31, SD 5.1)	17.4 (10-30, SD 5.0)	16.5 (10-31, SD 5.3)	.14[a]
Gender child, boys	154/312 (49.4)	80/159 (50.3)	74/153 (48.4)	.73
Child can crawl	303/311 (97.4)	154/158 (97.5)	149/153 (97.4)	.96
Child can pull up to standing	288/311 (92.6)	145/158 (91.8)	143/153 (93.5)	.57
Child can walk independently	221/311 (71.1)	117/158 (74.1)	104/153 (68.0)	.24
Child can climb	211/271 (77.9)	108/137 (78.8)	103/134 (76.9)	.70
Safe and unsafe behaviors				
Risk of falls				.27
Safe behavior	198/312 (63.5)	99/159 (62.3)	99/153 (64.7)	
Unsafe behavior	90/312 (28.8)	44/159 (27.7)	46/153 (30.1)	
Not applicable[c]	24/312 (7.7)	16/159 (10.1)	8/153 (5.2)	
Risk of poisoning				.62
Safe behavior	198/312 (63.5)	103/159 (64.8)	95/153 (62.1)	
Unsafe behavior	114/312 (36.5)	56/159 (35.2)	58/153 (37.9)	
Risk of drowning				.03
Safe behavior	190/310 (61.3)	90/158 (57.0)	100/152 (65.8)	
Unsafe behavior	107/310 (34.5)	57/158 (36.1)	50/152 (32.9)	
Not applicable[d]	13/310 (4.2)	11/158 (7.0)	2/152 (1.3)	
Risk of burns				.03
Safe behavior	14/312 (4.5)	11/159 (6.9)	3/153 (2.0)	
Unsafe behavior	198/312 (95.5)	148/159 (93.1)	150/153 (98.0)	

[a]Mann-Whitney *U*-test

[b]Low educational level: intermediate secondary education or less

[c]Not applicable on falls; when no staircase and balcony is present

[d]Not applicable on drowning; when parents do not bath their child, parents do not go swimming with their child, and no pond is present

Health Care Professionals' and Parents' Evaluation of the Use of the Tailored Safety Advice During the Well-Child Visit

After the well-child visit, health care professionals reported the duration of the visit for both conditions on their evaluation form. Furthermore, health care professionals were invited, directly after each face-to-face consultation, to complete items regarding the following topics: (1) adequacy of the generated tailored safety advice, (2) usefulness of the tailored safety advice during the well-child visit, (3) the rating for the application of the tailored safety advice on a scale from 1 (most negative

evaluation) to 10 (most positive evaluation), (4) whether the information of the tailored safety advice was in accordance with what the parent indicated (yes/no), (5) health care professionals' satisfaction with the information given to the parent, and (6) health care professionals' overall satisfaction with the well-child visit. Health care professionals rated both the use of the tailored safety advice and the well-child visit on a scale from 1 (most negative evaluation) to 10 (most positive evaluation).

In both the E-health4Uth condition and the care-as-usual condition, all parents that attended the scheduled well-child visit, at the end of the visit, were invited to complete items regarding the satisfaction with the safety information they received (tailored or generic), the overall satisfaction with the well-child visit, and the rating for the well-child visit on a scale from 1 (most negative evaluation) to 10 (most positive evaluation). Parents in the E-health4Uth condition completed an additional item on whether discussing the tailored safety advice was a valuable supplement.

Furthermore both parents in the E-health4Uth condition and the care-as-usual condition had to report their intention to change safety in or around the home after the well-child visit (ie, prevention of falls, poisoning, drowning, and burns: yes/no).

Statistical Analysis

Statistical analyses were performed using SPSS 17.0 (SPSS Inc., Chicago, IL, USA).

Frequency tables were used to explore the socio-demographic characteristics of the total study population and of both conditions (E-health4Uth and care-as-usual). The frequency of safe and unsafe behavior on each safety topic was determined. The differences were examined with chi-square tests. Items about the well-child visit and the intention to change safety behavior after the well-child visit were compared between the current method of providing safety information (care-as-usual condition) and the tailored safety advice (E-health4Uth condition). Differences were determined with student's *t* tests. Mann–Whitney *U* tests were used to assess data that were not normally distributed.

Results

Family and Child Characteristics

A total of 312 parents (312/958, 32.6%) provided informed consent and participated in the study—159 parents were assigned to the E-health4Uth condition and 153 to the care-as-usual condition. The mean age of the parents was 32.5 (range 20-48, SD 5.4) years, 87.8% (274/312) of parents were mothers and 17.3% (54/312) of parents had a low educational level (intermediate secondary education or lower). In this study, 90.4% (282/312) of responding families included both parents and 50.6% (158/312) of families had one child. The age of the children ranged from 10-31 (mean 16.9, SD 5.1) months, 49.4% (154/312) of children were boys. Almost all children could crawl (303/312, 97.4%), and 92.6% (288/312) could pull up to standing (Table 2). Unsafe behaviors related to risk of falls were performed by 28.8% (90/312) of the parents, while 36.5% (114/312) of parents performed unsafe behaviors with regard to risk of poisoning, 34.5% (107/312) with regard to drowning, and 95.5% (298/312) of parents performed unsafe behaviors with regard to risk of burns. More parents in the E-health4Uth condition performed unsafe behaviors with regard to the risk of drowning compared to the care-as-usual condition (36.1% vs 32.9%, *P*=.03). More parents in the care-as-usual condition performed unsafe behaviors with regard to the risk of burns compared to parents in the E-health4Uth condition (98.0% vs 93.1%, *P*=.03).

In the E-health4Uth condition, 38.4% (61/159) completed the online version of the questionnaire (allowing Web-based tailored safety advice), while 61.6% (98/159) preferred to complete the questionnaire via paper (allowing only a hardcopy of the advice to be sent by regular mail).

Evaluation of the Web-Based Tailored Safety Advice Module (Immediately After Receiving the Tailored Safety Advice)

All of the parents in the E-health4Uth condition who completed the questionnaire via the Internet completed the Web-based evaluation of the safety advice and the safety advice module, directly after receiving the advice (n=61). Of these, 82.0% (50/61) of parents reported having read their safety advice completely, 13.1% (8/61) of parents read the advice only partly, and 4.9% (3/61) of parents (5%) did not read the advice at all (Table 3). Parents considered the tailored safety advice to be reliable (mean 4.6, SD 0.6), understandable (mean 4.6, SD 0.5), relevant (mean 4.2, SD 0.9), and useful (mean 4.3, SD 0.8). Furthermore, these parents evaluated the Web-based, tailored safety advice module as easy to use (mean 4.5, SD 0.7) and found it a pleasant information source (mean 4.0, SD 0.9).

Health Care Professionals' and Parents' Evaluation of the Use of the Tailored Safety Advice During the Well-Child Visit

We received 65 evaluation forms completed by health care professionals with regard to the well-child visits (43 in the E-health4Uth condition, 22 in the care-as-usual condition) and we received 61 evaluation forms from parents who attended the scheduled preventive youth health care visit (31 in the E-health4Uth condition, 30 in the care-as-usual condition).

The mean duration of the well-child visit, as reported by the health care professionals, was 27.2 minutes (SD 11.1) in the E-health4Uth home safety E-health4Uth condition versus 23.7 (SD 8.0) minutes in the care-as-usual condition (*P*=.32).

Health care professionals who completed and submitted the evaluation forms regarding the well-child visits found discussing the tailored safety advice with the parents to be adequate (mean 4.0, SD 0.4) and useful (mean 3.9, SD 0.4, Table 4). They rated the application of the advice positively (mean 7.3, SD 1.0). Eighty-one percent (29/36) of youth health care professionals reported that the information found in the tailored safety advice was in accordance with what the parent indicated. Health care professionals were satisfied with the information they gave to the parents of both conditions (mean 4.1, SD 0.6 for the E-health4Uth condition and mean 4.3, SD 0.5 for the care-as-usual condition, *P*=.31), and there was also no difference in overall satisfaction of the well-child visit between the

E-health4Uth condition and care-as-usual condition (*P*=.16). Health care professionals rated the well-child visit with parents in the care-as-usual condition slightly higher than that with parents in the E-health4Uth condition (ie, mean 7.8, SD 0.8 vs mean 7.5, SD 0.9 respectively, *P*=.23).

Among parents that attended the scheduled well-child visit and who completed the evaluation forms, parents of both the E-health4Uth condition and care-as-usual condition were satisfied with the information received during the well-child visit (mean 3.7, SD 0.8 and mean 3.4, SD 1.3, respectively). Discussing the tailored safety advice with the youth health care professional was a valuable supplement to the well-child visit (mean 3.4, SD 1.3). No significant difference was found in satisfaction between the E-health4Uth condition and care-as-usual condition (*P*=.51). Parents in both the E-health4Uth condition and care-as-usual condition gave the well-child visit a mean rating of 8.0.

More parents in the E-health4Uth condition showed intentions to change safety in or around the home with regard to the prevention of falls (43.3% vs 18.5%, *P*=.04), the prevention of poisoning (53.6% vs 29.6%, *P*=.07), the prevention of drowning (35.7% vs 14.8%; *P*=.08), and the prevention of burns (57.1% vs 22.2%, *P*=.008) compared to parents in the care-as-usual condition.

Table 3. Parents' evaluation of the tailored safety advice and the Web-based, tailored safety advice module (n=61).

Reading of the Web-based, tailored safety advice	**n (%)**
Have read their advice completely	50/61 (82.0)
Have read their advice partly	8/61 (13.1)
Have not read their advice	3/61 (4.9)
Tailored safety advice	**Mean (SD)**
Was the safety advice reliable?[a]	4.6 (0.6)
Was the safety advice understandable?[a]	4.6 (0.5)
Was the safety advice relevant?[a]	4.2 (0.9)
Was the safety advice useful?[a]	4.3 (0.8)
Web-based, tailored safety advice module	
Was the module easy to use?[a]	4.5 (0.7)
Was the module a pleasant information source?[a]	4.0 (0.9)

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

Table 4. Health care professionals' and parents' evaluation of the well-child visit and the use of the tailored safety advice during the well-child visit (if applicable).

	E-health4Uth condition	Care-as-usual condition	*P* value
Health care professionals:	**Mean (SD) n=43**	**Mean (SD) n=22**	
Was discussing the safety at home adequate?[a]	4.0 (0.4)	NA[c]	
Was the tailored safety advice useful to discuss during the well-child visit?[a]	3.9 (0.4)	NA[c]	
Rating for the application of the tailored safety advice[b]	7.3 (1.0)	NA[c]	
Was the information of the tailored safety advice in accordance with what the parent indicated? n (%)	29/36 (80.6%)	NA[c]	
Satisfaction with information given[a]	4.1 (0.6)	4.3 (0.5)	.31[d]
Overall satisfaction with the well-child visit[a]	4.2 (0.4)	4.3 (0.4)	.16[e]
Rating for the well-child visit[b]	7.5 (0.9)	7.8 (0.8)	.23[d]
Parents:	**Mean (SD) n=31**	**Mean (SD) n=30**	
Satisfaction with information discussed[a]	3.7 (0.8)	3.4 (1.3)	.51[d]
Was discussing the tailored safety advice valuable supplement?[a]	3.4 (1.3)	NA[c]	
Overall satisfaction with the well-child visit[a]	4.4 (0.5)	4.4 (0.5)	.92[d]
Rating for the well-child visit[b]	8.0 (1.2)	8.0 (0.9)	.92[d]
Intention to change safety behavior in or around the home after the well-child visit, in the prevention of:	**n (%)**	**n (%)**	
Falls	13/30 (43.3)	5/27 (18.5)	.04[f]
Poisoning	15/28 (53.6)	8/27 (29.6)	.07[f]
Drowning	10/28 (35.7)	4/27 (14.8)	.08[f]
Burns	16/28 (57.1)	6/27 (22.2)	.008[f]

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

[b]Scores from 1 (most negative evaluation) to 10 (most positive evaluation)

[c]Not Applicable

[d]Chi square

[e]Student's *t*-test

[f]Mann-Whitney *U*-test

Discussion

Principal Results

In the present pilot study, we evaluated a Web-based tailored safety advice and the application of an eHealth module compared to the use of generic safety information leaflets in well-child visits. This pilot study showed that although the tailored safety advice and the E-health4Uth module turned out to be positively evaluated, the majority of parents declined to complete the online questionnaires that enabled online tailored safety advice, and preferred to use paper-and-pencil to complete the questionnaires. This diminishes the convenience of the use of Internet to deliver online tailored safety information. In the small subgroup of parents that attended the scheduled well-child visits and those that completed the evaluation form after the visit, the ratings regarding satisfaction in the E-health4Uth condition were equal to those in the care-as-usual condition, stating that parents have no preference with regard to the method of providing safety information during the well-child visit. However, among these parents, more parents in the E-health4Uth condition reported a favorable intention to change the safety situation in and around the home compared to parents in the care-as-usual condition.

Limitations and Considerations

In this study, the participation rate (312/958, 32.6%) was relatively low. One reason for the low participation rate could be the lack of sending reminders. There is no data available on the characteristics of parents who did not wish to participate in this study. Baseline characteristics show that in the study population, over 90% of children were living in a two-parent home. In the general population of the Netherlands, the percentage of two-parents homes is comparable with the numbers we found in our study [25]. The relatively low participation rate might limit the generalizability of the results.

Slightly more parents in the E-health4Uth condition carried out unsafe behaviors with regard to the risk of drowning compared to the care-as-usual condition and slightly more parents of the care-as-usual condition behaved unsafe with regard to the risk of burns compared to parents of the E-health4Uth condition. Given the random allocation to both conditions, this was a chance finding.

All parents who provided informed consent completed the safety behaviors questionnaire, either by using Internet or by paper-and-pencil; and all parents in the E-health4Uth condition who completed the online questionnaire, provided answers to the evaluation form regarding the online tailored safety advice. However, relatively few evaluation forms from both parents (n=61) and professionals (n=65) were collected after the scheduled preventive youth health care visit. At the time of the study, there was no digital database regarding the preventive youth health care visits; so we were unaware whether the scheduled visits were realized or not. Furthermore, the empty form (that should have been completed) might have been missing in the dossier of the child (due to logistical problems), or the parent/professional did not want to complete the form. There was no significant difference in parent and child characteristics between parents who did and who did not complete the evaluation (P>.05, data not shown).

For the present study, since most well-child visits did not involve a vaccination (which is in the Netherlands associated with a high attendance), we might assume that circa 50% of the invited parents attended the scheduled visit. If this was the case, only circa 4/10 evaluation forms after the visits were collected. In future studies, we recommend the use of digital patient files to record attendance to the scheduled visits and the topics that were discussed during these visits. Brief evaluation questions may be integrated in such digital patient files with informed consent from the study participants. In the present study the results with regard to the evaluations after the preventive youth health care visits should be interpreted with utmost care, since non-response bias may have occurred, and given the relatively low numbers of completed forms. Furthermore, the evaluation of the well-child visit could depend on more items than just the ones we measured in this study.

Over 60% of parents preferred completing the safety behavior questionnaire by paper-and-pencil. In the E-health4Uth condition, this meant that less than 40% of participants could benefit from the online tailored safety advice. In this study, a hard copy of the tailored advice was generated after data-entry of the paper-and-pencil questionnaire results and mailed to both parent and health professional. This is however time consuming, costly, and diminishes the convenient nature of using the Internet to deliver online tailored safety information. According to Statistics Netherlands, the number of Internet connections in the Netherlands was 80% during the time of the study, rising to 94% in 2011 [25]. Lack of Internet connections does not fully explain why parents preferred to complete the health behavior questionnaire by using paper. Apparently, the majority of parents did not highly appreciate the possibility of online tailored advice. On the other hand, the parents that did complete the online version of E-health4Uth home safety read the advice and provided favorable ratings. We recommend, however, developing strategies to improve the uptake of eHealth applications and the perceived benefits of online tailored information in the practice of preventive youth health care by involving both parents and professionals.

One element may be to increase the perceived benefits from online tailored advice as opposed to current generic advice (most often provided as leaflets during well-child visits). This study showed, unexpectedly, a lack of difference between levels of satisfaction regarding tailored safety information provided between the E-health4Uth module and the generic safety information leaflet. We saw that parents were highly satisfied with both the current generic version as well as the tailored safety information, which implies that parents might not have a preference for either method. Safety information is only one topic in preventive youth health care. When the E-health4Uth module covers more relevant topics in the future, more advantage may be gained by providing tailored advice. We recommend involving both panels of parents and health professionals in such developments, in order to achieve maximum profit for the target audience of such eHealth tools. The current pilot study shows that a high uptake, let alone higher appreciation of tailored advice compared to high-quality generic advice cannot be taken for granted.

Although the difference was not statistically significant, the well-child visit lasted slightly longer in the E-health4Uth condition compared to the care-as-usual condition. The youth health care professionals reported a significantly longer duration of the visit in the E-health4Uth condition when a Web-based, online tailored information was generated and provided to both parent and professional (n=21, mean 31.4 minutes, SD 11.8) compared to when parents completed the questionnaire online and a hard copy of the advice was generated and provided to both parent and professional (n=22, mean 23.1 minutes, SD 8.8, P=.01, data not shown). For practical reasons we suppose the online generated tailored advice was more likely to be available at the moment of the health visit to both professional and parent, compared to the hard copy that had to be generated and mailed. Presence of the tailored advice might trigger more and longer discussions between parent and professional. Although this may be beneficial from the viewpoint of behavior goals to be attained, the duration of visits after provision of online tailored advice requires attention in future projects for logistical and financial reasons.

The current study, although in a relatively small, and potentially biased subgroup, illustrated that the tailored advice may induce more intention to change behaviors in a favorable direction. This supports favorable results from early initiatives [20,26]. To determine whether the Web-based tailored safety advice is more effective to promote parents' child safety behaviors compared to generic advice using information leaflets, it is recommended that an effect-evaluation of E-health4Uth home safety is performed [27,28].

Conclusions

There are many potential benefits of gathering health and health behavior data [29-31] and providing tailored information and support through eHealth in preventive youth health care. Online information sources and algorithms to generate tailored

information can be easily updated, and wide-scale distribution can be arranged at relatively low cost. However, given the fact that the majority of parents did not accept the invitation to complete E-health4Uth home safety online and preferred paper-and-pencil instead, we recommend developing strategies to improve the uptake of eHealth applications and the perceived benefits of online tailored information in the practice of preventive youth health care by involving both parents and professionals. An example could be that parents are unaware of the benefits of tailored health information, due to lack of knowledge about this way of providing information. This lack of knowledge could lead to the fact that parents rather choose the regular approach in receiving health information, ie, with generic leaflets. Health care professionals could explain the goals and benefits to parents, so parents can better choose between these two forms of information provision. To examine why parents may not prefer an eHealth intervention, an overview of the advantages and disadvantages of the eHealth intervention by users could be collected, for instance how to deal with privacy issues.

Tailored information has the potential to be more effective in realizing favorable health behaviors compared to generic information, but not all potentially effective elements were already included in the prototype in this study. The current Web-based, tailored safety advice module and the use of the safety advice during the well-child visit could be extended using personal cognitive factors, social factors, or parents' barriers to show safety behavior [32].

Changing behavior is difficult, requiring time, effort, and motivation. Health care professionals could benefit from techniques to help them motivate parents to change their behavior. Previous research has shown positive effects of motivational interviewing on health behavior [33-35]. Motivational interviewing provides techniques that can be applied by health care professionals to promote safe behavior. Motivational interviewing could be applied to the discussion of the tailored safety advice by the health care professional with the parent [36].

We propose future effect-evaluations of tailored safety advice, by exploring whether tailored safety advice is more effective on parents' child safety behaviors compared to generic safety leaflets. When proven to be effective, eHealth combined with personal counseling could also be used in health promotion on multiple other areas relevant for prevention such as nutrition, physical activity, or sleep. It may be useful for parents to prepare themselves for the well-child visit and to formulate specific questions on these topics. Furthermore eHealth could help parents and youth health care professionals to focus on issues that need further attention.

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Conflicts of Interest

None declared.

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Original Paper

Usability Evaluation of an Online, Tailored Self-Management Intervention for Chronic Obstructive Pulmonary Disease Patients Incorporating Behavior Change Techniques

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Abstract

Background: An eHealth intervention using computer tailored technology including several behavior change techniques was developed to support the self-management of chronic obstructive pulmonary disease patients.

Objective: The goal of this study was to evaluate and improve the usability of the eHealth intervention.

Methods: We conducted a usability evaluation with 8 chronic obstructive pulmonary disease patients, with a mixed methods design. We improved the usability through iterative cycles of evaluation and adaptation. Participants were asked to think aloud during the evaluation sessions. Participants then completed a semi-structured interview. The sessions were observed and recorded. Descriptive statistics and content analysis were used to uncover usability issues.

Results: Areas for improvement were layout, navigation, and content. Most issues could be solved within 3 iterations of improvement. Overall, participants found the program easy to use. The length of the program urged us to further analyze the appreciation of behavior change techniques. Some were perceived as helpful and easy to use, while others evoked frustration.

Conclusions: The usability study identified several issues for improvement, confirming the need for usability evaluation during the development of eHealth interventions. The uncovered strengths and limitations of behavior change techniques may lead to optimization of eHealth interventions, but further insight is needed.

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KEYWORDS

usability testing; Internet intervention; computer tailoring; chronic obstructive pulmonary disease; self-management

Introduction

Chronic obstructive pulmonary disease (COPD) is one of the major causes of morbidity and mortality worldwide [1]. COPD patients suffer a progressive deterioration of respiratory function along with significant systemic consequences [2]. Although the airflow limitation is not fully reversible, hospital admissions can be reduced and health-related quality of life can be improved by adequate patient self-management [3,4]. Self-management interventions should focus on behavior modification, such as

smoking cessation, physical activity, and medication adherence, in order to attain improvement in health status [5]. Many home-based disease management programs have been developed to improve the health of chronically ill patients [6] including COPD patients [7]. These programs make use of eHealth.

EHealth interventions have become quite popular in number and reach. They are accessible over the Internet or mobile technologies and can offer information to support health-related behavior change to large population segments at any time with decreased personnel demands [8]. Especially the usage of computer-tailored technology for patient education and changing lifestyles is becoming increasingly popular in eHealth programs. Computer-tailored technology has been shown to effectively support behavior modifications [9,10]. For example, smoking cessation studies by Strecher et al [11] and Te Poel et al [12] showed higher continued abstinence rates in the group that received a Web-based tailored smoking cessation intervention compared to the control group. Computer tailoring principles can also be applied for changing multiple behaviors [13,14]. By tailoring feedback messages to a person's responses, messages become more personalized and matched to key theoretical determinants of the behavior and characteristics of the person [15,16]. For example, a smoking relapse prevention program of Elfeddali et al [17] used name, gender, and motivational characteristics, such as perceived pros and cons of not smoking, levels of self-efficacy, and perceived stress. Personalization and adaptation of computer-tailored messages result in increased attention, appreciation, and processing of information [14,16].

Despite the growing popularity of eHealth interventions, it is very common for users who experience difficulties with the program to discontinue program use or drop out of a study before completion [18,19]. A critical factor for the uptake and retention of consumers for these programs is a high quality user-centered design [19]. To make a program efficient, effective, and satisfying to use, a usability study on the program can be conducted [20,21]. Usability studies enable developers to discover problems with the program and to explore end users' experiences. In many practical usability engineering situations where it is not necessary to collect quantitative data for benchmark purposes, it is possible to gain sufficient insight with a small test group [22]. Iterative cycles of evaluation and adaptation can be followed to obtain this information to improve the prototype and increase its user-friendliness [20,23].

In the MasterYourBreath project (AdemDeBaas in Dutch), a computer-tailored program is accommodated to support self-managed behavior change of COPD patients. This paper reports findings from one of the first phases of this project—the evaluation of the usability of the program. A pragmatic approach was followed, with 3 iterations of detection and resolution of usability problems.

Methods

Design

This was an exploratory study with a mixed methods design. The study contained a usability evaluation with an iterative design to assess and improve the user-friendliness of the program. In addition, research was carried out to examine end users opinions on the behavior-change techniques (BCTs) integrated in the program.

Recruitment

We recruited 8 Dutch speaking COPD patients from the Maastricht region, the most Southern part of the Netherlands. All participants were capable of using a computer. To create a heterogeneous sample of COPD patients, half the patients were recruited through their family doctor and the other half through flyers in the Maastricht University Medical Center.

Ethical Considerations

This study was in accordance with all applicable regulations and was approved by the Medical Ethical Committee of Maastricht University Medical Center. All participants received an information letter about the study and participated in an informed consent procedure with a researcher. All participants received a gift voucher after the evaluation session.

Prototype Description

The prototype described in this paper was a further development of existing computer-tailored programs for behavior change, originally developed for public health research. The Internet application Tailorbuilder (OverNite Software Europe, Sittard, NL) based on Perl and a MySQL5 database served as a container for domain-specific knowledge such as routing procedures, tailoring rules, and feedback messages.

The kernel of the program is a reasoning engine, which is based on the I-Change Model for behavior change [24,25]. It incorporates 8 BCTs in a predefined order (Table 1, [26,27]). Researchers can enter domain-specific knowledge about smoking cessation, physical activity, and other desired behaviors. This knowledge will be captured into specific questions, rules, and advices. Via a Web interface, patients and other users can access the program to seek advice. They can choose between different modules, including a general assessment module for health risk appraisal and 3 modules targeted to change specific behaviors. These behaviors are smoking cessation, medication adherence, and physical activity.

So far, the program has only been used in the general population. The modules for smoking cessation and physical activity were based on earlier projects [14,25] and were adapted for the COPD target group. The medication module was developed specifically for the MasterYourBreath project.

Table 1. BCTs defined by Michie et al [27].

BCTs used in this prototype	Definition
1. Provide information on consequences of behavior in general	Information about the relationship between the behavior and its possible or likely consequences in the general case, usually based on epidemiological data, and not personalized for the individual (contrast with technique 2).
2. Provide information on consequences of the behavior to the individual	Information about the benefits and costs of action or inaction to the individual or tailored to a relevant group based on that individual's characteristic (ie, demographics, clinical, behavioral, or psychological information). This can include any costs or benefits and not necessarily those related to health (eg, feelings).
3. Provide information about others' approval	Involves information about what other people think about the target person's behavior. It clarifies whether others will like, approve, or disapprove of what the person is doing or will do.
4. Goal setting (behavior)	The person is encouraged to make a behavioral resolution (eg, do more exercise next week). This is directed towards encouraging people to decide to change or maintain change.
5. Barrier identification/problem solving	This presumes having formed an initial plan to change behavior. The person is prompted to think about potential barriers and identify the ways of overcoming them. Barriers may include competing goals in specified situations. This may be described as problem solving. If it is problem solving in relation to the performance of a behavior, then it counts as an instance of this technique. Examples of barriers may include behavioral, cognitive, emotional, environmental, social, and/or physical barriers.
6. Provide feedback on performance	This involves providing the participant with data about their own recorded behavior or commenting on a person's behavioral performance or a discrepancy between one's own performance in relation to others'.
7. Plan social support/social change	Involves prompting the person to plan how to elicit social support from other people to help him/her achieve their target behavior/outcome. This will include support during interventions (eg, setting up a buddy system or other forms of support and following the intervention including support provided by the individuals delivering the intervention, partner, friends, and family).
8. Prompt identification as a role model/position advocate	Involves focusing on how the person may be an example to others and affect their behavior (eg, being a good example to children). Also includes providing opportunities for participants to persuade others of the importance of adopting or changing the behavior (eg, giving a talk or running a peer-led session).

Prototype Walkthrough

A typical scenario for using the program is as follows. After logging in to the program for the first time, participants filled out the assessment module, measuring smoking behavior, medication adherence, and physical activity. The assessment module consisted of demographical questions, questions to assess smoking behavior, the Fagerström Test for Nicotine Dependence [28], the Medication Adherence Report Scale (MARS-5) [29] to assess medication adherence, the Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH) [30] to assess physical activity, and questions assessing the stages of change [31] and intention to change these 3 behaviors on a Likert scale. This questionnaire elicited health risk appraisal feedback, which contained information on the users' lifestyle.

When participants logged in the second time, they were invited to choose from one of the behavior modules. The module started with the assessment of the motivational beliefs toward a particular behavior. Responses then generated tailored feedback. Consequently, the program assessed social influence on the behavior and provided feedback. Plans for behavior change were then assessed and tailored to the feedback in an action planning step. Finally, the program attempted to improve self-efficacy by identifying barriers participants experienced when changing or maintaining the behavior and by assessing plans that participants made to overcome these barriers. This yielded feedback on the identified barriers and approaches to overcome them. See Table 2 for an overview of the program including the BCTs used per intervention component.

Table 2. BCTs used in the program.

Users actions	Intervention components	BCTs integrated in the intervention components[a]
Users fill out the assessment module and receive health risk appraisal feedback	Questionnaire assessing demographics, intention for behavior change, stages of change, and a health risk assessment. Health risk appraisal feedback was based on the outcomes of the assessment.	1, 6
Users receive feedback in one of the modules (smoking cessation, physical activity, or medication adherence)	Motivational beliefs	1, 2
	Social influence	3, 7, 8
	Action planning	4
	Self-efficacy	5

[a] These steps correspond to those shown in Table 1.

Procedure and Data Collection

All evaluation sessions took place in a laboratory setting at Maastricht University Medical Center, except one, where a participant was visited at home due to his medical condition. The test scenario for the users was to log on, follow the instructions presented in the program, and complete the program. A test script for the moderator was written out in detail. Analysis guidelines were written out in advance. Prior to starting the usability study, the procedure was pretested on one individual, who was not participating in the usability study and not diagnosed with COPD, to ensure that all aspects of the usability evaluation would function adequately.

The study was performed in successive series of individual tests. For each series we asked 5 test subjects, or less if saturation was reached. We planned for 3 series, with the possibility to proceed should new usability problems arise continually. All series were conducted by the same moderator and observer, and both were not involved in the development of the program. The moderator guided the participants through the test but did not intervene or disrupt the thinking process. She would only provide help if participant explicitly requested help to proceed with the tests. Both the moderator and the observer noted the problems participants encountered.

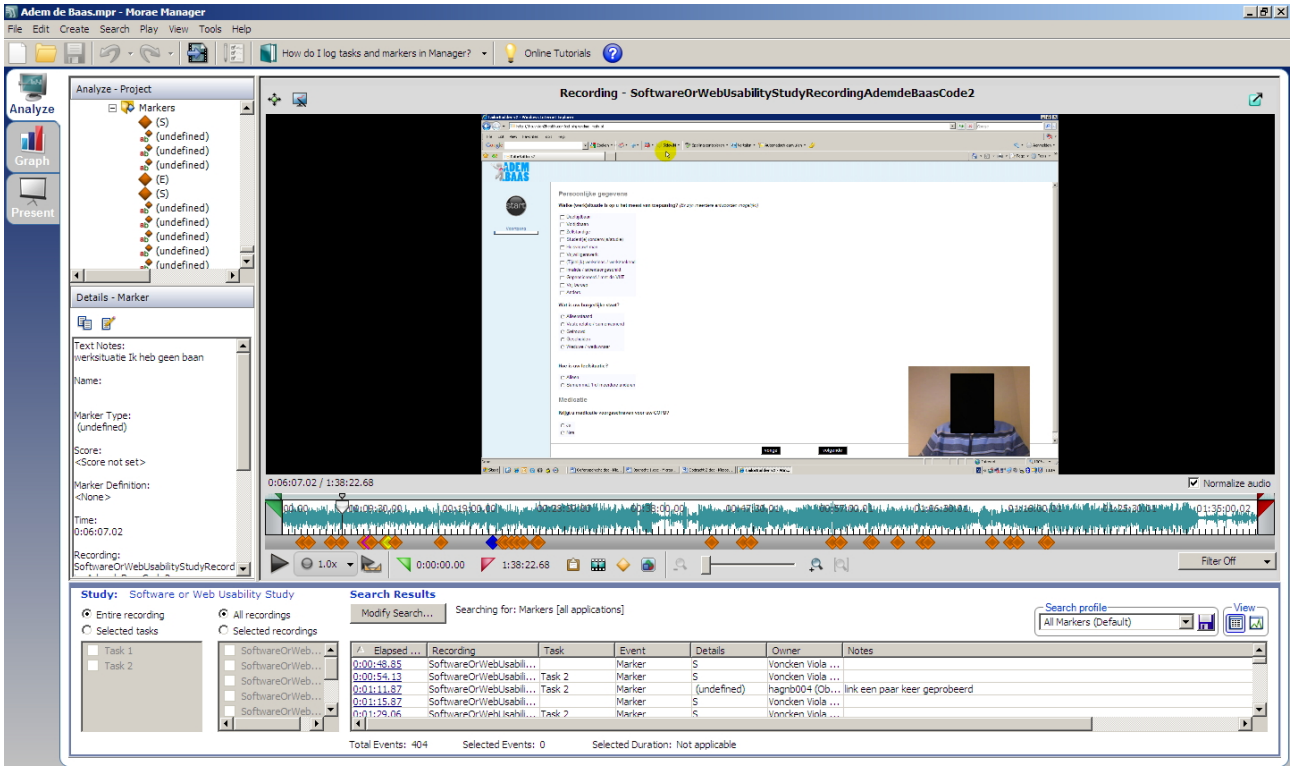
Participants were asked to perform 2 tasks, which were the same as those that would be performed by future program users. The first task was to go to the website, log on, and complete the assessment module to receive health risk appraisal feedback. The second task was to complete one of the modules aimed at changing a specific behavior. Within each task, the users had no freedom of navigation, which assured that every participant encountered the same elements of the program. The think aloud method was used to assess participants' reasoning and the source of their problems while using the computer program [32]. Participants were asked to verbalize their thoughts while performing the tasks. We emphasized that the intention was to evaluate the program and not the participants' behavior, in order to encourage participants to talk freely. Because thinking aloud is an unusual task, participants were given one chance to practice this task. Morae video-analytic software (TechSmith Corporation, Okemos, MI, USA) was used to capture screen display, mouse clicks and participants' verbal comments along with nonverbal reactions using a webcam. This allowed the moderator and observer to review the sessions to identify problems that were missed during the sessions. Figure 1 shows a screenshot of a recording of the pretest.

In the last step of each session, participants were interviewed about their experiences with the tasks and their prior computer experience. At the end of the interview, the users were asked to rate the program on a scale from 0 to 10, with 0 being very bad and 10 being excellent. The observer took field notes and composed a descriptive summary from each interview.

Analysis

Descriptive statistics (ie, median and range) for task completion rate, completion time, program rating, and demographical characteristics of participants were computed. To uncover usability issues, the think aloud data, keystrokes, and mouse clicks were reviewed by both the observer and the moderator. They independently placed markers in the video recordings at times that participants encountered problems during task performance or commented on the content of messages. These markers, along with descriptive summaries, field notes, and the interviews, were used to identify the problems participants experienced working with the prototype. Quantitative criteria for usability problems were completion time, number of help questions, and number of errors. For the qualitative data, a content analysis approach was used [33]. Observer and moderator together grouped these problems into 3 categories (content, layout, and navigation) and identified the major problems from the list of problems. Major problems were system errors, problems that repeatedly occurred, problems that caused user irritation, and problems that were recalled by the user in the interviews. All other marked problems were labeled as minor problems. When no new major problems were identified by a participant, the results were used for program refinement. This process was repeated in the following rounds, until saturation was reached. The observer and moderator met frequently to discuss findings, interpretations, and data synthesis.

Figure 1. Screenshot of a recording.



Program Improvement

After each evaluation round, the detected problems of major importance were further classified into 2 groups. These groups were problems that could be solved with simple solutions implemented by the research team quickly before the next round of usability evaluation, and problems that required complex solutions. The solutions to the more complex problems had to be implemented by the vendor of the system, therefore these items were put on a wait list for a future upgrade.

Results

Participant Characteristics

The tests were conducted in 3 series. In the first round, 4 participants were tested, 2 in the second round, and 2 in the third round. Of the participants, 4 were recruited by their family doctor and 4 from the hospital. The ages of the 8 participants ranged from 51-70 years, (median 59.5). There were 5 male and 3 female participants. The education level of the participants varied—5 had a high level of education, 2 had an intermediate level, and 1 a low level of education. Internet experience ranged from 5-20 years, while current computer use varied from 3-21 hours per week. None of the participants were familiar with the prototype that was evaluated. The severity of disease ranged from mild COPD to very severe COPD, needing oxygen therapy.

Usability Issues

The completion time of both tasks together varied from 42-120 minutes with a median of 67 minutes (71 minutes in round 1, 82 minutes in round 2, 59 minutes in round 3). Filling out the assessment module and receiving the health risk appraisal feedback (task one) took less time (15-39 minutes, median 29 minutes) than completing one of the modules aimed at changing a specific behavior (22-84 minutes, median 40 minutes). Completion rate was 100% in all cases. The number of help questions per participant varied from 0-2 (median 1) and the number of errors from 0-6 (median 1). Participants in the third round had the least usability problems, with only 1 help question (font size) and 1 navigation error (scrolling).

The participants' rating of the program ranged from 6-9 on a 10-point scale (median 7.75). They were generally satisfied with the layout of the program. All participants were able to navigate through the program with minimal interference of the observer. During the interviews participants commented that the program was overall easy to navigate and the content was comprehensible. Nonetheless, suggestions for improvement were made. Analysis revealed specific problems in 3 domains: layout, navigation, and content. These problems and the changes we made after each round of testing are explained below and the major problems are summarized in Table 3. In the third round only some new minor problems arose as major problems reached saturation.

Layout

Most participants in the first round overlooked the information regarding the option of increasing the font size. As a solution, we improved the visibility of this instruction by repositioning it to the top left hand corner of the page, adding a title and increasing the font size of the instruction. All participants in the next round of testing noticed it.

Another problem concerned filling out a question matrix. A participant clicked in the wrong check box, which led to incorrect answers. This problem was solved by leaving a blank line after every 3 lines of questions with answer options.

A minor problem was uncovered in the third round of testing and related to the utilization of the unfolding questions. An unfolding question is a question that appears only when a certain answer is given to the previous question. The position of these questions confused a participant, because the unfolding question appeared right after the given answer instead of after the former question.

Navigation

Every participant completed both tasks without any navigation problems in the first round. In the second round of testing, participants noticed the instruction to change the font size, but this introduced 2 new navigation problems. Participants pressed the wrong keys in trying to increase the font size by pressing the key combination "Ctrl +". Thereafter, we improved the instructions. Despite this change, a participant still struggled with increasing the font size in the last round of testing. Another navigation problem was linked to the need to scroll to view all of the information after increasing the font size. Three participants who increased the font size forgot to scroll down to see the rest of the page.

Content

We detected 4 major usability problems concerning the content of the questions and feedback messages. The first content problem manifested in the physical activity questionnaire (SQUASH) that was part of the health risk appraisal. Participants who were retired or unemployed were irritated by the 4 work/school related questions. One participant commented that "one would almost feel discriminated against". All participants in the first round of testing used these questions to fill out the time they spent walking and bicycling at their leisure, being unaware of the fact that they would be asked about these activities later. As a consequence, they reported the same activities twice, which resulted in an overestimation of the amount of minutes spent walking and bicycling. We solved this problem by adding an option "I do not have a job/go to school" and changing the sequence of the questions (see Table 3 for changes across rounds). During the last round of testing, participants completed this part correctly.

The second problem concerned the perceived similarity of 2 questions—the question that assessed the stages of change and the question that measured the intention to change on a Likert scale. These 2 questions were very similar and all participants in the first round of testing perceived this as unnecessary and expressed frustration. We initially solved this by adding an explanation to the second question that these questions might look similar, but have different response options. In the second round participants showed no frustration, but still a participant commented that asking this question twice was unnecessary. We decided to eliminate the second question.

The third problem concerned the length of the program. As a matter of fact, each behavior module urges the user to pass through all BCTs, which takes time. One participant recommended shortening the feedback messages. Also, participants often did not take the time to read all feedback messages and commented that it was a lot to read.

The last problem was brought to our attention by a participant who suffered from severe COPD. He stated that the feedback was not appropriate to his situation, due to the severity of his condition. "If this is for people like me, there should be adjustments for functional limitations. Here they talk mainly about the possibilities, about people who are mobile etc., but the people who cannot get out of the house, for those adjustments should be made." He also expressed that the term "physical activity norm", which was used in the feedback, sounded too negative. He reflected that achieving the norm highly depends on a person's possibilities to achieve the norm. We removed the term physical activity norm, but still gave the recommendation to be physically active for 30 minutes a day.

In addition to the above modifications, some minor changes were made. A participant suggested that an extra question about breathing problems during physical activity was missing. This question was added. A clarifying example for a question about medication intake was removed, since this led to confusion and incorrect responses. Also, some changes to word choice were made in response to comments. For example, one participant found the terminology "COPD patients" rather offending. She reasoned that a person is more than a patient. "I find the word COPD patient or cancer or lung patient a nasty slogan... I am not the disease, I have it." We followed this recommendation and replaced "COPD patient" by "people with COPD".

Post-Hoc Analysis: Evaluation of the BCTs

One of the problems identified by the participants was that the program length was too long. As the length of the program was hindered by the requirement that all participants must pass through all the BCTs, we reanalyzed the think aloud data using content analyses to assess the users' opinions about each BCT.

Participants agreed with the information on consequences of behavior in general (BCT 1) and talked about how this was applicable to their own lives. One participant thought that it was more useful to younger people, who are not yet familiar with the disease.

Opinions concerning BCT 2, information on the consequences of behavior to the individual, were mixed. One participant claimed to know all of the information presented in this section already, while another participant stated that the information may stimulate behavior change.

The opinions about the 3 BCTs focusing on social influence (BCT 3, 7, and 8) were mixed—comments were mainly negative for BCT 3 and 7, while some participants thought that BCT 8 gave good suggestions (ie, joining a sports club or finding a buddy to exercise with). Information about others' approval (BCT 3) was bypassed by some participants. They indicated not to be concerned about what other people think or do. Prompting identification as a role model/position advocate (BCT 7) was not appreciated as some particiants thought that behaviors that require change should only be identified by themselves, not others. A participant considered this awkward and patronizing. "I find that hurtful... everybody has their own motives, you should not talk to people about that. I almost find that patronizing." Another participant was afraid that his friends would not appreciate it if he talked to them about behavior

change in a persuasive manner. However, this participant understood that he could also just set the right example instead and talk about his health achievements without trying to persuade others.

A variety of views were expressed towards BCT 4, goal setting (behavior). One participant had difficulties understanding the questions about plans they made for behavior change. Another participant thought that it was useful to make plans, while two other participants found planning useless. One argued that he was physically active without the need to think of a plan and felt that this part of the program was not applicable to him.

Five participants had difficulties identifying barriers and thinking of ways to overcome them (BCT 5)—they had to read the questions multiple times. These questions were perceived as hard and annoying. Participants did not have any problems regarding the feedback that helped them solve their problems. One participant mentioned that the tailored feedback she received to overcome the barriers enabled her to plan more consciously.

Five participants agreed with the feedback on performance (BCT 6) and accepted it. One participant commented that it was objective, not too strict or pedantic, and initiated thinking about behavior, while 2 other participants found it too strict. One of them said she would not take the feedback into consideration. Participants were happy to receive compliments.

Table 3. Major usability issues and resolutions per round of testing.

Round	Type of problem	Problem emerged	Resolution
1	Layout	Information on increasing the font size was overlooked	Information was made more apparent
	Content	The work/school questions in the SQUASH were annoying and answered incorrectly	The answer option: “I do not have a job/I do not go to school” was added to skip the remaining job/school questions
		The assessment of intention and stages of change was perceived as unnecessary and because of that frustrating	A short explanatory introduction was added
		Program and feedback messages too lengthy	[no quick solution]
	Navigation	Scrolling after increased font size	[no quick solution]
2	Layout	Participant clicked in the wrong check box, when filling out answer options	An empty line was inserted after each 3 lines
	Navigation	Participants noticed the option to change font size, but did not succeed changing it	Instruction was simplified
	Content	The work/school questions in the SQUASH were annoying and answered incorrectly [solution not sufficient]	1. A warning to fill out the answer option:” I do not have a job/ I do not go to school” was added 2. A short overview of the questions was added 3. The sequence of the questionnaire was changed
		The assessment of intention and stages of change was perceived as unnecessary [solution not sufficient]	One question was removed
		Some feedback on physical activity disturbed the participant suffering from severe COPD	[no quick solution]
3	Navigation	One participant had problems changing the font size [solution not sufficient]	[no quick solution]

Discussion

The purpose of this study was to assess and improve the usability of a computer-tailored program aimed at supporting self-management of COPD patients. We found a need for various improvements concerning layout, navigation, and most importantly content. This is in line with other studies evaluating the usability of eHealth applications [34,35]. A remarkable finding was from a participants’ comment that some feedback was not adequate for severe COPD patients because of their progressive physical limitations. This finding demonstrated that feedback should be tailored to the severity of disease.

This study had several limitations. One limitation was inherent to its pragmatic approach. While as few as 5 test subjects are considered enough to find the majority of usability problems [22] and the best revenues from usability evaluations come from iterative testing [23], such a limited number of participants (we used 8) is not enough to generate valid and reliable metrics that can be analyzed [36]. On the other hand, this pragmatic approach enabled us to correct most problems and retest the program with corrections implemented.

Another limitation was that we were unable to solve all usability problems that were found, given the time frame of the usability study and the technical means. For example, the problem associated with the lengthiness of the program remains unsolved. This becomes an issue particularly for future users of the program, who will not be aided by a moderator. Their frustration with the long program length may lead to discontinued use of the program. This is the reason why we decided for a post-hoc

analysis of the BCTs to explore the possibility of making the program more elective rather than compulsory.

The question related to that issue is whether the selection of BCTs should be based on the stage of change [31], the users' preferences [16], or other considerations. There are many studies that evaluate the impact of BCTs provided by computer-tailored programs. For example, a program can enhance the self-efficacy of carrying out certain behaviors of a user by assessing the individual's perceived barriers to physical activity and giving feedback to increase confidence for dealing with the identified barriers. Another technique may be to invite persons to make action plans on how to prepare a new behavior [14,37,38]. Some BCTs used in eHealth interventions have been shown to be more effective than others [39]. However, less is known about how users appreciate the BCTs used in these programs [40]. BCTs have a different content in each study, and it is unclear which aspects appeal to the users.

The evaluation of responses in our study pertaining to the content of questions and feedback messages, based on the BCTs, showed that it is important to achieve an appropriate balance between positive and objective feedback considering performance (BCT 6). The rationale for this BCT is to stimulate behavior change [27]. However, the feedback needs to be carefully tested. Feedback that is too strict results in frustration while feedback that is not strict enough does not make patients aware of their unhealthy behavior. The comments on other BCTs varied. Some participants found the content useful, while others expressed a negative opinion. This is in line with the trans-theoretical construct that states that individuals move through stages of change and need a corresponding approach for each stage [31]. A number of computer-tailored programs provide individuals with the BCTs that match their stage of change [40]. However, the results of our study imply that users' characteristics should also be taken into account when selecting BCTs. For example, BCTs that described consequences of various behaviors were not appreciated when the participant felt that he/she already had sufficient knowledge on the topic. Some participants had problems understanding or appreciating BCT 4, goal setting (behavior) and BCT 5, identifying barriers and thinking of ways to overcome these barriers, while others had no problems and appreciated these BCTs. A computer-tailored intervention that incorporates these BCTs could be more helpful for users who prefer to use intensive cognitive processes, such as active planning and problem solving. According to dual process models (eg, Petty and Cacioppo's Elaboration Likelihood Model [41]), information can be processed via two routes, the central and the peripheral. The central route requires more cognitive effort and leads to more elaborations, whereas information processing via the peripheral route is more automatic. A personal preference for information processing, which can be measured by the need for cognition scale [42] or the information-processing questionnaire [43], could influence the processing intensiveness of BCTs 4 and 5. Nonetheless, simplifying the questions and feedback messages in BCT 4 and 5 and lowering the required effort to process the information could make these BCTs accessible for a broader population.

Several participants were reluctant to embrace BCTs that incorporated normative social influence. While the social environment can be an important factor to influence an individual's behavior [44], some participants resisted acknowledging social influence on their behavior or their influence on others, as this would compromise their integrity or that of others. Deutsch et al [45] argued that normative social influence could undermine individual integrity. Hence, we recommend that BCTs containing normative social influence should be carefully applied to prevent users from feeling that their individual integrity could be compromised, but emphasize that individuals have independent judgments and learn from each other to accomplish behavior change.

This usability study was conducted to improve a computer-tailored program aimed at improving the self-management of COPD patients, but the usability methods followed in this usability study can be applied as part of a user-centered design in any eHealth interventions. This study uncovered several inconveniencies in the program that could be resolved, which shows that a usability evaluation with end users of an eHealth intervention is highly recommended. This study also revealed that the users appreciated BCTs implemented in this intervention. These results may be helpful for developers to consider which BCTs they should use in their eHealth interventions. Further research is needed to uncover which user characteristics affect the use of computer-tailored programs and the choice of BCTs that fit best.

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Conflicts of Interest

Hein de Vries is scientific director of Vision2Health, a company that licenses evidence-based innovative computer-tailored health communication tools.

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Abbreviations

BCT: behavior-change techniques
COPD: chronic obstructive pulmonary disease
MARS-5: Medication Adherence Report Scale
SQUASH: Short Questionnaire to Assess Health-Enhancing Physical Activity

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Original Paper

Role of the Working Alliance on Treatment Outcome in Tailored Internet-Based Cognitive Behavioural Therapy for Anxiety Disorders: Randomized Controlled Pilot Trial

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Abstract

Background: Internet-based cognitive behavioral therapy (ICBT) is a form of guided self-help that has been found to be effective for addressing several problems. The target for this type of therapy is usually restricted to one specific disorder. Tailoring the treatment widens the scope of ICBT in that it can address comorbid conditions directly.

Objectives: The working, or therapeutic, alliance has been found to predict outcome in studies of face-to-face therapy. The extent to which these findings apply to ICBT is largely unknown. We therefore decided to find out whether the working alliance could predict outcome in tailored ICBT for anxiety disorders.

Methods: Data were obtained from the treatment group (n=27) in a randomized controlled trial aiming to test the effects of tailored ICBT for anxiety disorders. The forthcoming study was designed to test the hypothesis that the working alliance measured both pre-treatment and early in treatment (week 3) can predict treatment outcome as measured by the Clinical Outcomes in Routine Evaluation–Outcome Measure (CORE-OM) in a heterogeneous group of patients with anxiety disorders (n=27).

Results: Working alliance measured at week 3 into the treatment correlated significantly with the residual gain scores on the primary outcome measure (r=-.47, P=.019, n=25), while expected working alliance pre-treatment did not (r=-.17, P=.42, n=27).

Conclusions: These results raise questions about the importance of working alliance in ICBT treatments, and suggest that the working alliance could be important in ICBT.

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KEYWORDS

tailored Internet-based cognitive behavioural therapy; anxiety disorders; working alliance; prediction

Introduction

The working, or therapeutic, alliance is one of the concepts regarded as common to all forms of psychotherapy. Bordin proposed a model consisting of 3 parts—task, bond, and goal—which he stated could apply to all change situations [1]. He suggested that the working alliance was a key factor in these change situations, in which a person tries to achieve change with the assistance of another person, and argued that the concept was universally applicable to all forms of

psychotherapy. Following the publication of Bordin's original paper, the working alliance has been investigated in numerous studies. The results of this research on the relationship between working alliance and outcome indicate that there is a correlation between client-rated working alliance and post-treatment outcome in a variety of disorders and treatments [2,3]. There is evidence for the superiority of client-rated, compared to observer- or therapist-rated, working alliance at the beginning of treatment in predicting outcome [2], however the results are mixed [3,4]. These correlation effects seem to be fairly robust, independent of study design [3] and type of psychological treatment [4], and are replicated in physical rehabilitation [5]. Taken together, there is a body of evidence indicating that working alliance, especially if rated by the client, is an important factor in predicting treatment outcome.

Internet-based cognitive behavior therapy (ICBT) in the form of guided self-help has been proven to be effective for a range of conditions, with effect sizes that equal face-to-face cognitive behavioral therapy [6-10]. There is evidence to suggest that the benefits of ICBT are enhanced by personal contact [11-13]. There is further evidence to suggest that a relationship formed on the Internet is as strong and as deep as its offline counterparts [14]. In a recent review of the therapeutic relationship in the broader field of e-therapy [15], the authors concluded that even though this topic has been investigated, the studies that did take this into account showed that therapeutic relationships or alliance is equivalent to face-to-face therapy, and that there is a relationship between alliance and outcome. Previous studies showed similarities between working alliance measured during face-to-face treatment and working alliance measured during Internet treatment [16-18], by using comparision groups [16,18], and by comparing with earlier research on face-to-face therapy [16]. These findings lead the authors of these papers to conclude that a therapeutic relationship can be formed during Internet-based treatment.

While there is growing evidence to indicate that a working alliance is formed in ICBT [19], not much is known about the possible benefits this may have on outcome in these treatments; this has been investigated with mixed results. For example, Knaevelsrud and Maercker [20] found a nonsignificant correlation between alliance ratings and treatment outcome in patients with post-traumatic stress disorder (PTSD), while a small correlation has been shown for adolescents with anxiety disorders [21].

In a recently published study by our research group [22], no significant correlations were found in the analysis of working alliance as a predictor in patients with generalized anxiety disorder (GAD), social anxiety disorder (SAD), and depression treated with ICBT in 3 separate studies. There are several differences between that study and the one reported here. The participants in the Andersson et al [22] study were included only if their primary diagnosis were matched with the focus of the study (ie, major depression, social anxiety disorder, or generalized anxiety disorder), comorbidities were not assessed or addressed in the treatment, and the ICBT treatment was strictly manualized. In the study presented in this article, we were using the novel format of a tailored ICBT treatment protocol. This may seem like a small difference, but this format makes it possible to address participants' comorbidities directly, and also to tailor the treatment due to patients' preferences. We believe that this format is more similar to face-to-face CBT where a personalized functional analysis or case conceptualization is used, and therefore the therapeutic alliance may be shown to yield a stronger correlation with the outcome.

There is also the possibility that, in Internet-based treatments as well in other treatment formats, alliance is at least partly based on patient expectations before treatment and may therefore exist even before the start of therapy [16,23]. The definition of expectation here relates both to the patients' treatment expectation (eg, beliefs about what the respective roles might be, the treatment format and the duration of treatment), and outcome expectations, which answers questions about the possible beneficial effects of the treatment [24]. We believe that the persons who were recruited to this treatment study knew about the format and length, since this information was clarified on the study website before patients started to fill in the application form, but could have different expectations regarding roles and to what extent this might be a proper treatment for their unique set of problems. The possible differences regarding roles and possible benefits of treatment may stem from the novelty of the treatment format and the fact that neither of the participants had any earlier experience from ICBT.

Little research has been conducted on the predictors of ICBT outcomes. As the use of ICBT broadens, it is increasingly important to establish which factors contribute to outcome. Therefore, the aim of this study was to investigate whether self-reported working alliance, as measured by the Working Alliance Inventory Short form (WAI-S) scale early in treatment (week 3), could serve as a predictor of outcome in tailored ICBT for a heterogeneous group of mixed anxiety disorders. In order to control the possibility of expected working alliance, we also measured alliance before treatment. We expected alliance ratings to be high on the basis of previous research, and measured early in treatment to be a possible predictor of treatment outcome. The potential implication from this study is twofold: (1) to further add to the body of evidence showing that a working alliance can be formed over the Internet and that can equal the alliance rated in face-to-face therapies, (2) if alliance is shown to predict treatment outcome, it could be important for the therapists guiding these programs to work explicitly on trying to foster a working alliance in order to improve outcome.

Methods

Recruitment

The data for this study was collected in association with a randomized controlled study of tailored ICBT for anxiety disorders [25], and has not been presented previously. Participants were recruited via newspaper articles in the national and regional press, national radio, interviews about previous studies, and information on a variety of websites. Neither comorbidity nor concurrent medications were criteria for exclusion, provided that anxiety disorder was the principal diagnosis and, if medication was used, that doses were stable for 3 months prior to and during the treatment. Participants were randomized using an online true random number service,

independent of the researchers and therapists, to either 10 weeks of individually-tailored, guided Internet-based treatment of anxiety, or to an active control group (online discussion forum). The study was approved by the regional ethical board, and written informed consent was collected from all participants.

Procedure

Participants applied to participate via the study website and completed an online screening questionnaire in which the CORE-OM [26] served as the primary outcome measure. As part of the screening, participants also completed the WAI-S [27,28] in a slightly modified version, measuring to what extent participants thought that their online therapist would share their point of view, goals, and focus of treatment. This was done before any personal contact with the participant was made. The alliance measure was also completed during the third week of treatment, and post-treatment. Before inclusion, applicants were diagnosed in a face-to-face structured psychiatric interview, Structured Clinical Interview for DSM-IV Axis I disorders (SCID-I) [29]. With exception of the diagnostic interview, all data were obtained using Internet-based questionnaires.

The timing of the WAI-S measurement at week 3 was set in order to measure the alliance before symptom change, where the alliance could be viewed as an indicator of successful treatment [3], but after enough time had passed for the patient and therapist to form a mutual agreement [4,30].

Participants

The mean age of the 27 participants included was 39.3 years (SD 11.2, range 22–63), 67% (18/27) were female, and 44% (12/27) had a history of previous psychological treatment. 30% (8/27) of the participants had a history of previous, but discontinued anxiolytic or antidepressant medication, 30% (8/27) had continuing medication that had been at a stable dosage for at least 3 months, and 40% (11/27) had no history of any psychiatric medication. The majority of the participants (17/27) were married or living together, while 33% (9/27) reported their marital status as single. Almost half of the participants (12/27, 44%) reported completion of university or college education.

Treatment

The treatment consisted of a combination of text modules (ie, chapters) previously used in ICBT for panic disorder, social phobia, generalized anxiety disorder, and depression. In total there were 16 modules. Participants were prescribed 6-10 modules to work with during the 10-week treatment period. The treatment, presented in greater detail in Carlbring et al [25], was tailored to match the clients' unique characteristics and comorbidities (including preferences). Each module included information and exercises, and ended with between 3 and 8 essay style questions, which served as the participants' homework assignment together with worksheets and reports on the outcome of exercises. The participants were given feedback on their homework assignment from an identified (by name and picture on the study website) therapist, usually within 24 hours. The therapists were 3 master's students who had completed their clinical training and they were randomly assigned to 7-10 participants each. The therapists were instructed not to exceed 15 minutes/participant/week for email feedback.

Measures

The primary outcome measure for this study was the CORE-OM [26], a 34-item scale covering 4 subscales. The subscales are: subjective well-being, symptoms (anxiety, depression, physical problems, and trauma), functioning (general functioning, close relationships, and social relationships), and risk (to self and others). Items are scored from 0-4 and relate to the preceding week. CORE-OM clinical scores can range from 0-40, with higher scores indicating greater severity. Internal consistency measured by alpha was reported as .94 [31].

We used a modified version of the WAI-S to measure working alliance. This is a 12-item self-reporting process measure of working alliance [27,28]. The short form of WAI used in this study was generated from the original 36-item scale, Working Alliance Inventory [32], and has 3 subscales—task, bond, and goal—and an overall alliance score (ie, the total score). The scale is available in 3 versions, a client version, a therapist version, and an observer version. The short version consists of the items with the highest load on each of the 3 subscales [33]. Each item is rated on a 7-point scale, with higher scores indicating higher alliance. The WAI-S shows good psychometric properties for both client and therapist versions [33], but large intercorrelations between subscales have been found, and the 3-scale model of WAI and WAI-S remains a subject of debate [27,34,35]. The modifications of the scale were minor, consisting of adaptations for the Internet rather than face-to-face delivery (ie, the word "treatment" was changed to "Internet treatment", and "contact" was changed to "email contact"). In addition, the WAI-S was adapted according to the assessment point, where the first assessment related to expected alliance. The adaption consisted of changing past and present to future tense. It was also made clear that filling out their expected relationship with their therapist would not affect their possible future participation in the study. We only collected measurements of the client-rated working alliance. Psychometric properties were reported to be excellent for the online version of the WAI-S in Andersson et al [22].

Treatment Outcome

Results on the CORE-OM showed a large between-group effect size (d=1.00) in favor of the treatment group. The within-group effect size for CORE-OM in the treatment group was d=1.24. A more detailed description of the results is provided in the original report [25].

Statistical Analysis

We used bivariate correlations and multiple regression models to investigate the possible relationship between outcome and working alliance. For the analysis, we calculated residual gain scores on the composite CORE-OM raw score to control the initial differences pre-treatment, and possible measurement errors due to repeated use of the instrument [36]. Using residual gain scores makes it possible to interpret individual scores relative to typical gains made by other participants at the same initial level [36]. The formula used to calculate residual gain scores was z2 - (z1*r1 2) [36], where z2 represents the

z-transformed post-treatment CORE-OM raw score, and *r*1 2 represents the Pearson correlation between pre- and post-treatment assessments.

The residual gain score from CORE-OM served as measurement of treatment outcome, and the client-rated WAI-S score was used as the measurement of working alliance. Changes in alliance were tested by means of paired *t* tests. All statistical analyzes were made with IBM SPSS statistics 19 for Windows.

Results

Mean alliance ratings on the WAI-S including correlations with residualized gain scores on CORE-OM are presented in Table 1. Alliance ratings increased from pre-treatment to mid-treatment, (t_{26}=5.5, *P*<.001) and the expected alliance correlated significantly with the early alliance rating (*r*=.57, *P*=.002, n=27). The post-treatment score on the WAI (mean 6.2, SD 0.90) did not change from mid-treatment.

WAI-S measured early in treatment correlated significantly with residualized gain scores from CORE-OM post treatment (*r*=-.47, *P*=.019, n=25), while WAI-S measurements at pre-treatment did not (*r*=-.17, *P*=.425, n=25). Alliance ratings at post-treatment were also correlated with residualized gain scores (*r*=-.42, *P*=.037, n=25).

Table 1. Mean working alliance inventory short version ratings pre-, during, and post-treatment, and correlations with residualized change scores on CORE-OM.

	n	Mean (SD)	*r*	*P*
WAI-S total, pre-treatment	27	5.25 (0.72)	-.17	.425
WAI-S total, week 3	25	6.00 (0.80)	-.47	.019
WAI-S total, post-treatment	25	6.20 (0.90)	-.42	.037

When controlling expected working alliance measured pre-treatment, in a multiple regression model the role of the alliance rating during treatment did not change (B=-.53, *P*=.027, n=25) In addition, controlling a history of psychological treatment (B=-.42, *P*=.039, n=25), and levels of symptoms (B=-.44, *P*=.036, n=25) also did not change the association. Controlling age did not change the role of the working alliance (B=-.49, *P*=.016, n=25), whereas controlling gender made the association between working alliance and outcome fall slightly (B=-.40, *P*=.058, n=25).

Discusion

The aim of this paper was to investigate whether client-rated working alliance could predict outcome, measured by CORE-OM, for a tailored ICBT for anxiety disorders. We found significant correlations between alliance ratings made early in treatment (week 3) and treatment outcome.

ICBT has been found to be effective for a range of psychiatric conditions [18,37], but the underlying mechanisms of change are not well known [38]. There is evidence to indicate better treatment outcome when personal support is combined with online material, compared to unguided self-help [12]. There is, however, also evidence indicating that a technician can be as effective as a therapist [39-41]. Working alliance is regarded as important in face-to-face treatments with a robust, albeit moderate, effect on outcome [4], and as alliance ratings have been shown to be as high in ICBT as in face-to-face therapy [17,18], investigating the possible effect on treatment outcome in this therapy format was of interest. In our sample, we found alliance ratings equal to those typically found in face-to-face therapy, and the tentative conclusion drawn from this study is that it may be possible, at least in a self-recruited sample, to form a working alliance in ICBT. Moreover, alliance ratings increased from baseline, which suggests that ICBT does not lead to worsened alliance. We also found significant correlations between alliance ratings made early in treatment (week 3) and treatment outcome, raising the possibility that early working alliance does affect outcome and might be an important factor even in this treatment format. This is consistent with previous research suggesting that early alliance may predict lower levels of anxiety in cognitive therapy [42]. The findings are, however, mixed in ICBT with regards to the strength of the association between alliance and outcome [20,22]. In this study, we found a significant correlation between working alliance measured early in treatment and outcome in a small sample of patients with comorbidities, and with one third using medications for their condition. If this is explained due to the treatment format of tailoring the treatment, the face-to-face diagnostic interview, or other sample specific variables is not known. These might all be possibilities. In the Andersson et al study [22], the ICBT treatments were manualized and this might be an explanation for the lack of significant alliance outcome associations in their study. This could also be seen in the context of the suggestion by Andrusyna et al [27] that working alliance should be measured differently in CBT than in other forms of psychotherapy. They proposed a 2-factor model consisting of agreement/confidence and relationship. The mixed results may stem from the possibility that the working alliance should be measured differently in CBT.

There has been some debate (eg, [43]) about whether patient expectation could be a factor contributing to early patient-rated working alliance. In an attempt to clarify this, we measured expected working alliance at the time of the application to participate in the study. These measurements were made before any personal contacts had been made with the participants. It is possible that the self-recruited participants in this study were more positive about the treatment format from the start and about the therapists who provided the treatment, even if the data does not suggest this to be the case.

There are other limitations to be considered. Firstly, the small sample size of 27 participants makes it hard to draw conclusions from this study alone, especially since gender seems to affect the association between working alliance on outcome. In this small sample consisting of only 9 men and 18 women, it is hard to take this matter any further, and we believe that this study needs replication with a larger sample to make it possible to explore this issue further. The results are, however, consistent with findings from research on face-to-face therapy, and research showing that Internet relationships can be as important as face-to-face relationships [44].

Secondly, we used the total score of the WAI-S and did not analyze the subscales, given the high intercorrelation between the 3 subscales. This could be seen as a limitation, as we did not investigate whether some subscales showed higher correlation with post-treatment CORE-OM scores. In order to improve the WAI and WAI-S psychometric properties, a new version called Working Alliance Inventory-Short Revised (WAI-SR, [35]) has been developed. Munder et al [34] have shown that WAI-SR distinguished more clearly between the task and bond aspects of the therapeutic alliance, as defined by Bordin's 3-factor model, making WAI-SR more reliable for subscale division.

Thirdly, the fact that WAI-S was originally designed for face-to-face treatment could be regarded as a limitation. Minor amendments were made for the study (eg, "treatment" was changed to "Internet treatment", and "contact" to "email contact"), with which we hoped to adapt the scale to this treatment format. As regards measuring outcomes via the Internet, research has shown that this is as reliable as paper-and-pen administration of self-reported measures [45-47].

Fourthly, measurement of the working alliance at week 3 was not accompanied by symptom measurement, so we were unable to estimate to what extent outcome was due to the working alliance and how much was due to the treatment itself.

In spite of the limitations, this study provides some evidence that the quality of the relationship between patient and therapist can be important in Internet treatment, although the working alliance alone may not entirely account for its effectiveness. Our research group has, as a first step, conducted a randomized controlled trial with a larger sample size (n=100) to test the effectiveness of tailored ICBT treatment for anxiety disorders on a primary care population. The next step might be to replicate this study, with the larger sample size, in order to further investigate the relationship between therapist and patient and its effects on outcome.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT Ehealth Checklist V1.6.1 [48].

[PDF File (Adobe PDF File), 566KB - resprot_v2i1e4_app1.pdf]

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Abbreviations

CORE-OM: Clinical Outcomes in Routine Evaluation-Outcome Measure
GAD: generalized anxiety disorder
ICBT: Internet-based cognitive behavior therapy
PTSD: post-traumatic stress disorder
SAD: social anxiety disorder
SCID-I: Structured Clinical Interview for DSM-IV Axis I disorders

WAI-S: Working Alliance Inventory Short form
WAI-SR: Working Alliance Inventory-Short Revised

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Original Paper

Barriers and Facilitators of Online Patient Portals to Personal Health Records Among Persons Living With HIV: Formative Research

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Abstract

Background: Federal meaningful use standards are promoting adoption of online portals to personal health records (PHRs). However, relatively little is known regarding barriers and facilitators for vulnerable groups such as persons living with human immunodeficiency virus (PLWH).

Objective: The objective of this study was to assess barriers and facilitators to use of online PHRs among PLWH.

Methods: We conducted formative research using a written waiting room survey among 120 PLWH regarding barriers and facilitators of portal PHR use. We supplemented findings with data collected from a PLWH focus group, where some members had personal experience with use of a portal.

Results: The survey had 90 respondents. Eight PLWH participated in the focus group. Most patients (77/90, 86%) reported having at least some experience using the Internet and most expressed interest in features offered by the portal. Notably, 70% (63/90) expressed some interest in being taught how to use it to communicate with their provider. Focus group themes reinforced these findings, but also voiced concern regarding access to private computers.

Conclusions: Many PLWH in our sample have experience using computers and most are interested in PHR features. However, computer or broadband access and privacy are important barriers.

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KEYWORDS

HIV; health records; personal medical informatics; education of patients

Introduction

Personal health records (PHRs), typically accessible through secure Web-based portals, represent a practical way for patients to access their health information anytime and anywhere [1]. The federal meaningful use standards require providers to make PHRs accessible to patients [2]. Some predict that patient portals will eventually become the primary means through which patients access their PHRs, request and cancel physician appointments, request medication refills, view test results, and exchange messages with their health care team [1]. However, the emergence of online PHRs may worsen the disparity of

health care access on the basis of the well-documented digital divide [3,4].

Mounting data point to the growing sociodemographic disparities in patients' use of Web-based portals for PHRs [5-8]. This disparity in access is particularly relevant for patients living with chronic conditions such as human immunodeficiency virus (HIV) who are a racial/ethnic minority and disproportionately poor [9]. Data from early adopters of PHRs suggest that theses disparities in PHR use will emerge among persons living with HIV (PLWH) [10].

Barriers to Web-enabled technology can be largely grouped into 3 categories, including cost, knowledge and attitude, and skills [11]. Cost is the most obvious contributor. Low-income families often report they are not able to afford the cost of personal computers and monthly fees for broadband access [11]. However, some have access to computers or the Web through friends, family, work, libraries, or handheld devices [11]. The second contributor relates to attitude. Many nonusers report they see little value in computers and/or the Internet [11]. This is particularly true of older persons who grew up in an era without this technology in social networks that reinforces these negative attitudes through social norms. Lastly, computer use and attitudes are shaped by self-efficacy and skill level related to computer and Internet use. Many persons with low education and older persons lack the necessary skills and confidence to access health information online [11,12]. Interestingly, neither mental health nor substance use disorders is correlated to portal use by PLWH [13].

We conducted formative research to understand the barriers and facilitators on PLWH in using key features associated with PHRs. To obtain a more complete picture, we supplemented the survey with PLWH with input from a PLWH focus group, where members had varied experience with online PHR.

Methods

Survey

Over a 2 week period, 120 written surveys available in English and Spanish were distributed to patients 18 years and older by the front staff during their appointments at an HIV clinic that serves roughly 1000 HIV patients. Survey questions were adapted from the Health Information National Trends Survey (HINTS) and addressed barriers and facilitators of Web use and the level of interest to key PHR features, such as scheduling appointments, requesting refills, viewing test results, and exchanging electronic messages with one's providers [14]. The final survey contained 18 items, including patient demographic characteristics (age, sex, education, insurance, and marital status), computer access and comfort, level of interest in specific features available through patient portals, and desire for assistance. Over a 2-week period in November 2011, the survey was handed out to all patients 18 years of age or older that checked-in for an appointment.

Focus Group

An online PHR focus group was formed by 8 PLWH participants recruited by offices and organizations that provided care for PLWH. A trained research assistant conducted the group, which lasted for one hour. All participants provided verbal informed consent and were compensated for their time and travel. The research assistant began with a brief presentation of Web-enabled PHRs using slides that included screenshots of a PHR. (Figures 1 and 2). The presentation was followed by a series of open-ended questions regarding barriers and facilitators of PHR use among PLWH. The research assistant concluded the group session by inviting participants to offer suggestions to improve access. Data were compiled based on an audio recording of the focus group and notes by the research assistant. The survey and focus groups were approved the University of Rochester Institutional Review board.

Data Analysis

Survey Analysis

We examined univariate responses for each item and collapsed categories to create dichotomous categories. We compared responses across items using chi-square statistics. We examined independent associations among multiple factors using logistic regression.

Focus Group Analysis

The principal investigator KF and the research assistant analyzed the focus group using qualitative methods. We assigned participant responses to de novo categories and then developed codes for each category. These codes included specific barriers to use of PHR portals (lack of physical access, privacy concerns, computer literacy, and patient interest) and facilitators (pro-active engagement, easy-to-use technology, training, and privacy). The codes were then applied to the entire data for analysis [15].

Figure 1. Test results in personal health records.

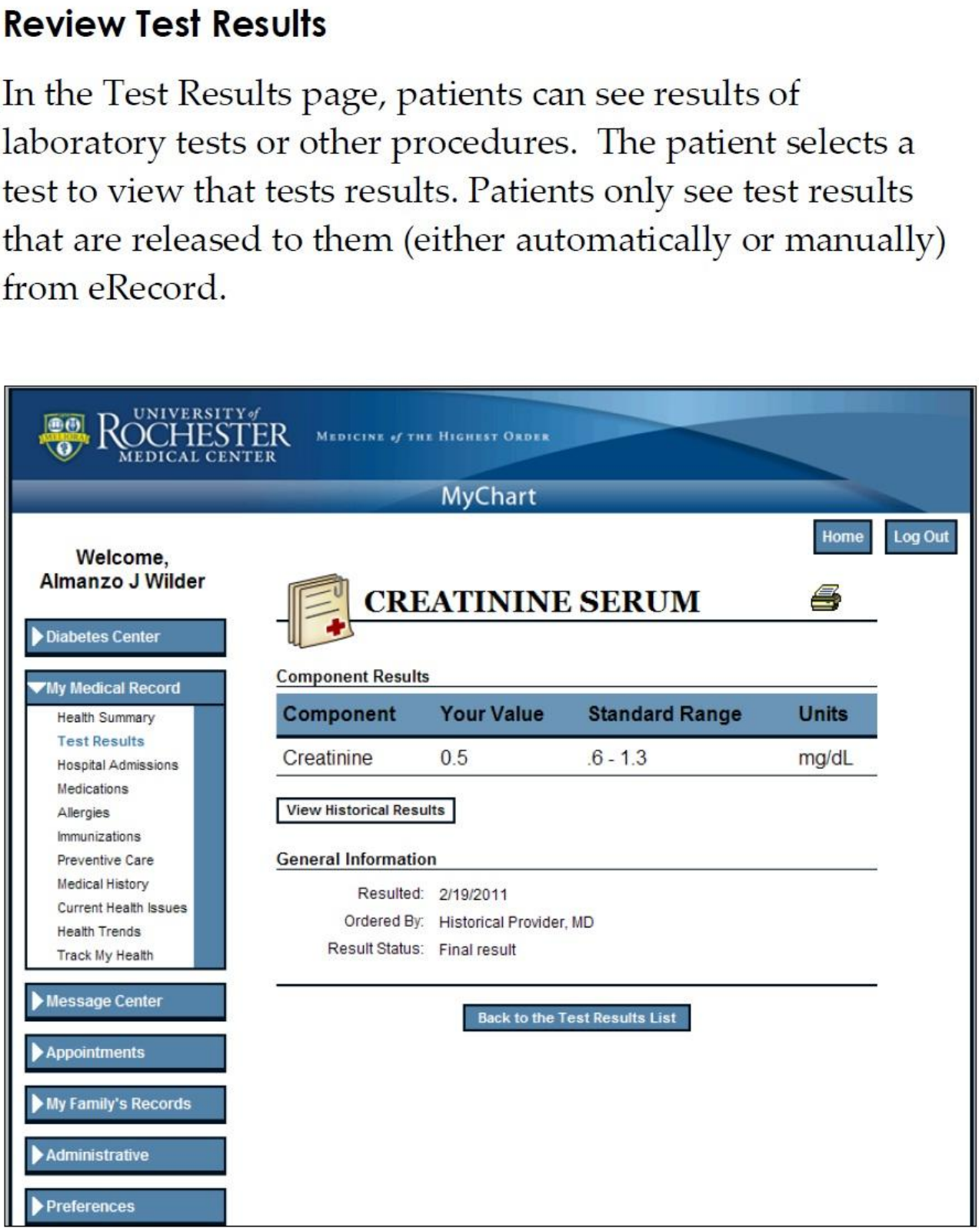
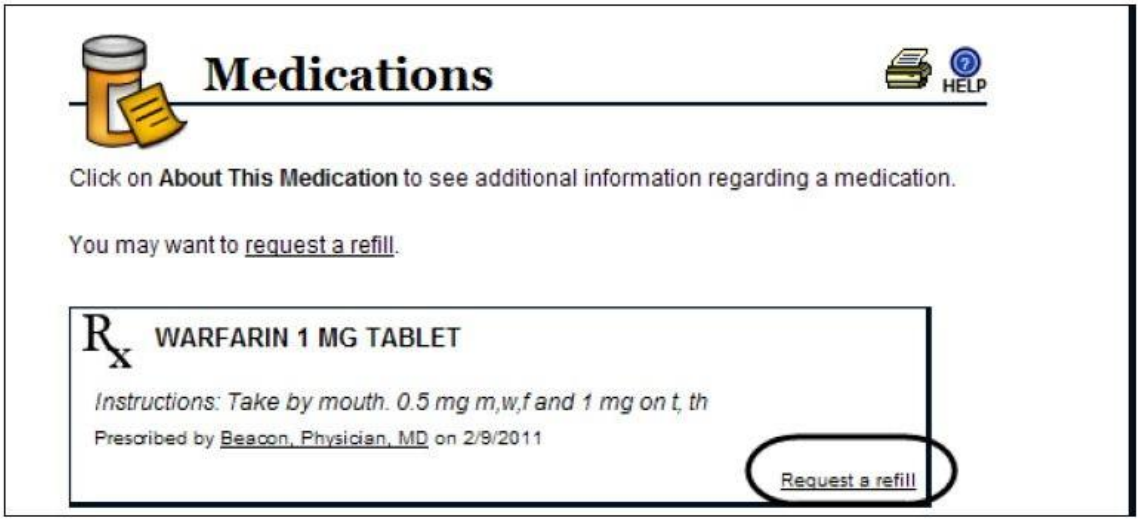


Figure 2. Prescription refill requests in personal health record.



If a medication has a refill available, the patient can select the Request a refill hyperlink to renew the prescription.

The patient can specify a Pickup Pharmacy from the list of available pharmacies or they can select other and enter the name of their pharmacy in the box provided.

Results

Survey Findings

Of the 90 patients (Table 1), most identified themselves as black (38/90, 43%) or 8% (7/90) Hispanic, male (54/90, 61%), 64% had a high school education or less and 38% indicated they had Medicaid as their primary insurance coverage, with 22% having private insurance and 20% relying on the AIDS Drug Assistance Program (ADAP). Thus, while we did not ask about income, based on educational levels and insurance, the sample is likely low-income.

Table 1. Demographic characteristics.

Patient characteristic (N=90)	n (%)
Age	
< 35	24 (29)
35-49	33 (39)
> 50	27 (32)
Sex	
Female	32 (36)
Male	54 (61)
Transgendered	3 (3)
Race/Ethnicity	
Black	38 (43)
Hispanic/Latino	7 (8)
White	39 (44)
Other	5 (6)
Education	
< high school	27 (30)
high school	31 (34)
> high school	36 (36)
Marital Status	
Single	57 (63)
Married	16 (18)
Divorced/separated	14 (16)
Widowed	3 (3)
Health Insurance	
Medicaid	32 (39)
Private	18 (22)
ADAP	17 (20)
Other	15 (18)
None	1 (1)

Surprisingly, most respondents reported at least monthly Internet use despite only about half owning a computer (Table 2). Other means for accessing the Internet access included a smartphone, work, friend, family, or library computer. Barriers cited by respondents were cost (16/90**,** 18%), lack of interest (6/90, 22%) and do not know how to use (5/90, 19%).

Table 2. Internet use and barriers to use.

Internet use and barriers (N=90)	n (%)
Monthly or more Internet use	
	77 (82)
Primary location of Internet use	
Own computer	45 (52)
Smartphone	7 (8)
Work computer	12 (14)
Friend/Family computer	15 (17)
Library computer	2 (2)
Other	5 (6)
Barriers to use	
Do not know how to use	5 (19)
Costs too much to use	16 (18)
Not interested in using	6 (22)

Most respondents reported at least some interest in obtaining test results and scheduling appointments online (Table 3). In addition, most (77/90, 86%) reported they would use the computer if available on-site at the clinic and most (54/90, 70%) expressed an interest in being taught how to use a patient portal to communicate with their provider. In multivariate analysis, no single factor was statistically associated with interest in PHRs suggesting that interest was distributed across all groups fairly equally. However, participants who reported more interest in PHR features were significantly more likely to report interest in being taught how to communicate with their providers ($P<.001$).

Table 3. Interest in patient portal features and assistance.

Features (N=90)	n (%)
Interest in key online PHR features	
Obtaining test results online	76 (86)
Schedule appointments online	63 (73)
Refilling prescriptions online	74 (83)
Interest in improve access or assistance	
Use a computer in waiting room	77 (86)
Having someone teach you how to use it to communicate with your doctor	54 (70)

Focus Group Findings

The focus group participants cited the lack of Internet access and not knowing how to use these online PHRs as barriers, but mentioned an additional barrier to use of online portals—privacy when accessing a portal outside of one's home. Most of the participants reported they did not have home Web access. While the group acknowledged the availability of Web access through libraries and homes of friends and family, most were concerned about using a public computer or a computer in someone else's home to access PHR. One participant commented, "You wouldn't try to access your online bank account in public. Why would you access your personal health record there?" When asked about use of computers within clinics, participants preferred use of a small hand held device such as an iPad to that of a desktop computer because they felt it would be easier to preserve privacy by concealing personal information on the screen and also easier to learn to use. When the issue of computer literacy was raised, participants agreed that this represented a barrier but did not view it as insurmountable. Many felt that it would be feasible to train patients in 10-15 minutes to use a touch screen device such an iPad on-site at clinics.

Discussion

PLWH in our sample reported notable interest in use of Web-enabled PHRs. This finding is consistent with findings from national surveys that document significant interest in PHRs [16,17]. It bodes well for greater engagement of PLWH in their self-management and is a means for potentially improving medication adherence through greater self-monitoring of test results, efficient medication refills, and greater access to providers through electronic messaging. Yet, promoting adoption of PHRs will require addressing key barriers including knowledge, attitudes, access, cost, skills, and self-efficacy. These barriers identified in our survey are broadly similar to those from the national survey, which included lack of perceived

need, costs, time required, and lack of interest in computers [18]. In addition, patients in the national surveys cited concerns with privacy [18]. This concern also emerged from the focus group in the context of using a public computer.

Ensuring that unequal adoption of Web-based PHRs does not worsen existing disparities requires practical strategies to address incentives and various barriers [19]. The first barrier identified by our participants was physical access, which is driven in part by the cost of computers and monthly broadband access fees. This might be mitigated if public libraries and medical providers offered on-site access to Web-enabled devices. However, it means offering this access in ways that protect the privacy of those accessing their PHR while they are viewing their health information.

Second, the barriers of computer skills and self-efficacy need to be resolved [20]. Most patients expressed interest in on-site guidance and instruction. Given relatively low rates of use of PHRs (when available) including by PLWH and emerging disparities [5-8,21-23], pro-active engagement of patients with limited computer literacy coupled to basic hands-on instruction may be needed to forestall these disparities [24]. Personal demonstration and role modeling use of the technology may spark interest among those with limited knowledge about PHRs and among those who see limited benefit. Our findings suggest that patients will welcome on-site availability and instruction provided that their privacy is ensured.

These findings are limited by our methods. Our sample was based on recruitment from a waiting room. This precludes assessment of response bias. Thus, it is possible that patients with the lowest computer literacy might have been less likely to respond, perhaps viewing the survey as less relevant to them. Similarly, we recruited patients from a single practice. Although the demographic characteristics of the responders are similar to that of PLWH nationally we cannot be sure that the findings generalize to other settings. Last, we conducted only one focus group. It is possible that additional themes would emerge with additional groups.

In conclusion these findings provide cause for some cautious optimism. They suggest that PLWH are interested in features offered by PHR, but that significant barriers remain. Some of these barriers can potentially be overcome through on-site online PHR access coupled to training.

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Conflicts of Interest

None declared.

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Abbreviations

ADAP: AIDS drug assistance program
HINTS: Health Information National Trends Survey
HIV: human immunodeficiency virus
PHR: personal health record
PLWH: person living with HIV

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Original Paper

Constructing a Theory- and Evidence-Based Treatment Rationale for Complex eHealth Interventions: Development of an Online Alcohol Intervention Using an Intervention Mapping Approach

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Abstract

Background: Due to limited reporting of intervention rationale, little is known about what distinguishes a good intervention from a poor one. To support improved design, there is a need for comprehensive reports on novel and complex theory-based interventions. Specifically, the emerging trend of just-in-time tailoring of content in response to change in target behavior or emotional state is promising.

Objective: The objective of this study was to give a systematic and comprehensive description of the treatment rationale of an online alcohol intervention called Balance.

Methods: We used the intervention mapping protocol to describe the treatment rationale of Balance. The intervention targets at-risk drinking, and it is delivered by email, mobile phone text messaging, and tailored interactive webpages combining text, pictures, and prerecorded audio.

Results: The rationale of the current treatment was derived from a self-regulation perspective, and the overarching idea was to support continued self-regulation throughout the behavior change process. Maintaining the change efforts over time and coping adaptively during critical moments (eg, immediately before and after a lapse) are key factors to successful behavior change. Important elements of the treatment rationale to achieving these elements were: (1) emotion regulation as an inoculation strategy against self-regulation failure, (2) avoiding lapses by adaptive coping, and (3) avoiding relapse by resuming the change efforts after a lapse. Two distinct and complementary delivery strategies were used, including a day-to-day tunnel approach in combination with just-in-time therapy. The tunnel strategy was in accordance with the need for continuous self-regulation and it functions as a platform from which just-in-time therapy was launched. Just-in-time therapy was used to support coping during critical moments, and started when the client reports either low self-efficacy or that they were drinking above target levels.

Conclusions: The descriptions of the treatment rationale for Balance, the alcohol intervention reported herein, provides an intervention blueprint that will aid in interpreting the results from future program evaluations. It will ease comparisons of program rationales across interventions, and may assist intervention development. By putting just-in-time therapy within a complete theoretical and practical context, including the tunnel delivery strategy and the self-regulation perspective, we have contributed to an understanding of how multiple delivery strategies in eHealth interventions can be combined. Additionally, this is a call for action to improve the reporting practices within eHealth research. Possible ways to achieve such improvement include using a systematic and structured approach, and for intervention reports to be published after peer-review and separately from evaluation reports.

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KEYWORDS

early intervention; at-risk drinkers; hazardous drinking; harmful drinking; intervention mapping; Internet, cell phone, eHealth, short message service

Introduction

Improved reporting of intervention rationales within eHealth will extend the evidence base and may improve the design of future intervention programs [1-9]. Research and development teams that set out to create interventions are informed in 2 basic ways—directly, based on empirical reports, and indirectly, through systematic or meta-analytic reviews. However, descriptions of the treatment rationales within empirical reports, including theoretical backdrop, treatment goals, causal mechanisms, behavior change techniques, delivery, and content, tend to be confined to a few paragraphs in the methods section [1]. Researchers need to be able to compare the treatment rationale across programs to adequately interpret the results from the empirical findings of the field. Therefore, the confined descriptions disable researchers who need to form hypotheses about how to improve intervention design during the process of creating new interventions [10]. Systematic reports of interventions should inspire creators of eHealth interventions toward use of a broader array of methods, just as treatment manuals do for clinicians who practice face-to-face psychotherapy [11]. The lack of detail in empirical reports also limits the insights possible within systematic reviews [2,3,12]. The findings from such reviews thus tend to be broad and lack detail. For example, a high quality review reported that "more extensive use of theory was associated with increases in effect size interventions that incorporated more behavior change techniques also tended to have larger effect…and the effectiveness of Internet-based interventions was enhanced by the use of additional methods of communicating" [12]. The insufficiency of these insights within systematic reviews is not due to the reviewers, but due to the limited reporting. As such, incomplete reports prevent reviewers from examining detailed hypotheses concerning the relationship between the intervention rationales and the outcomes [13].

Generally, we can say that eHealth interventions [14-19], such as alcohol interventions [20-22], show promise in terms of feasibility and efficacy, but we know little about what distinguishes the effective from the less effective interventions [12,22-24]. To increase the opportunity to extract insight and knowledge from eHealth studies, and to ultimately advance intervention design, it is necessary to improve the reporting of intervention rationales. Hence, the aim of the current article is to give a systematic and comprehensive description of the treatment rationale of an alcohol intervention (Balance).

Methods

This paper uses intervention mapping (IM) to give a systematic and comprehensive description of the treatment rationale. The IM protocol [1] provides a structured approach to develop and describe health programs. It is a logical, methodic, step-by-step procedure that helps researchers organize their thoughts as they move from theory and evidence to practice, and it provides tools to describe the development process. For each of the steps in the mapping process, theory and evidence is approached differently [25], meaning that different theories play different roles throughout the mapping process. The end product constitutes a comprehensive blueprint of the intervention and a detailed treatment rationale, that may facilitate reproducibility, support the interpretation of subsequent evaluation studies, and ease the comparison of treatment rationale across intervention [25,26].

The objective of the paper is to describe treatment rationale, hence, we focused on the 4 applicable steps of IM: (1) a brief needs assessment, (2) defining the goal and the objectives of the intervention, (3) identification of intervention methods and applications, and (4) developing the actual program materials. Step 2 is further broken down into 3 levels of detail, which are the overall program goal, the performance objectives, and the change objectives. The program goal is the result you want to achieve with the intervention (eg, to make at-risk drinkers drink less), the performance objectives describe the actual behaviors that each client must perform to reach the program goal, and the change objectives outlines what needs to change with regard to specific behavior determinants for the program participants to do each of the performance objectives. In this way, the performance objective is a specification of the program goal, and the change objective is a specification of the performance objectives. The end result of step 2 is a matrix in which the performance objectives are crossed with the behavior determinants to form a set of change objectives. This matrix constitutes the core of the treatment rationale of which the subsequent steps of the development process is based upon.

Results

Needs Assessment

Alcohol use is the third leading contributor to the global burden of disease [27]. Currently, there is a need for alcohol interventions [28-30]. Typically, only those with the most severe alcohol problems are treated, while those with moderate problems go undetected [31-33]. This is unfortunate because the majority of alcohol-related harm and socioeconomic cost is not attributable to drinkers with severe alcohol dependence, but to the much larger group of at-risk drinkers, a group that receives little treatment attention today [34,35]. Therefore, we decided to focus on the at-risk drinkers, which include both hazardous and harmful drinking [28]. Hazardous drinking refers to a pattern of use that is of public health significance despite of the absence of any current disorder, while harmful drinking refers to a pattern of use that is already causing health damage. There exists no good estimate of at-risk drinking prevalence among the general Norwegian population. However, in Sweden, a comparable nation with regard to alcohol consumption, the prevalence of at-risk drinking has been reported as 18% for men

and 5% for women [36]. A study of the private sector workplaces in Norway revealed that 11% of both male and female workers met the criteria for hazardous drinking [37].

While face-to-face alcohol screening and brief interventions are effective in reducing alcohol consumption [38], diffusion into routine health care has been slow [28,39] and limited by general practitioners' time, competency, and willingness to implement them [40,41]. Internet-based programs have several advantages to these procedures, including a potentially higher reach to lower cost, accessibility, 24/7 availability, convenience, and anonymity [42,43]. Due to the stigma of receiving alcohol treatment and the high number of at-risk drinkers, eHealth interventions seem particularly well suited to this population [32]. The most common design of online alcohol interventions is the single-session screening and feedback format [20-22]. Based on the indirect comparisons of systematic reviews, the efficacy of simple single session interventions tend to be outperformed by the more complex multi-session interventions [12,22]. Hence, there is a need for novel and complex approaches to such treatment. Specifically, the tailoring of intervention content with just-in-time therapy in response to self-reported change in target behavior or emotional state is a promising and emerging trend to eHealth design [2,44-54].

Defining the Goals and Objectives of the Treatment Program

Defining the Overall Goals of the Program

With regard to the intended aims of an intervention, the first level is the program goal, and the result one wants to achieve with the program. The goal of the current program is to diminish health risk and mitigate negative consequences of alcohol by encouraging lowered alcohol consumption among at-risk drinkers (ie, hazardous and harmful drinkers). Stated differently, the intervention is intended to make at-risk drinkers drink less. The performance objectives, change objectives, and sub-aims of the intervention will specify how this goal can be achieved.

Defining the Performance Objectives of the Program

A specific intervention may target one or several performance objectives. Performance objectives make up the actual behaviors that each client must perform for the program goal to be reached and their behavior to be changed. A performance objective is a specification of the program goal, and it defines more precisely what it is to drink less, in terms of behavior. The goal of the program was to make at-risk drinkers drink less. Self-regulatory processes appear to play key roles in both the causes and effects of alcohol consumption [55], and the self-regulation perspective can account for several of the topics we believed to be important for this type of behavior change, like maintenance of the efforts to change over time, lapse and relapse prevention, as well as mood regulation. Hence, self-regulation theory was used to specify the program goal and identify the performance objectives. In this way, the overarching idea of the current treatment is to support continued self-regulation throughout the behavior change process. Although the self-regulation perspective was essential at this level of intervention development, other theories play important roles in subsequent steps of the development.

In a broad sense, self-regulation refers to any effort to alter personal responses, including thoughts, actions, feelings, and desires. Without regulation effort a person would respond to a situation according to habit, previous learning history, innate tendencies, or biological needs. Self-regulation is comprised of 3 sub-processes: (1) self-observation, (2) self-evaluation, and (3) self-reaction. These processes are interdependent and take place in an ongoing circular process [55]. As they are interdependent, all 3 should be reflected in the performance objectives and targeted by the intervention.

Self-observation, or self-monitoring, refers to conscious efforts to explicitly identify one's own impulses. It is important to observe the thoughts, feelings, or environmental factors that precede craving or deciding to have a drink (eg, "the argument with my spouse made me feel poorly, and I had a drink to cheer me up" or "meeting my friend at the pub made me feel like drinking"). Self-evaluation involves using criteria or standards to assess situations, problems, or behaviors according to personal goals (eg, "my goal today was maximum 2 beers, but now I've emptied the fourth bottle - this was not what I planned for"). Self-reaction refers to any active effort to alter an unwanted impulse and comes as a response to self-observation and self-evaluation. Self-reaction includes self-stopping, rewarding or punishing oneself, making implementation intentions, coping, and action plans [56,57] "The next time someone offers me a drink I will reply, 'no thanks', even if I really want one", is an example of a self-reaction that involves making both an action and a coping plan.

The decisions and processes involved when initiating a behavior change attempt may be different from those involved in maintaining a new behavior [58,59]. Thus, in terms of performance objectives it is useful to distinguish between implementing the change attempt and maintaining the change attempt. A meta-analysis suggests that relapse prevention is particularly effective for alcohol treatment [60]. Moreover, experiencing setbacks during attempts to change habits seems to be the rule rather than the exception. If not coped with adaptively, they may lead to impaired self-regulation [55,61,62]. Setbacks include lapse and relapse, and drinking more than a predefined target is a characteristic of both. The small but important difference between them is the cognitive interpretation of the situation. Specifically, when the person falls short of meeting the predefined target but keeps his/her resolve and continues the change attempt, it is a lapse, and when the person gives up the efforts to change and returns to the previous pattern, it is a relapse [63,64]. While avoiding lapses is a primary goal, one must cope adaptively with them when they occur. It is important that the person does not give up, but instead continues their efforts to change habits. Within Balance, these theoretical insights were translated into two separate performance objectives: (1) avoid lapse by coping adaptively with the antecedents of drinking, and (2) avoid relapse by resuming efforts to change following a lapse.

Self-regulatory processes place demands on people's mental capabilities and when these mental resources are depleted, people are vulnerable to self-regulatory failure. Such failures, like a lapse or a relapse, are more likely to occur when people are tired or experience negative emotions [64-66]. Relatedly,

enhancing positive affect can build resilience and help maintain behavior change attempts over time [67-71]. What is more, people drink to regulate emotions. Alcohol is often consumed in hopes to alleviate negative or enhance positive feelings and may thus be regarded a mood regulation strategy. This is an inexpedient strategy for the at-risk drinkers and they need help to discover more appropriate tools. Constructive regulation of own emotions was thus included as a third performance objective within Balance. In summary, to reach the overarching goal of the intervention program, clients must complete the performance objectives outlined in the first column of Table 1. This set of performance objectives is what we refer to when we say that the overarching idea of the treatment is to support continued self-regulation throughout the behavior change process.

Defining the Change Objectives of the Program

To develop the change objectives of the program, 2 considerations were made. First, what the clients needed to do to successfully change their behavior was defined (ie, the performance objectives above). Second, what makes people carry out these actions was identified (ie, the behavior determinants). For this purpose, the change objectives related to knowledge, attitudes, norms, planning, self-efficacy, skills, and behavior were included [56,57,72-76]. The performance objectives, determinants, and change objectives are displayed in Table 1. Each change objective is operationalized such that it is measureable within an evaluation, and phrased as a response to the question, "What needs to change related to the determinant for the program participants to do the performance objective?" [1]. The change objectives can be considered the basic building blocks of the behavior change process, whereas the performance objectives together with the determinants provides the overall plan of the process. Each of these three core concepts represents different levels of abstraction in the planning, and they are based on different sets of theory and evidence. Together, the elements of the matrix in Table 1 constitute a logic model for the change process that the intervention is expected to bring about. The matrix can be looked upon as a map of the active ingredients of the intervention, and constitutes the core of the treatment rationale that underpins the current intervention.

Table 1. The matrix of change objectives.

Performance objectives for at-risk drinkers	Determinants		
	Knowledge and outcome expectancies	Attitudes and self-efficacy	Planning, skills, and actions
1. Continued self-observation and self-evaluation	Express that sustained effort in self-observation/ evaluation is necessary	Active involvement in own change attempt	Keep a record of drinks and compare with personal standard
		Express positive attitudes towards behavior change (eg, it is interesting, entertaining, instructive)	Adjust the maximum limits for consumption according to recent experience
		Express confidence in ability to observe and evaluate self	Be able to detect the antecedents of drinking
2. Implementation of the behavior change attempt	Know how own drinking relates to official guidelines	Express positive feelings for receiving help to drink less	Set exact maximum limits for the number of drinks to be consumed
		Express confidence in ability to implement change	Make informed choice of whether to drink less or not
3. Maintenance of the behavior change attempt over time	Recognize relapse vulnerability and need for long-term efforts	Express that intervention provides help that are personally relevant and according to own goals	Plan how and when to reward oneself for achievements
			Log on to the program regularly
		Express confidence in ability to maintain change.	Activate support from the environment
3a. Avoid lapse by coping adaptively with the antecedents of drinking	List the most personally relevant antecedents of drinking	Express confidence in ability to cope with urges and temptations etc	Make implementation intentions about activating tools and strategies to handle craving or temptation, including techniques to improve mood
3b. Avoid relapse by resuming the change effort after a lapse	Know the psychological consequences of having a lapse and the distinction between lapse and relapse	Attribute failures to transient situational factors and achievements to self	Make implementation intention, after a lapse, about sticking to original plan (drink less)
		Express importance of achievements and downplay setbacks	
		State that starting to drink more after a lapse is a deliberate choice	
		Express confidence in ability to recover after a lapse	
3c. Constructive regulation of emotions	List a set of techniques to improve mood	Express confidence in ability to regulate mood	Apply the learned mood regulation techniques

Theory Informed Methods and Practical Applications

The previous step of the mapping process is largely concerned with what needs to change (ie, conceptual theories), while the current step is concerned with how change is brought about (ie, action theories). As demonstrated in the previous step, self-regulation theory [55] was essential to the treatment rationale, in that the self-regulation perspective was used to develop the performance objectives. The performance objectives are in turn used to deduce the more specific change objectives and to select methods and practical applications that address these change objectives. In this way the performance objectives, and thereby the self-regulation perspective, guided how additional theories and models were included in the treatment rationale. Specifically, cognitive behavior therapy [74] and the transtheoretical model [76] describe several methods to stimulate the 3 basic sub-processes of self-regulation, self-observation, self-evaluation, and self-reaction, respectively. These methods include raising awareness, psychoeducation, dramatic relief, self-reevaluation, environmental reevaluation, modeling, relaxation training, training in problem solving skills, reinforcement, and feedback [74,76]. The Health Action Process Approach [77] was used to distinguish between pre-action self-efficacy, maintenance self-efficacy, and recovery self-efficacy. This means that the self-efficacy should be targeted in relation to important behavior change challenges like the abilities to maintain the change attempt and recover from setbacks. Stated differently, self-efficacy needs to be targeted in relation to each performance objective. Social cognitive theory was used to specify 3 sources of self-efficacy: overt mastery experiences, vicarious experiences, and verbal persuasion that each provides specific targets for intervention [73].

Making heavy drinkers track their own alcohol consumption on a daily basis using automated technology may help to reduce drinking [78]. Also, to set specific personal goals for themselves with regard to lowering consumption is a recommended method for drinking with moderation [79]. Setting specific goals in combination with behavioral monitoring allows for comparison of goals with actual behavior, which is a crucial ingredient of the self-regulation process (self-evaluation). Moreover, goal setting combined with behavioral monitoring may serve as a trigger system for launching a just-in-time relapse prevention therapy [53]. Planning and forming implementation intentions are also promising methods to reduce drinking [57,80]. Positive psychology, in addition to cognitive behavior therapy [74], was instrumental in informing the design team on methods for emotion regulation [81-84], relevant to the last performance objective. Giving the program human like features, or making it person-like (ie, personification of the program) can increase persuasiveness [85]. Last but not least, inspiration was drawn from the principles of motivational interviewing, including express empathy, develop discrepancy, avoid argumentation, roll with resistance, support self-efficacy, and emphasize client autonomy [73,86,87]. Taken together, the principles of motivational interviewing and of persuasive technology, and the elements from positive psychology, are important in building client confidence in the program, and fostering therapeutic alliance [70,88].

In translating methods into practical strategies, one needs to consider the feasibility and the practical context. Thus, this task has to be done in iterative steps with the next task, developing the actual materials, to fit the strategies with this context. For example, the combination of goal setting and behavioral monitoring to serve as a trigger system for launching the just-in-time therapy would not be feasible in the practical context of group therapy with biweekly meetings. Table 2 gives an overview of selected theoretical methods, practical strategies, and considerations for use. These considerations are the conditions under which the methods are believed to be effective. They can be drawn from theory, empirical findings, or could be practical concerns, and they are essential to keep in mind when translating methods into practical strategies and program components.

Table 2. Theoretical methods, practical strategies, and considerations for use.

Theoretical method	Practical strategy: What should be done?	Considerations for use: How should it be done?
Active learning	Give information in texts (a psychoeducational approach). Cognitive and behavioral assignments. Quiz for repetition purposes.	Should be relevant, plain, rewarding to follow, and vary in format and media. Learning moments should be short and many, rather than few and lengthy.
Consciousness raising	Provide information, guidelines, assignments, examples and tips to increase self-awareness.	Feedback and confrontation should be followed by increase in problem solving ability and self-efficacy.
Self-reward	Encourage self-reward.	Should be a clear criterion for acquiring a pre specified reward.
Reattribution	Teach to explain setbacks and successes in terms of adaptive attributions (ie, transient and external attributions for failure, and stable and internal attributions for mastery).	Optimistic attribution pattern should be primed early, and reinforced after lapse (just-in-time).
Provide social cues	Provide social cues (physical, psychological, language, social dynamics, and social roles) that elicit instinctive social responses.	Excessive use of these techniques may backfire into annoyance.
Visible expectations	Stimulate thinking about expectations from significant others.	Timing: prior to drinking situations, weekends.
Self-reevaluation	Further cognitive and affective assessments of one's self-image with and without at-risk drinking (eg, comparing self-image of being at-risk versus no-risk).	Raising awareness must be quickly followed by increase in problem solving ability and self-efficacy.
Environmental reevaluation	Further affective and cognitive assessments of how the presence or absence of risky drinking affects one's social environment (eg, describes how drinking affects family and reflect on self as role model).	Raising awareness must be quickly followed by increase in problem solving ability and self-efficacy.
Anticipated regret	Stimulate anticipation the negative affective consequences of continued at-risk drinking.	Must stimulate imagination.
Modeling	Show potential role models and how they coped with difficulties etc.	Model should be reinforced.
Resistance to pressure	Promote making of counter arguments.	Requires building of refusal skills.
Positive self-talk	Encourage making positive statements to inner ear about self, own abilities etc.	Not applicable.
Reframing	Teach how to put negative facts into another frame of reference that makes the fact positive or neutral.	Not applicable.
Support	Stimulate mapping the environment for potential supporters. Encourage contact, and provide suggestion for contact email.	Not applicable.
Implementation intentions	Stimulate formation of implementation intentions, by texts, prompts and assignments.	Must include specification of when, where and how to act.
Planning coping responses	Promote identification of potential barriers and ways to overcome these.	Not applicable.
Mastery experiences	Teach to imagine and write down previous mastery experiences, and encourage a focus on what is mastered until now (eg, you have kept your targets for many days).	Beneficial with domain similarity. Can be used for just-in-time therapy in critical situations.
Vicarious experience	Provide stories of mastery/success from others, and encourage identification of such stories in own environment.	Requires identification with model.
Persuasion	Communicate optimism about the outcomes, and point out that change is not an instantaneous venture.	Enhanced by the prior development of confidence in treatment provider.
Behavioral monitoring	Prompt to perform daily logging of target behavior.	Not applicable.
Goal setting	Encourage setting specific and time-targeted goals with regard to drinking.	Not applicable.
Count the good things in life	Promote noticing and appreciating the positive aspects of life—anticipate future pleasures, mindful of present pleasures, and reminisce about past pleasures.	Not applicable.
Socializing	Encourage mapping social network for doing pleasant activities. Encourage contact, and provide suggestion for contact text messages or phone calls. Tips to make or improve social bonds.	Persons should decide in advance not to drink, go to places without alcohol, or with persons that do not drink.

Theoretical method	Practical strategy: What should be done?	Considerations for use: How should it be done?
Cognitive defusion	Encourage combating the tendency to reify thoughts, emotions, and memories.	Acceptance and defusion is not an end in itself, but a mean to increase psychological flexibility and value based action.
Mindfulness	Provide exercises that fosters contact with the present moment and self as a context, not self as the content of thoughts.	Not applicable.
Identify value-based goals	Promote defining core values, deciding specific value based goals, and acting on the goals.	Goals should be specific, measurable, achievable, realistic and time-targeted.
Nonviolent communication	Teach to distinguish an action from the assessment of or the feelings evoked by the action, identifying and expressing the feeling, the need and what one want in a non-demanding way.	Client should practice the distinctions and the concept and be given feedback.
Doing kind acts	Encourage ideas for kind acts, keep track of them, and plan them ahead of time.	Not applicable.
Visualizing best possible life	Encourage envisioning scenarios of a future life in which many goals and dreams are actualized and personal potential had been met.	Recognize what is already achieved, challenge barrier thoughts, and break major goals down into achievable sub-goals and milestones.

Program Components and Materials

Screening

Screening may support an informed choice about whether to change drinking habits or not, and starting alcohol interventions with screening is standard practice [21,28,38]. Screening is also important in that it serves as a vehicle for recruiting persons from the target group to a more comprehensive treatment program. The current intervention is therefore initiated with a screening procedure, based on the Fast Alcohol Screening Test [89]. During the screening, the person receives brief individualized feedback, comparing the reported alcohol habits with health authority recommendations. After the screening and feedback, the at-risk drinkers (those with a Fast-score of 3 or higher) are recommended they sign up for the comprehensive follow-up intervention.

Day-to-Day Tunnel Design and Program Structure

The program relies on 2 distinct and complementary strategies for delivering intervention content—tunnel information architecture and just-in-time therapy. The tunnel information architecture is a core organizing feature of the program. Tunnel designs use a screen-by-screen and a session-by-session approach in which the user follows a predetermined sequence of units of content. As opposed to in a hierarchical design, where the user must navigate menus to find the desired content, the user is guided through the various program materials in a fixed sequence in a tunnel design. To avoid distraction, a tunnel program restricts access to any ancillary or related content, and oftentimes it limits user navigation to the “next” and “prior” buttons, thus offering low user workload [90].

A tunnel design is double-edged sword. Upon entering a tunnel the user accepts a lowered degree of autonomy, and there is a danger that reduced autonomy may lead to frustration and dropout. On the other hand, a tunnel design may also increase the chances that the user will engage in activities and see content that would otherwise not be encountered [85]. A recent randomized trial [91] compared a tunnel design to a high user control version of the same intervention content. Subjects in the tunnel design condition perceived the efficiency of the intervention to be lower, compared to subjects in the freedom of choice condition. In terms of outcome, however, the tunnel design was found to increase the number of screens visited and knowledge gained from the eHealth intervention, compared to the freedom of choice condition. In other words, there was discordance between user preference and the actual outcome. This trial demonstrates that although users seem to prefer freedom of choice, restricting this choice by using a tunnel design, can in some cases more than compensate for the disadvantages of a tunnel design. Also, two trials of a smoking cessation intervention that used a tunnel design similar to the current one showed high program adherence and efficacy [54,92,93], thus demonstrating the feasibility of the tunnel design to behavior change and adding to the promise of a tunnel approach.

In the current program, the tunnel design was applied both at micro and macro levels. On a micro level, it dictated that each session was broken into smaller portions or pages; the user can flip between pages but not sessions (Multimedia Appendix 1). On a macro level, it meant there was a fixed day-to-day sequence of sessions that require users to go through the sessions in the predetermined sequence. A session that is accessed on one day cannot be accessed the day after. If the client does not log onto the site for a period, however, he or she can catch up by accessing the preceding, unread sessions. This tunnel design is in accordance with the need for continuous self-regulation, and in line with the recommendation that self-help alcohol interventions should provide support for a minimum of 6 weeks [94]. The distributed and frequent contact points stimulate awareness of one’s own change attempts, serve as frequent prompts for self-regulation, and represent a tacit way of telling the clients that behavior change is a process that call for sustained effort.

Including proactive elements and supplementary modes of communication can improve adherence to Web-based interventions [12,95,96]. Hence, for each session the client is sent a reminder email that contains a link for the session of that day. During the active behavior change phase, which is the first

2 months of the program, the client is given access to a new and unique session each day. This is followed by a low-intensity maintenance phase. Here, the numbers of sessions are reduced, first to 1 per week for the first month, then to every second week for the next month, and finally, to once every month for 8 months. In total, Balance comprises 73 sessions. An average session typically consists of 1000 words, split between 10 to 15 screens. The language is categorized as the easiest out of 6 levels on the LIX readability measure (ie, "very easy to read, equivalent to juvenile books") [97]. Each session takes from 3 to 10 minutes to complete, depending on the clients' depth of processing and speed of reading.

Although a tunnel design restricts user self-determination, such a design does not dictate passive users, as the tunnel design is well suited to foster interactive dialogues with the user [90]. Hence, the sessions include interactive tasks and cognitive behavioral assignments. For example, each week there is a quiz, consisting of 5 multiple choice questions, pertaining to the most important learning points of that week. Along with a brief summary statement of the learning point, the client gets immediate feedback on whether the response is correct or not for each question (Multimedia Appendix 2). Moreover, cognitive behavioral assignments that the clients are supposed to do between sessions can be provided in one session and then the assignment can be elaborated on during the next session. An example of a cognitive task to support self-regulation, used in the current intervention, is to make up and write implementation intentions of what to do in a tempting situation, and then later the client is later asked to adjust and improve this list according to recent experience.

Goal Setting, Behavior Logging, and Just-in-Time Therapy

In the current intervention, goal setting, behavior logging, and the just-in-time therapy are practically and theoretically intertwined. Each session the client is asked to log the number of drinks had on the previous day. Such behavior logging is important because it stimulates self-awareness. During each Monday session, the client determines their drinking targets for the coming week. To support this goal setting, a graph presenting the targets set and the logged consumption (week totals from all previous weeks in the program), and a detailed comparison of target and result for each day from the last week, is displayed. Then the client is asked whether the goals from previous week should be kept or adjusted. If they choose to adjust the targets, they are provided with a form where they fill in the maximum number of drinks to be consumed for each day of the week. The client is encouraged to cut down slowly at first, and then gradually cut further down as the initial targets are met. The client is told to set targets that he/she perceives to be achievable. By making the clients set their own targets, client autonomy is maintained. However, if the week goal is higher than baseline, this is pointed out to the client and the client is asked whether he/she is sure about the targets. The client may either respond "Yes, this week is special and I want to allow myself such goals", or "No, I want to set myself lower goals." As such, behavior logging and goal setting may contribute to successful behavior change [78,79]. These elements are essential within Balance because they are used as part of a trigger system for providing 2 instances of just-in-time therapy—a relapse prevention system and a lapse prevention system.

Relapse Prevention System

After logging of the drinks consumed on the previous day, the datum is compared with the target that was previously set by the client for that day (Multimedia Appendix 1). This happens in every session. If the result is below or on target, the client is praised, for example, "Well done! You drank less than your goal yesterday," or "Great! You did well yesterday. You are right on target!" However, if a client drank above target, he/she is asked: "What happened yesterday? Was it just a slip-up or do you think you are about to fail?" The clients are taught the distinction between lapse and relapse earlier in the intervention, and therefore can make the distinction between a slip-up and failure. If the client reports that it was "just a slip-up" or a lapse, the client can simply move on to the session. If not, then 1 of 3 relapse prevention therapies is launched. The system will remember previous lapses, so that each client will not receive the same therapy twice before the fourth reported lapse. In this way, the goal setting and behavior logging procedures taking place in a day-to-day tunnel design provide a platform from which the just-in-time therapy is launched.

The therapy consists of a prerecorded dialogue between a client and a counselor (a 5 minute audio recording, Multimedia Appendix 3), as well as 3 text screens (Multimedia Appendix 1). This therapy has several purposes including increasing self-efficacy by making the client realize what is achieved up until now [73] to avoid attributing the lapse to internal and stable factors, and instead attributing the lapse to situational factors to prevent negative emotions and a full-blown relapse [61]. Finally and most importantly, the client should recognize that if he/she relapses, it is part of a deliberate decision and not something he/she is powerless in preventing.

Lapse Prevention System

During each session, the lapse prevention system follows the relapse prevention described above. Here, the client is reminded of that day's target and asked how confident he/she feels about reaching it. The lapse prevention therapy is activated if the client replies, "I'm not sure" (as opposed to, "I'm fairly certain I'll manage"). Before the therapy starts, the client is asked to elaborate, by selecting 1 of 3 options: (1) "I feel worn out and down", (2) "I don't feel so sure of myself today," and (3) "I seem to have lost some motivation." The options are intended to cover depletion of resources, self-efficacy, and motivation, respectively (Multimedia Appendix 1).

At the final screen of the lapse prevention therapy, the client is asked to provide a time point for that day or evening for the program to send an encouraging mobile phone message via short message service (SMS). The client is encouraged to provide a time point when they would need it the most. The content of the SMS is related to the topic of the lapse prevention therapy. For example, if the therapy included planning how to cope with a challenging situation, the SMS would be a reminder about the coping plan; if the topic is previous mastery experiences, the SMS would be a reminder of those previous experiences.

Personification

People tend to react to and interact with objects in their environment, including media applications, as if it were real people [98]. It is assumed that mimicking features from human-to-human interaction in human computer-based communication can foster a sense of relationship or alliance between the program and user. This may in turn increase program impact [71,85,88,96,99]. Each session thus starts with a greeting and ends with a "goodbye", as if Balance is a person (Multimedia Appendix 1). The language is informal in tone, and oftentimes, personal pronouns are used. Additionally, pictures of 3 different guides or coaches that each represent their special topic, embodies or personifies the intervention. For example, each time the topic has to do with emotion, the client sees a picture of the "mood coach" along with the text. The 2 other guides are the motivation and willpower coaches. The idea behind such personification of the program is that humans are predisposed to respond to cues that they can easily connect with. Pictures and language (praising, greetings, turn-taking, interactivity) provide social cues that may in turn elicit the corresponding social responses from the client [85]. Speaking directly to patients about their patient status or the working alliance, however, was avoided, as this can be counterproductive and cause resistance [100].

Emotion Regulation Components

Emotion regulation makes up a significant proportion of the intervention content, and consists of 7 distinct tracks, each covering a unique topic including gratitude, socializing, turning negative thoughts, nonviolent communication, doing acts of kindness, optimism, and pleasant activities. The contents and assignments from these tracks are taken from the positive psychology tradition and from cognitive behavioral therapy [81,82,101-103]. Each user, however, follows only 4 of the 7 available tracks. Each week during the active behavior change phase, emotion regulation is targeted in 4 of the 7 sessions. This means that all 4 topics are visited once weekly during the initial 2 months of the program.

Two of the tracks are provided to all users, the gratitude track and the socializing track. The gratitude track involves assignments like counting ones blessings, writing down 3 good things that happened during the day, writing a letter of gratitude, and saying "thank you" more often than usual. The socializing track is about encouraging social interaction with friends and relatives (without alcohol). Assignments in this track includes calling a friend and inviting him/her out, mapping one's social network, advice on how to get new friends, and strengthening existing relationships (eg, find out about a friend's plan and follow up the next week by asking how it went, or give compliments to a partner or friend).

Then, based on a cue-reactivity test [104], designed to distinguish those mainly triggered by conflict situations from those triggered mostly by negative emotions and pain [61], users get either the turning negative thoughts or nonviolent communication tracks. In the test, clients are briefly shown a drawing depicting a potential trigger situation for drinking, and are subsequently asked to what extent they would feel able to resist having a drink after such a situation. The drawings incorporate a title word describing the potential trigger situation. For conflict situations, the picture headings include confrontation, aggression, fight, and criticism, while the negative emotion drawings include guilt, sadness, sickness, and stress. Those primarily triggered by conflict situations are recommended to follow the nonviolent communication track, while those triggered by negative emotional states are recommended to follow the turning negative thoughts track. To preserve client autonomy, however, the client is given the option of overruling the recommendations and select tracks regardless of test results.

The turning negative thoughts track is based on the acceptance and commitment therapy [105] and uses a combination of acceptance and mindfulness to help people distinguish themselves from thoughts, feelings, sensations, and memories. It also clarifies their personal values and take action based on those. This track includes a cognitive defusion technique called the word repeating technique, and a mindfulness exercise called "take your mind for a walk". In the mindful exercise, the client envisions a mental journey through a forest, and each time a thought that is irrelevant to the forest comes up, the client is instructed to visualize putting the thought under a stone and keep on walking. Additionally, clients are encouraged to define their values, rank them in importance, and set concrete goals for the most important ones. The goal of this track is to help turn around negative thinking, and thereby reduce the likelihood of lapse or relapse. Nonviolent communication serves as a basis for another track [106]. Here, empathy and honest self-expression is emphasized. First, the client is trained to distinguish an action from the assessment of, or the feelings evoked by, the action. Second, the client identifies and expresses the feeling. Third, the client identifies and expresses the need. Last, the client expresses the need in a non-demanding way. The goal of this track is to help clients reduce the level of conflict in their everyday interactions, and hence reduce the likelihood of relapse.

Then based on a person-activity fit diagnostic [107], the client is recommended to choose 1 of 3 tracks—acts of kindness, optimism, and pleasant activities. Again, to preserve client autonomy, he or she is given the option of overruling the recommendations and select tracks regardless of test results. In the acts of kindness track, clients are encouraged to do acts of kindness to others, keeping track of such acts, and plan them ahead of time. Examples of kind acts are provided, and clients are encouraged to figure out such acts for themselves. The track targeting optimism is based on "the best possible self" exercise taken from positive psychology [82,108]. Here, the client is encouraged to envision scenarios of a future life in which many goals and dreams had been actualized and where much personal potential had been met. Assignments in the coming week will ask him or her to elaborate on the scenarios, to recognize what they have already achieved is in line with the best possible life scenario, challenge and turn around obstructive thoughts, and break major goals down into achievable sub-goals and milestones. The pleasant activities track is based on cognitive behavioral therapy [103], and starts by prompting the client to compile a list of activities that make him/her feel good. In the subsequent weeks, the client is asked to schedule one or more

of these activities. He or she is also asked to determine a goal for one of the activities, which is something to achieve by repeating the activity over time.

Discussion

We have used IM to give a systematic and comprehensive description of the treatment rationale of an alcohol intervention, named Balance. Its treatment rationale is essentially based on a self-regulation perspective [55,61,64], in that the overarching idea of the program is to support continued self-regulation throughout the behavior change process. Maintaining the change efforts over time and coping adaptively with challenging situations are key factors to successful behavior change [55-71,109]. In achieving this, 3 elements of the treatment rationale are of particular importance: (1) emotion regulation as an inoculation strategy against self-regulation failure, (2) avoiding lapses by adaptive coping, and (3) avoiding relapse (if lapses occur) by resuming the change efforts after a lapse. In terms of delivery, the current intervention relies on 2 distinct but complementary delivery strategies, including a day-to-day tunneled psycho-educational approach in combination with the just-in-time therapy. The tunnel design is in accordance with the need for continuous self-regulation and at the same time it functions as a platform from which the just-in-time therapy can be launched. Two instances of just-in-time therapy are included as part of an emphasis on coping during critical moments of the change process (before and after a lapse). First, a lapse prevention system, which starts when the client reports low self-efficacy, and second, a relapse prevention system that is activated when the client reports drinking above target level.

Tailoring of intervention content in response to dynamic processes in target behavior or emotional states, as described above, is an emerging trend to eHealth design [2,44-54]. This and similar forms of intervening just-in-time can potentially play a more significant role in future interventions as advances in mobile technology make it more feasible, and increasingly available at a population level [2,44,50]. More research is needed to determine how this potential is to be released. For example, we do not know which theoretical frameworks are the most appropriate to underpin such interventions. As opposed to the more common approach to tailoring interventions that is based on differences between participants at baseline, just-in-time adaptations need to lean on models that are dynamic representations of within-person processes [2]. As the self-regulation theory focuses on within-person processes in behavior change, it may be one of the feasible perspectives for this purpose. In the current paper just-in-time components was placed within a complete theoretical and practical context, including the tunnel delivery strategy and the self-regulation perspective. By describing this treatment context we have contributed to an understanding of how multiple delivery strategies in eHealth interventions can be combined—for general behavior change interventions, as well as alcohol specific interventions.

Limitations

There are several limitations to the current research. The target group of the program is very broad. On one side of the spectrum, the target group includes persons with a long history of harmful drinking that might be very conscious about the negative impact from alcohol on their life, that are already motivated to change. On the other side of spectrum, the target group also includes persons that drink only marginally above the limits for sensible drinking. They have probably never experienced any serious negative consequences of alcohol, their drinking pattern is largely within the borders of what is culturally acceptable, and many of them probably do not think that they need to change at all. Targeting such a diverse population, with regard to motivation for change, drinking pattern, and alcohol history, with one single intervention may turn out to be overly optimistic. That is, the intervention will be more or less acceptable to use for certain sub-groups within the broader target population. Exactly what outcomes to expect in the various sub-groups, however, is an empirical question, which we will try to shed light on in later evaluation reports.

The dropout rates from eHealth interventions, including alcohol interventions, tend to be high [22,110]. For example, in a sample of problem drinkers, enrolled in a 12 session Web-based intervention, a dropout rate of 45% was reported, and the authors concluded that “the challenge of Web-based alcohol treatment programs no longer seems to be their effectiveness but keeping participants involved until the end of the treatment program” [111]. In terms of number of sessions (73) the current intervention is probably the most comprehensive of its class [20-22]. For each session added to an intervention, a further opportunity to drop out is also added. Hence, there is no reason to believe that the current intervention will be an exception from “the law of attrition” [110]. Rather than counting how many people drop out before the end of treatment, we think it is more important to focus on the number of sessions completed, and by whom (in combination with reach and effectiveness). Therefore, our conclusions differ slightly from the conclusion of Postel [111]. The criterion for success in eHealth is not to keep participants until the end of treatment, but to keep them long enough to achieve a clinically significant effect on the relevant health behavior. Furthermore, what is a sufficient dose may vary from subject to subject. For one sub-group, the screening and feedback session might be enough, while another sub-group, may benefit only if they complete 10 or more sessions. We stress that, the rate of uptake in the target group, the program adherence among users of the intervention, as well as the efficacy across sub-groups, remains open empirical questions that we aim to elucidate in subsequent research.

Advantages to the IM Approach

EHealth is an applied science in which interventions are designed to solve specific health problems, meaning that the design process ought to be problem driven [1]. To meet a treatment or prevention challenge and solve the health problem, the main tools are theory and evidence. Theory can however be approached and applied in many different ways. The design process thus require several decisions to be made, for example, regarding which theories are needed, how many, when to use conceptual theories, when to use action theories, and if one should stick to theories that predict the health problem or focus more on evidence that accounts for behavior change. In answering these and other questions, IM offers a set of

guidelines on how to approach theory and evidence, in what order to use them, and for what purpose [25]. In this way, IM allows the researcher to integrate theory and empirical evidence from multiple sources to form a single causal model (eg, Table 1), which shows how the researchers intended the intervention to work, and the hypothesized causal links of the treatment [1]. IM constitutes a multi-theoretical approach as opposed to a single-theoretical approach to intervention design that ensure a problem driven focus, necessary for the researcher to stay on track with regard to solving the health issue. However, the problem driven approach is not suitable for researchers focusing primarily on theory building and testing, only for researchers focusing on intervention building and testing [25].

The step-by-step manualized approach of IM prescribes a process to designing an intervention that functions as a useful planning tool. The manualized approach is also advantageous in that it provides a clear structure to the reporting that may aid in writing it, reading it, and in comparing the rationale across interventions. In completing the IM steps, theory and evidence is systematically linked to eHealth practice through a logical chain of decisions. Each step and decision shapes how an intervention influences its users, and by making the choices explicit, they are subjected to the test of evidence [10]. This is valuable because it extends the evidence base for subsequent intervention development. Therefore we recommend the use of a structured approach, like the IM protocol, in describing intervention rationale.

EHealth and Intervention Reporting

Scientists, reviewers, and editors alike are inevitably influenced by the trial report conventions [112,113]. These conventions together with word limits in journals result in intervention descriptions where the main focus is to describe how the intervention was evaluated rather than describing what it is [10,13]. The focus on the evaluation also manifests in the abstract, making the evaluation visible and accessible in bibliographic databases without emphasis on the intervention rationale. This situation makes it harder for a researcher and development team to compare treatments and learn from previous development efforts. When performing literature reviews, the design rationales are often embedded within multiple sections of multiple trial reports, and it can be difficult to get a full understanding of what exactly is being evaluated. This is not a problem for simple interventions, or when testing a single theory, but for complex interventions that are problem driven and multi-theoretical in nature, it becomes an issue.

Several solutions to this issue have been suggested, including digital preservation of intervention content in a Web archive [8], publishing addendums or appendixes along with the trial reports [7], as well as reporting in online journals, which tend to have less restriction on word limits [6]. These suggestions offer more space for reporting interventions. However, descriptions in an addendum or a Web archive will not be fully targeted by the peer review, thus evading quality assurance. Additionally, all these alternatives evade the full visibility afforded by academic search engines. Stated differently, these reporting practices make the important initial stages of intervention research a backstage performance. As an alternative, we espouse the view that eHealth researchers should publish the intervention protocols separately and peer-reviewed prior to publishing their evaluation studies [6,9]. Reviews that systematically assess the link between intervention rationale and outcome [12,23,114] can play a vital role in improving eHealth practice as they potentially synthesize the experiences from the entire field. The quality of these reviews depends on the quality of the intervention descriptions they build upon [13]. We believe that the above can improve the quality of available descriptions and ease comparisons of treatment rationale across interventions. Provided that reporting of interventions is improved across research teams and that reports of intervention development are combined with findings from clinical trials, the possible scope of systematic reviews will be broadened. A broadening of scope in future systematic reviews assessing the link between intervention rationale and outcome, may ultimately guide researchers in designing interventions with improved efficacy, reach, and user acceptability.

Conclusion

The descriptions of the treatment rationale for the alcohol intervention Balance, provides an intervention blueprint that will aid in interpreting the results from future program evaluation, it will ease comparisons of intervention rationale across interventions, and it may assist intervention development. By putting the just-in-time therapy within a complete theoretical and practical context, including the tunnel delivery strategy and the self-regulation perspective, we have contributed to an understanding of how multiple delivery strategies in eHealth interventions can be combined. Additionally, this is a call for action to improve the reporting practices within eHealth research. As one way to achieve such improvement, we advocate for using a systematic and structured approach, and for intervention reports to be published peer-reviewed and separately from evaluation reports.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

A compilation of screenshots from the Balance program.

[PDF File (Adobe PDF File), 12MB - resprot_v2i1e6_app1.pdf]

Multimedia Appendix 2

Sample items from the weekly quizzes.

[PDF File (Adobe PDF File), 28KB - resprot_v2i1e6_app2.pdf]

Multimedia Appendix 3

A transcription of one of the audio therapies for managing a recent lapse (relapse prevention).

[PDF File (Adobe PDF File), 13KB - resprot_v2i1e6_app3.pdf]

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Abbreviations

IM: intervention mapping
SMS: short message service

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Original Paper

Development and Usability Testing of an Internet Intervention to Increase Physical Activity in Overweight Adolescents

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Abstract

Background: Internet interventions may provide opportunities for low threshold counseling using feedback to guide and support health behavior, including increased physical activity. Research shows that overweight and obese adolescents are less physically active than their peers of normal weight. There are good reasons to believe that Internet-based interventions may be particularly suitable for motivating adolescents to increase physical activity, but we need to gain further knowledge of what features are effective and how to design such interventions.

Objective: To describe the process of development and evaluation of usability of a Web-based program for increasing physical activity in overweight adolescents.

Methods: Informed by the self-determination theory, motivational interviewing, and perspectives on self-regulation, this intervention was developed in a stepwise process by an interdisciplinary team of researchers, designers, developers, and representatives from the target group. An iterative qualitative usability testing approach (observation, survey, and interview) was applied in 2 sequences, first in the lab and second in the field, to assess how adolescents (aged 12-16 years) used and experienced the program and to make adjustments to the program based on evaluation of their response.

Results: The following components were included in the program: self-monitoring through planning and registration of physical activity and graphical response on progress, autonomy supportive individual Web-based counseling, forum for social support, and relevant age-adjusted information about physical activity. The first usability test resulted in adjustments related mainly to making the content and aim of the different features more visible and explicit. The second test evaluated the program with adjustments from the first test, revealing that the program was well accepted by the participants and only small aesthetic adjustments had to be made to complete the final version of the Internet program, Young & Active.

Conclusions: Thorough preparation, with clear theory foundation and close monitoring in the developmental phase, as well as contribution and iterative evaluation from the target group, is essential to create a user-friendly and engaging program. The efficacy of the program will be evaluated in a controlled trial.

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KEYWORDS

Internet; intervention; development; usability testing; adolescents; physical activity; overweight

Introduction

Background

Investigations point to a decrease in physical activity (PA) from childhood to adolescence [1]. Adolescents who are overweight with obesity are even less active compared to peers of normal weight [2]. Research also shows impairment in health-related quality of life among overweight and obese children and adolescents [3]. Aerobic fitness is positively associated with physical and mental health independent of body mass index, and a substantial weight reduction and maintenance over time may be unachievable for many overweight individuals [4,5]. Thus, there are good arguments for interventions to emphasize increased habitual physical activity more than individual weight regulation. It is also essential to focus on interventions to increase and maintain PA in adolescence because of the relations between activity patterns in adolescence and adulthood [6,7].

Recent research suggests that Internet technology is a promising way to change a person's health behavior and therefore provide opportunities for low threshold counseling using feedback to guide and support health behavior [8]. It might seem paradoxical to use an inactive device to promote activity among adolescents. However there are good reasons to believe that Internet interventions for promoting PA may be particularly suitable for this age group. Digital media is an area in which adolescents are experts and technology is the means of their empowerment [9]. Instead of thinking of digital media solely as the cause of physical inactivity, becoming overweight, and obesity, we can choose to use adolescents' competence as a valuable basis for raising the efficiency of communication in health promotion efforts. Despite promising results of Web-based interventions to promote PA in children and adolescents, well designed research is needed to further enhance our understanding of intervention characteristics that best promote behavior change [10-12].

An Internet program called Young & Active was developed aimed at motivating overweight adolescents (aged 13-14) to increase and maintain PA and thereby enhance their fitness and health-related quality of life. The intervention study is built upon the framework for researching complex interventions given by the Medical Research Council [13]. This framework is developed for the purpose of evaluating interventions in natural or everyday practice. The development and evaluation process is divided in 4 phases: (1) development—identifying and developing the evidence base, theory, modeling processes, and outcomes, (2) feasibility and piloting—testing procedures, estimating recruitment and retention, and determining sample size, (3) evaluation—assessing effectiveness, understanding change process, and assessing cost effectiveness, and (4) implementation—dissemination, surveillance and monitoring, and long term follow-up. This article describes the process and result of the development and how theory informed Young & Active with a particular focus on how the end users, the adolescents, through development and usability testing, contributed to the final version of the program (Phase 1). The development and usability testing will be followed by a 12 week controlled trial (Pilot-Phase 2), and finally by a full scale RCT (Phase 3).

Theoretical Basis and Content of Young & Active

Extensive use of theory and inclusion of behavior change techniques is important in Internet interventions to increase effectiveness [8]. The present intervention aimed to stimulate adolescents to engage in self-chosen activities that they find fun, meaningful, and want to do. Research shows that individuals who have more autonomous reasons for exercising are more positive toward PA [14] and more likely to initiate and maintain PA [15]. Fun, enjoyment, social support, and to a lesser extent health benefits, are reported as predictors of participation in PA. Especially for girls, the activity must be on their own terms [16]. Self-determination theory (SDT) has proven useful in understanding motivational, cognitive, and affective processes of physical activity [15-17]. Therefore, it was chosen as the theoretical framework for this intervention, supplemented by aspects of self-regulation theory [18,19]. Central to SDT is the question of how people internalize and integrate extrinsic motivations and come to self-regulate their behaviors in order to engage autonomously in their daily life [20]. According to this theory, developing a sense of autonomy and competence as well as relatedness is essential to make a person more self-regulated and able to sustain the behavior [21,22]. Autonomy reflects the need to engage in activities with a sense of choice, competence represents the feeling that one can accomplish tasks and reach goals, and relatedness refers to the sense of being understood and respected by significant others [21,23]. SDT supplemented by perspectives on self-regulation of behavior change gives suggestions on how an autonomy-supportive counseling style can motivate people to change health behavior, in this case, to increase physical activity [24]. Autonomy support, structure, and intrapersonal involvement are the 3 dimensions of the social environment that can support the need for autonomy, competence, and relatedness. If these factors are presented in an autonomy supportive manner [25], they can facilitate physical activity adoption and maintenance [26]. By giving the adolescents opportunity to form goals for PA, make a plan for how to reach these goals and monitor them, the program might facilitate autonomy. Individualized autonomy supportive feedback from a counselor based on the adolescents' registrations in the program is believed to provide users with a sense of autonomy, competence, and relatedness. It is also shown that SDT can offer a theoretical rationale for understanding the efficacy of motivational interviewing (MI), a client centered counseling method to promote behavior change [27]. MI involves avoiding controlling behaviors and direct persuasion. By expressing empathy, making the participant more aware of discrepancies between goals and actions, encouraging personal reasons for change, and supporting self-efficacy, the MI approach seeks to empower the participants' own reasons for change [27]. Thus, theoretical inputs from SDT and principles from MI are used

in the counseling of the adolescents to promote behavior change in this intervention. Table 1 presents this in a schematic form. We aimed to develop a need-supportive program which hopefully will make the adolescents experience support in a way that enhances their self-regulation and autonomous motivation to increase and maintain PA.

Table 1. Relations between motivational styles from SDT and MI—how strategies can be applied to facilitate autonomous motivation to increase and maintain physical activity.[a]

Principles from autonomy supportive counselling:	Principles from MI:	Examples of practical use:
Support autonomy	Avoid coercion and pressure	Do not pressure or argue the case for change (eg, "you have to be more active and exercise more").
	Explore the adolescent's own reasons for change	Let the adolescent explore his/her own reasons for being active and exercising.
	Encourage change talk	Affirm and reinforce expressions of problem recognition, exercise, desire, and intention to change.
	Explore options	Let the adolescent choose his or her preferred courses of action (ie, how and when to exercise).
Provide structure	Develop goals	Help to set goals for PA and exercise. Make sure the goals are appropriate, realistic, and achievable.
	Give clear information	Give information about what to expect from exercising and what it takes to achieve self-determined goals. Make sure the information is neutral, clear (understandable), sufficient, and repeated.
	Offer advice	Offer advice when appropriate, but avoid imperatives (eg, "you must exercise regularly").
	Provide feedback	Follow up goals and plans with regular feedback. Ensure that the feedback is received and understandable.
	Support self-efficacy	Make sure to affirm effort, success, and progress.
Be involved	Express empathy	Display interest in the adolescent and his/her well-being.
	Explore concerns	Reassure the adolescent that their concerns are natural. Acknowledge and explore worries.
	Demonstrate understanding	Try to see the adolescents' point of view.
	Avoid judgement	Do not blame or criticise the adolescent (eg, "you have failed in following your plan this week").

[a] adapted from [27,28]

Considering the age of the target group, we wanted to develop a program with self-explanatory and time-efficient functions [29]. This included a system that could, based on online registrations by the participants, calculate the accurate amount of self-reported low-, moderate-, and high-intensity activities related to time spent, and to make graphic presentations showing progress. Activities relevant for Norwegian adolescents were adapted from the Compendium of Energy Expenditure for Youth [30]. The compendium provides a classification system that standardizes the metabolic equivalent of task (MET) intensities of physical activities used in research. Based on categorization as light (< 3 METs), moderate (3-6 METs) or vigorous (> 6 METs) intensity activities [31,32], we coded activities as green, blue, or red, respectively. Thus, total amount of activity of different intensities would be easily identified in a graphic presentation of bar charts. Self-monitoring is central to the process of self-regulation [18,19], and is shown to increase effectiveness in interventions designed to promote healthy eating and physical activity [33]. It was expected that monitoring of progress and getting autonomy-supportive feedback emphasizing progress will enhance the Young & Active participants' perception of competence and make them more conscious about how active they are and how increasing all kinds of PA throughout the day can contribute to a total enhancement of activity. Supplied with the narratives, such registrations will provide the counselor with broad information on the participants' process.

The intervention includes daily registration and narratives on PA by the adolescents along with weekly individual Web counseling from trained health counselors. The initial components of Young & Active and their main content are outlined in Table 2. Except for one initial face-to-face meeting with a counselor to map PA, to be introduced to the program and be assisted in the making of the first PA goals and plan, all contact between participant and counselor will be online. The choices of components for the intervention were supported in a systematic review of Internet-delivered health interventions [34]. The review points to peer support, counselor support, email/phone contact, and updates of the website as intervention characteristics related to better exposure. Internet interventions aimed at adolescents or young adults seem to be most effective when they include combinations of several strategies [35].

Table 2. Overview of planned content of Young & Active.

Mapping of physical activity	Face-to-face interview between counselor and participant based on principles of MI and autonomy supportive counseling (ASC) from SDT, to help the participant reflect on PA, map current level of PA, and outline the possibilities for change.
Goals and plan for physical activity	Instruction on how to fill in (preliminary) goals and a plan for PA during the day and week. Focus on the value of self-determined goals and activities.
Registration of daily physical activity	Registration of activities during the day (time of day, type of activity, time spent, and alone/together with someone else).
Narratives of PA experiences during the day	Free text comments on experiences, feelings, and thoughts on physical activity and exercise and on life in general.
Automatic feedback on progress	Graphic feedback displaying planned and registered activity for present week and past weeks participating in the program.
Tailored feedback from counselor	Weekly individual written response from the counselor based on the participant's goals, plan, logs, and diary notes. Feedback based on principles from ASC and MI.
Evaluation and adjustments of goals and plan	Encouragement via tailored feedback to regularly evaluate and adjust goals and plan in accordance with progress.
Forum	User-driven forum for support and the sharing of physical activity related experiences and tips.
Information on physical activity	Relevant information on PA and sports activities. Regularly updated and edited.

Usability Testing

Young & Active focuses on how adolescents can find their own source of motivation for increasing and maintaining PA. It is proven that the intervention in itself is motivating to use in the sense that the end users choose to visit, use, and revisit it [29]. We aimed for the intervention to be appealing, to include intuitive functions, to be easy to navigate, and provide understandable and meaningful information. Testing by the end users—the adolescents—is necessary to ensure that these components are met. Usability testing refers to evaluation through the analysis of typical end users interacting with the program, allowing for iterative modifications [36]. Qualitative feedback through testing with representatives from the target group can give valuable information on user experience and help developers determine if a program will turn out to be effective and achieve its purpose [37,38]. The vast amount of usability problems and issues can be identified with only a small number of test subjects, as few as 8 to 10 participants [36]. A cycle of design-evaluation-redesign has the potential of major reduction in usability problems [39], which makes usability testing a powerful method for evaluation before inclusion in a trial.

Method

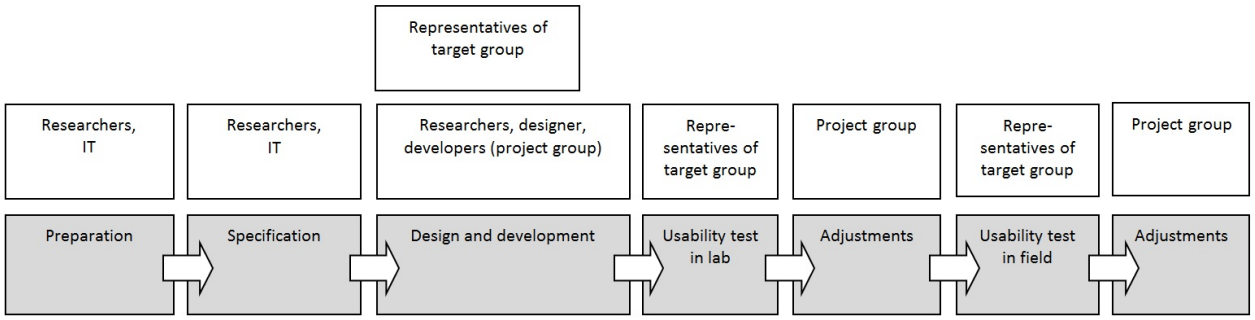
Development of the Program

The process of development of Young & Active covered the following steps, including preparation, specification, development, usability testing in 2 different settings, evaluation, and adjustments (Figure 1).

The preparation step included choice of theoretical framework and mapping of user needs related to physical activity and use of Internet. Risk analyses were made with assistance from the Department of Information Technology at Oslo and Akershus University College of Applied Sciences to assure that potential threats to the anonymity of the adolescents were accounted for. A detailed specification of requirements for the program was developed. An interdisciplinary team of health and education researchers, graphical designers, and application developers formed the project group.

Based on risk analyses and specification of requirements, the outlined content was transformed into wireframes (a visual guide that represents the skeletal framework of a website) to visualize and illustrate the link between text and graphics and interactive features. Development started with ideas being picked from well-established websites for adolescents with functions such as forums, ask-the-expert, and information on sexuality, health, and adolescence in general for instance. Design, language, use of symbols, and site architecture were studied. Representatives from the target group of adolescents (n=4), strategically sampled from an ongoing project for obese youth, participated in a workshop to help decide on design, content, and functionalities. The workshop was an informal setting with open discussions on the presented wireframes. Comments and suggestions from the adolescents were noted and included in the ongoing developmental process when found relevant.

Figure 1. Development process of Young & Active.



Testing Usability in Lab and in Field

An iterative qualitative usability testing approach with observation, a questionnaire, and focus group interview was used to assess how the participants use and experience the intervention. Usability tests were carried out in 2 sequences, first in a lab setting and second in the field, over a period of 2 weeks. The Honeycomb model [40] served as a guideline for the tests. According to this model, the quality of experience of a program is dependent on whether the users find the program valuable, useful, usable, desirable, accessible, findable, and credible. The tasks and questions for the questionnaire and interviews were grounded in these facets to ensure that they were all focused in the different components of the program. The questionnaire included questions that were answered Yes/No/I don't know, and also the participants were encouraged to write suggestions for changing and improving the program. The focus group interviews allowed the adolescents to speak more freely about their impression of Young & Active.

As mentioned, the aim of the tests in lab and in field was to assess how adolescents in the target group used and experienced the prepared intervention. For this reason, strategic sampling was conducted among adolescents who were expected to give valuable information. The number of participants was decided upon according to an appraisal of achieved saturation of qualitative information about usability [41]. In order to strengthen the trustworthiness of the information, different types of qualitative material were gathered in the field through triangulation by using several research methods [42].

The first test (lab) was carried out in 2 groups of a total of 7 adolescents (aged 12-13 years), recruited from a school and a project for obese adolescents respectively, and took about 90 minutes per group. At this point, the program contained all the main functions except to the forum and feedback page. The participants initially received brief information about Young & Active. Listed tasks then guided them through the different parts of the program. Each participant was observed by one of the members of the project group. Following the practical tasks, the adolescents filled in the questionnaires. Finally, focus group interviews were conducted in both groups.

To perform technical evaluation, to assess how the users respond to using the program over time, and to get a more thorough evaluation after adjustments based on the first usability test, the Young & Active program was tested over a period of 2 weeks. From an exercise group for overweight and obese youths, 8 adolescents (aged 14-16 years) were recruited. Informed consent to participate was given by the adolescents and their parents. The participants first met with the researchers for an informal conversation focusing on feelings, thoughts, and experiences with different forms of PA. The conversation was informed by the MI approach [27] and was aimed at making the adolescents reflect on goals to increase and maintain PA. The participants received a personal user identifier and a password, and were given a brief introduction to the different functions of the program. If desired, they received help to form goals for PA and to set up an activity plan to reach these goals. The adolescents started registrations the following week after getting a reminder via SMS. The counselors gave individual feedback twice during the test period. Bugs and minor errors were reported by a message in the program or via the forum, and consecutively handled by the programmer. The researchers moderated the forum and message system. An extended version of the user experience from the first test and focus group interview followed the week 2 test. Registration of use (frequent registrations, diary notes, and posts in forum), were summarized.

Data Analysis

The combination of questionnaires, observations, and focus group interviews was used to triangulate data to control and support the different findings, as the discussions in the focus groups were used to broaden and support the outcomes of observation and questionnaires. After each of the 2 tests, data from the questionnaires were summarized. Answers from the open-ended questions from the questionnaire and notes from observations and interviews were analyzed as text, using simple content analysis [43]. These data were sorted to correspond with each of the different pages of the program (My page, activity plan, diary, feedback, forum, and info page). General categories like user performance, visual design, content, functionality, and motivation for use were identified.

Results

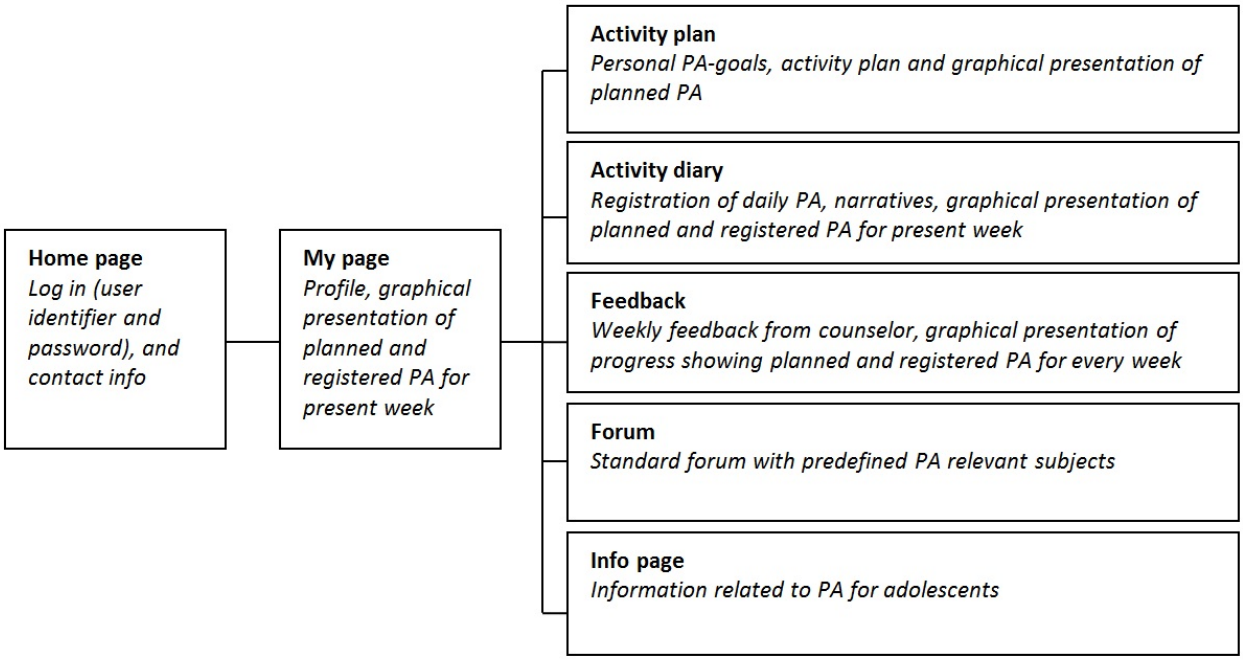
Results From the Process of Development

The first part of the development process resulted in a draft with suggestions on name of the program, logo, color scheme, and page layout, including the content and placement of different

functions distributed. A flow diagram of the Young & Active program as it was initially planned, showing the main content, interactive features and the links between the different pages, is provided in Figure 2.

No changes were made to this structure during development, and the pages described in Figure 2 are all represented in the final version of Young & Active. In addition, we designed a simple password-protected page for counselors. On this page, counselors can view a summary of each participant's registrations and diary notes, write and send weekly feedback, and monitor the forum. Young & Active was developed in eZpublish (version 4.4.0), based on Open Source technology and designed to support PCs, Macs, and newer versions of all browsers. Usability was not tested for mobile devices, but the program shows acceptable readability for smartphones and tablets.

Figure 2. Main content and interactive features of Young & Active.



Response From Workshop

The workshop participants liked the suggested name of the program. Colors and graphics, especially the smiley logo, met with approval. The participants focused on the advantages of using smileys in the communication as a way of making it easier to express feelings and the communication more effective. The benefits of written self-determined goals and detailed plans for activity were emphasized, but the adolescents did not immediately understand what kind of information the PA-registration page required. It was obvious that thorough explanation and specific examples were necessary to get a quick understanding of the different functions. The participants saw the advantages of bonding with other adolescents in the program to exchange experiences and opinions and to ask questions. On the info page, the adolescents indicated they would prefer to read about activity alternatives and how to make healthy food. Feedback on the wireframes was mainly positive. Suggestions on changes and supplements to graphics, features, content, and functionality from the workshop were incorporated in further development of the program.

Results From Usability Tests in Lab and in Field

The participants of both lab and field tests had a computer at home and regarded themselves as competent computer users. All of the participants in the field test used Young & Active at home in one way or another during the test period, meaning that they made at least 1 registration in the diary, posted in the forum, or sent a message to the counselors via the message system. Most of the participants (5/8, 63%) made regular, frequent registrations and used the diary, while 1 participant got ill, 1 had an ankle injury and 1 responded "this program is not for me, but I am sure others will find it useful". This last participant joined in on the survey and interview, while the other 2 infrequent users did not.

User Performance

The participants in the lab test had no problems logging in or navigating among pages. They tended to ask for help rather than using help buttons with explanatory text. All participants found relevant leisure sports activities, but did not intuitively choose activities for the entire day and week (to and from school, at school and so on). This occurred both when planning and making registrations in the diary. In the plan, the adolescents found it inconvenient to have to select days one by one for activities performed every weekday, such as walking to school. Searching through lists of activities in the plan and the diary were shown to be time consuming.

The most important adjustments after the first usability test concerned making the content and the aim of the different features more visible to the users. This included choosing bold

headings, making short introduction texts for every task and creating more visible help-buttons with pop-up texts for specific explanations and tips.

Observation during introduction of the program and the 2-week test period revealed that the participants in the second usability test very quickly grasped the different functions of the program. Due to the short test period, none of the adolescents made changes in their activity plan, but 2 participants supplemented their goals for activity. The 5 active users made registrations according to their activity plan and added other less regular activities if relevant. They estimated registration to take less than 5 minutes. All active users wrote in the diary, some almost every day and others less frequently. Except for minor bugs, no technical problems occurred that compromised use of the program in the field.

Visual Design

Visual design refers to the informants' impressions of how the program looks and how they find the colors, fonts, illustrations, and layout. Both groups in the lab test approved of the color scheme, the program smiley logo that has not been seen by some participants before, the design in general, and found it appropriate for both boys and girls. Participants in the second usability test also approved of the design and graphics and the smileys in particular. However, they had complaints on both visual and functional design of the forum. It did not appeal to them aesthetically, as the text fields were too spacious and the profile smileys too large.

Content

All in all, the participants in the lab test commented positively on the content of the program. They appreciated the opportunity to plan and log activity, but were mainly concerned with goals, plans and registration of sports activities and exercise, not PA in general. Some suggested pop-up text with tips on what to write about in the diary. The adolescents easily made goals for PA, although some were unsure about how specific the goals had to be and thus asked for help. The participants reported liking the info page, noting that it was understandable and the issues were relevant, but several of the informants asked for more facts about effects of exercise and more pictures and videos to illustrate the information.

No significant changes had to be made to the content after the lab test, other than adding pop-up boxes with tips, more pictures, and more fact-oriented information on the info page. Some requests were rejected due to security demands (personal profile) and time and budgetary constraints (exercise videos).

The adolescents participating in the usability test in field had no problems making goals, plans, and registering in the diary, but asked for more options for activities during school time (eg, field trips). They appreciated the opportunity to reflect on their daily activities and the day in general, but requested a less structured diary with fewer leading questions and 1 single text field with an open question ("How was your day?") instead of 3 fields with more specific questions. The info pages, both text and illustrations, were reported to be fine. Feedback from counselors was valued ("It motivated me!"), but could be given more often. All in all, the informants found the content of the program interesting and uncomplicated.

Functionality

Functionality refers to the interactive and adaptive features of the program. The participants appreciated the possibility of making a profile. Graphs and the fact that they interactively responded to changes in registrations got positive remarks. After the lab test, the project group decided on an additional feature to give the participant and counselor an opportunity to exchange short messages independently of the diary/feedback if necessary, and included a mailing system with a message box present on every page. This was mainly for security and practical reasons.

The adolescents in the second test found it easy and fun to keep track of amount and type of activities by observing the bar charts over time. However, 2 informants reported that the bars showed variable stability depending on the browser. The forum got the most negative feedback as the adolescents experienced it as "not user friendly" and indicated that it was "hard to get an overview". Response to this was given both as messages in the forum during the test period and in the interviews that followed. The interviews revealed that not all of the adolescents had noticed that they had received feedback from the counselor and that this had to be more explicitly announced on My page.

Motivation for Use

All of the participants in the lab test focused on the importance of making goals and a plan to increase PA, commenting that, "it is easier to hold on to goals that I have written". However, they were not convinced that they would make an effort to register and write in the diary every day, and they requested the possibility to backdate. Most participants (6/7, 86%) reported that Young & Active might contribute to making them more active. Based on this response we made the operations for registering activities more intuitive and time efficient, and made it possible to backdate within the same week so registrations did not have to be made every day.

In the field test, the youngest adolescents (age 14) were most positive regarding how useful and interesting the program was, giving comments like, "it made me more conscious about PA", "the program proves that I am more active than I think I am", "I liked the program, registrations are fun, I would like to continue to use it". The older adolescents (age 16) were more uncertain, commenting that, "it takes some time and it is hard to remember to register, so I am not sure if I would have liked to use the program over time".

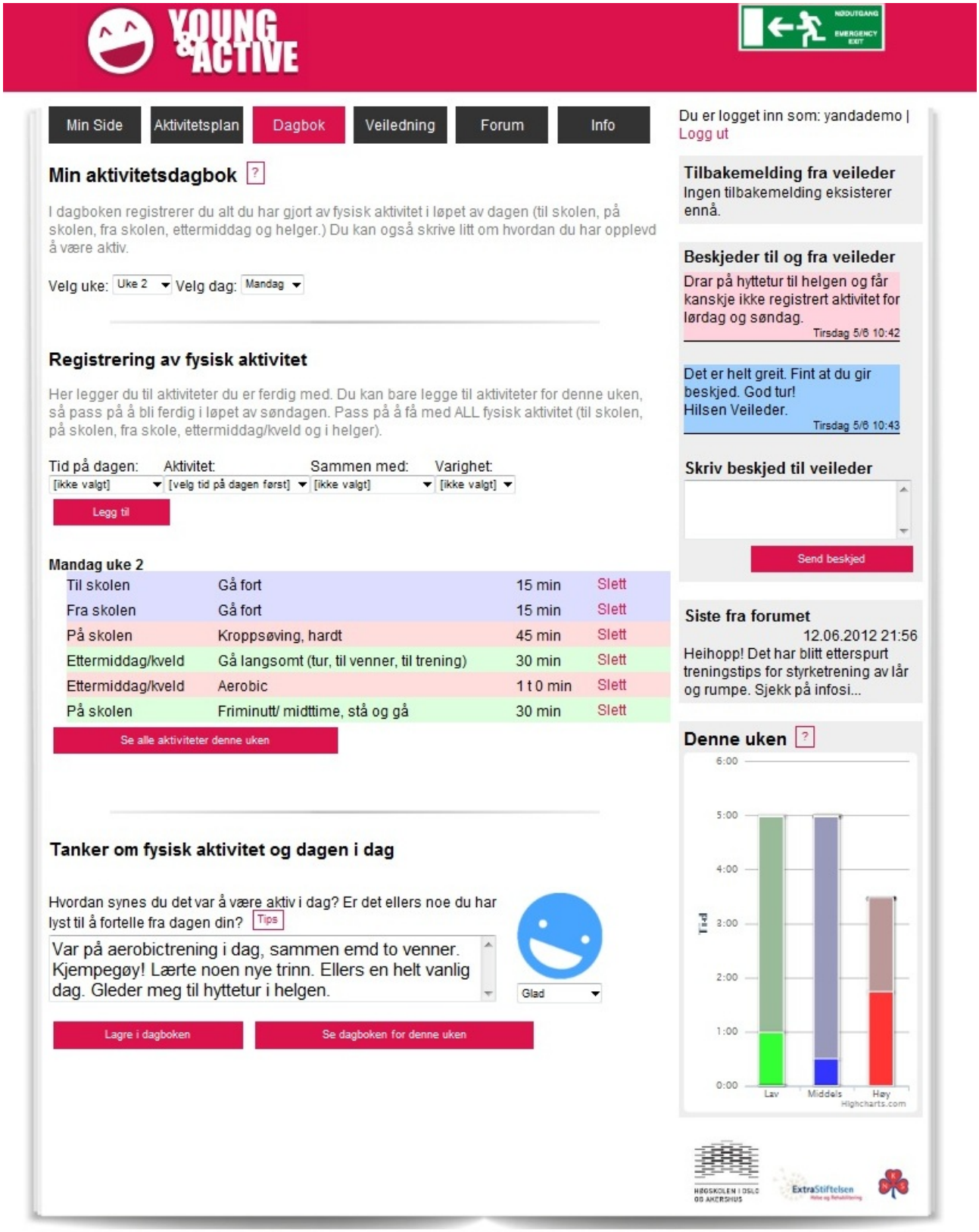
Results of Usability Test in the Field, the Finalized Young & Active Program

Only minor adjustments were made after the usability test in the field. These included better marking of feedback from the counselor, less spacious commentary fields in the forum, and 1 instead of 3 text fields and questions in the diary. Procedures for feedback once a week remained, but an initial personalized message by the message system was included in the intervention procedures. We also picked up responses from the preliminary workshop and positive feedback in the tests regarding the smileys, and added a function for choosing a smiley to

supplement the narratives in the diary for expressing the "mood of the day". Technical adjustments and subsequent tests were made to reassure stability independent of browser.

The end result of the development and usability testing was a program that included the components as described, but with cleaner design, clearer instructions, and more intuitive and time-efficient functions. See Figure 3 for an example of one of the program pages.

Figure 3. A screenshot of the page for daily registration and diary notes on physical activity. The right panel has links to the last feedback from counselor, short messages to and from counsellor, the last comment on the forum, and a graphic presentation of the planned and registered activity for the present week.



Discussion

This article describes the development and results of usability testing of Young & Active, an Internet intervention specifically designed to increase PA in overweight adolescents. A sample of representatives from the target group participated in the development and usability testing, and gave valuable suggestions regarding design, content, and functionality. Accessing the intervention website and actually using it is essential for an Internet intervention to succeed, that is, to induce behavior change [35]. To choose to stay online, engage in the intervention, and to revisit it to follow up and complete the different tasks is definitive to whether the intervention works or not. Only the adolescents themselves can express their preferences for a program like this, thus, they are valuable creative partners in the developmental process. Inclusion of end users in the making and formative evaluation of the program is also in accordance with the chosen theoretical framework in that the adolescents' perspective and competence is acknowledged [22].

Adolescents are considered familiar with many online programs and are well aware of their preferences regarding layout, graphic appearance, colors, illustrations, fonts, and so on. Feedback from the workshop and usability tests reassured us that the adolescents liked the design, and particularly the use of specially designed smileys, which originated from well-known emoticons (emotion icons), in the logo and profile. Such emoticons can be regarded as non-verbal cues and are considered a creative and salient way to add expression to strict text [44,45]. Although they were not included in the program by the time of the usability tests, we assumed that supplementing the diary with optional smileys might help the adolescents communicate about feelings toward PA, exercise and their day in general.

The workshop indicated that explicit descriptions, clear intentions, and logic procedures of the different functions of the program are most important. In spite of this being focused in the following development, the first usability test still uncovered challenges with the understanding of the function of the different tasks (ie, making plan and registrations). Literature on how to write for Web emphasizes the importance of making short, concise texts with meaningful sub-headings and one idea per paragraph [46]. Use of pop-up boxes with supplemental text made it possible to reduce static text on the page. Face-to-face introductory instructions and a short session of training prior to getting started assured that the participants in the field test understood the program, its tasks, and its functions.

In addition to appreciation and understanding of the practical use of the program, it is essential that the adolescents find the program useful and that they acknowledge and value the aim of the intervention [40], which is to increase and maintain self-chosen PA that they find meaningful and want to do. The workshop and the first usability test revealed that the adolescents tended to equate PA with exercise and sports. This is unfortunate for at least 2 reasons. First, there is some evidence that, compared with those of normal weight, overweight adolescents participate less in sports and have less positive feelings towards PA [47]. The Young & Active program introduces the adolescents to a broader meaning of PA, comprising, for example, playing with the dog, biking to school, walking about with friends, and playing soccer in the yard. This might make it easier to find and take part in feasible activities without prior negative associations. Second, meeting the recommendations of a total of 60 minutes of daily activity of at least moderate intensity (3 MET or more) [48] is unrealistic for most adolescents when solely including exercise or organized sports. Our intervention thus focuses strongly on the profits of engagement in all kinds of PA (in-school and leisure-time), not just planned and structured exercise, but also shorter bouts of PA. In the final version of Young & Active this message is included in the preliminary mapping interview (verbally), in the written instructional texts, and in the weekly feedback. In addition, the system for registration supports this by summarizing and visualizing the amount of all kinds of PA produced. Participants in the field test reported being motivated by the potential of increasing daily activity. The fact that they found changes in the bar charts rewarding gives hope to our goal of making adolescents more conscious and positive about daily PA when making specific goals, plans, registering, and monitoring the activity [19].

Computer-based interventions have several advantages. These include the benefits of standardization, tailoring, data collection, testing of theory, and practical use [23]. Standardization of the intervention ensures that the content is delivered equally to all participants. Young & Active also provides the flexibility of tailored automated feedback and need-supportive counseling based on registrations by the participants. As discussed, opportunity for daily PA recordings has potential benefits for the adolescents. Additionally, such recordings provide rich quantitative and qualitative data for the investigators. Another important benefit is the potential for reaching out to adolescents who might find it difficult to disclose sensitive information regarding their own health practices face-to-face with an adult. Computerized interventions also have the potential for increased cost-effectiveness compared to more time-consuming direct interventions.

More extensive use of theory has been associated with larger effect sizes [8], however, so far there is a lack of theory-driven interventions with the potential of explaining mechanisms of physical activity behavior change [23]. Young & Active represents an attempt to develop a such a theory-based program for the promotion and maintenance of PA in overweight adolescents. The ongoing study will assess the extent to which use of SDT as framework and the chosen modes of delivery might impact the efficacy of the intervention in the way that the participants increase their fitness and health-related quality of life.

The potentially biggest disadvantage for an Internet intervention such as Young & Active is its limited lifetime. The speed of development of Internet-based programs is vast and there is reason to believe that adolescent users are not particularly faithful in that their preferences shift rapidly. Considering the time-consuming process of development and testing in a research setting, it is a challenge to create a program that has not outlived itself before meeting its audience. Through development and usability testing of the program, we have taken

into account the preferences of the target group and hope that this ensured a program that is relevant for the time being. Technology is constantly developing, and new innovative applications appear, which in time will threaten to outdate the design and functions of Young & Active. Nevertheless, the ongoing study will add to the testing of our theoretically informed, individualized, computerized intervention and if the chosen characteristics are suited to promote behavior change.

This study highlights the importance of thorough preparation with explicit theory foundation in the developmental phase and iterative usability testing throughout program development. Most important is the engagement from a sample population for ensuring that the users like, understand, and value the program. Integrating such feedback from the target group is highly valuable in the developmental process and increases the chances of making a potentially effective program. The final usability test showed that the program was well accepted by the participants and can be considered ready for further evaluation in a controlled trial.

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KR, KL, TS, and SH were involved in the development of the Web program. They designed the study and performed the testing. KR had primary responsibility for analyzing the data, interpreting the results, and writing the paper. KR, KL, YO, and SH participated in drafting and revising the article. All authors approved the final version to be published. This project was supported by the Norwegian ExtraFoundation for Health and Rehabilitation through Norwegian Women's Health Association and Oslo and Akershus University College of Applied Sciences. We thank our young participants, without whom this study would not have been possible.

Conflicts of Interest

None declared.

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Abbreviations

ASC: autonomy supportive counseling
MET: metabolic equivalent of task
MI: motivational interviewing
PA: physical activity
SDT: self-determination theory

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Original Paper

Wellness Partners: Design and Evaluation of a Web-Based Physical Activity Diary with Social Gaming Features for Adults

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Abstract

Background: The United States is currently in an age of obesity and inactivity despite increasing public awareness and scientific knowledge of detrimental long-term health effects of this lifestyle. Behavior-tracking diaries offer an effective strategy for physical activity adherence and weight management. Furthermore, Web-based physical activity diaries can engage meaningful partners in people's social networks through fun online gaming interactions and generate motivational mechanisms for effective behavioral change and positive health outcomes.

Objective: Wellness Partners (WP) is a Web-based intervention in the form of a physical activity diary with social networking and game features. Two versions were designed and developed for the purpose of this study—"Diary" only and "Diary+Game". The objectives of this study included pilot testing the research process of this intervention design, implementation, evaluation, and exploring the effectiveness of social gaming features on adult participants' physical activity and anthropometric measures.

Methods: We conducted a field experiment with randomized crossover design. Assessments occurred at baseline, first follow-up (FU, 5-8 weeks after using one version of WP), and second FU (5-8 weeks of using the other version of WP). In the control condition, participants started with the "Diary" version of WP while in the experimental condition, participants started with the "Diary+Game" version of WP. A total of 54 adults (egos) ages 44-88, and their family and friends (alters) ages 17-69 participated in the study in ego-network groups. Both egos and their alters completed online surveys about their exercise habits. In addition, egos completed anthropometric measurements of BMI, fat percentage, and fat mass by bioimpedance.

Results: From October 2009 to May 2010, flyers, emails, and Web advertisements yielded 335 volunteers who were screened. Rolling recruitment resulted in enrollment of 142 qualified participants in 54 ego-network groups, which were randomly assigned to a study condition. The final analytic sample included 87 individuals from 41 groups. Data were collected from December 2009 to August 2010, and data analysis was completed in 2011. Overall, the participants were given access to the intervention for 10-13 weeks. Statistical analysis suggested an increase in self-reported exercise frequency (mean days per week) from baseline (2.57, SD 1.92) to first FU (3.21, SD 1.74) in both conditions. Stronger effects were seen in the condition where Diary+Game was played first, especially in network groups with larger age variation between the alters and egos. Overall, the decrease in egos' BMI was statistically significant from baseline to first FU, with greater decrease for those in the Diary+Game first condition (-0.26 vs -0.16 in the Diary first condition).

Conclusions: The Wellness Partners program increased physical activity among participants and resulted in health benefits among the egos. Web-based diary interventions designed with social gaming features hold potential to promote active lifestyles for middle-age adults and people in their social networks.

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KEYWORDS

physical activity; social networking; diary; game; Web-based intervention; behavior change intervention

Introduction

The United States is currently in an age of obesity and inactivity despite increasing public awareness and scientific knowledge of detrimental long-term health effects of this lifestyle [1]. Although increases in obesity prevalence are not continuing at the same rate as in the past 10 years, the prevalence of obesity in 2009-2010 was 35.7% among adult men and 35.8% among adult women [2], meaning one third of the American adult population is obese. Recent physical activity (PA) guidelines for Americans published by the US Department of Health and Human Services recommends that adults accrue 150 minutes of moderate-intensity aerobic PA per week, or 75 minutes of vigorous-intensity aerobic PA per week to maintain healthy body weight [3].

Self-monitoring is a long-standing and effective strategy for weight maintenance and weight loss [4-7]. Empirical evidence has supported Web-based self-monitoring diaries for weight loss [8]. In addition, specific Web features (such as past journal entries, indicators of progress, and platforms for social interactions and support) are found to be significant predictors of effective Web-based interventions for weight loss and maintenance [9]. As users of social networking sites and digital games continue to grow exponentially [10,11], studies have shown high acceptability of health behavior modification programs through interactive entertainment and social media [12-14]. Social network research has shown that behaviors spread through person-to-person contact [15,16]. Interventions designed to help friends and family initiate and sustain positive behaviors can be beneficial. Bahr and others suggest that social forces can be more effective when incentives are designed to engage social networks across their ecosystem [16]. Digital games can provide compelling incentives through computer-mediated social interactions as well as virtual reward mechanisms, such as points, badges, and gifts that symbolize achievement. The Entertainment Software Association reports the average age of game players in the United States to be 37 years old [10]. However, games targeting health-related outcomes have mostly been used with younger populations for nutrition [17], cancer [18], diabetes [20], the elderly affected by stroke [21], and other acute or chronic illnesses. Studies have shown evidence of mild to moderate energy expenditure when playing active video games or exergames [22-24]. The combination of social networking influences and an intrinsically motivating game environment hold great potential to help individuals change their exercise habits and sedentary lifestyles.

Early and middle adulthood are particularly challenging periods in life, with major life transitions in education, career, and family responsibilities that lead to changes in PA [25]. Elevated levels of stress tend to increase obesity, regardless of dietary intake [26]. Exercise is an effective strategy for managing stress [27] as well as for combating obesity [28]. Young and middle-aged adults are also frequent game players [10]. Although popular game consoles such as Konami's Dance Dance Revolution, Nintendo Wii, Sony PlayStation Move, and Microsoft Kinect can create opportunities for PA, they can also be expensive, time-consuming, and inconvenient to use. Therefore, developing interventions that promote and sustain PA with minimal technological requirements for middle-aged adults is a high public health priority.

This study had 3 objectives. First, we aimed to develop an intervention that combines social networking and digital game features in the form of a Web-based PA diary. Second, we aimed to pilot test the research process of this intervention design, its implementation, and its evaluation. We conducted a pre-study estimate of sample size and employed a rigorous procedure of recruitment, randomization, treatment, and follow-up (FU) assessments. Third, we aimed to explore the potential effectiveness of the intervention with social gaming features on participants' PA, body mass index (BMI), fat percentage, and fat mass. We hypothesized that participants would report an increase in PA using either version of the socially networked PA diary (one with and one without game features), with a greater increase expected for those who used the version with game features in addition to social networking. Given the brief duration of the study, changes in BMI, fat percentage, and fat mass were not expected but examined.

Methods

Intervention Design

Wellness Partners (WP) is a Web-based intervention in the form of a PA diary with social gaming features. It was designed by the first author in consultation with the other members of the research team and with contributions from an interdisciplinary group of students and alumni. We used iterative playtesting [29] to identify critical features for behavior tracking and social game, incorporated them into the intervention design, and tested them through paper and digital prototypes. A 10-day beta testing phase was conducted with 3 pairs (N=6) of participants ages 25-44. The intervention was named Wellness Partners because the primary participants (egos) were required to partner with their family and friends (alters) and interact on the website as ego-network groups. Two versions were developed for the purpose of this study: One version with Diary only and the other Diary+Game. The following diary and social networking features were included in both versions: (1) posting updates of physical activities or setbacks, (2) sending private messages, (3) reviewing complete history of updates posted by egos and

their alters, and (4) viewing display of a tag cloud of posted physical activities by all members in the egocentric network. Additional game features were included in the Diary+Game version, including: (1) displaying points as reward for updates, (2) naming of a virtual character, (3) choosing virtual locations for the virtual character's wellness activities, (4) collecting virtual items as reward, (5) acquiring virtual character wellness animations by spending earned points, (6) including virtual character wellness activities as part of the complete history of all public updates by network members as well as their virtual characters, and (7) exchanging virtual gifts earned through some virtual character wellness activity animations (Multimedia Appendices 1 and 2). In this interventional pilot study, participants could not see each other's virtual characters or game environment, but were able to read postings about their study partners and their virtual characters. In the Diary+Game version, the point system was balanced to enable enough points for redemption of some activities even for people who just logged on to report setbacks, which were worth less than actual PA. The point system was also balanced to allow very active users who logged on regularly and exercised regularly to be rewarded with more points. Given the expected study duration, players could visit a total of 11 locations with their virtual character, redeem up to 66 activities and earn up to 45 collectibles that could be gifted.

To facilitate the user experience, a question mark was placed next to each key feature on the WP website with descriptions in a pop-up window. Contact points for technical support were provided on the WP study website frequently asked questions page with an email and a phone number, a hyperlink to the bug report was included in the daily email reminders, and an open-ended question was offered for comments and suggestions at the end of each online survey. The qualitative feedback was obtained through participant interviews.

Research Design

This study used a randomized crossover design with two arms. Assessments occurred at baseline, at first FU (5-8 weeks) and at second FU (10-13 weeks) (Figure 1). From October 2009 to May 2010, rolling recruitment was used to screen and enroll qualified volunteers in ego-network groups. The study was advertised via flyers, emails and on a website. Each ego-network group was randomly assigned to start with one of the two versions of the intervention (Diary or Diary+Game). Data were collected from December 2009 to August 2010. Data analysis was completed in 2011.

Participants and Procedure

In coordination with the Center for Work and Family Life at USC, a mass email announcement and 12,000 paper advertisements were sent to all university staff directing volunteers to an email, voicemail, and website. Before they were contacted for screening, volunteers had to fill out an online consent for contact form. Volunteers were screened over the phone for the following inclusion/exclusion criteria: (1) age between 25 and 44, (2) English fluency (rating of at least 7 on a 10-point scale), (3) employment status (required to be university staff, employed full-time, or part-time), (4) daily Internet access, (5) cell phone ownership, (6) no current participation in any other formal studies of weight loss or healthy lifestyle, (7) no prior participation in WP, and (8) report of having a social support network containing at least 4 people.

Qualified volunteers became egos in the study and were instructed to fill out the online referral form, nominating members of their social network to join their ego-network group and enroll in the study as their alters. Volunteers who were referred by egos were asked to fill out the online consent for contact Form. Potential alters were screened over the phone for the following inclusion/exclusion criteria: (1) age between 12 and 85, (2) English fluency (rating of at least 7 on a 10-point scale), (3) daily Internet access, and (4) no prior participation in WP.

Employment by USC was not a criterion used for alters because we wanted to encourage participants to enroll any member of their friends or family, regardless of employment and where they lived. Egos had to be willing to come to campus for anthropometric measurement, but since alters did not have to be seen in person by our staff they could be located anywhere.

When an ego and at least one alter mutually confirmed their participation in the study, they were each asked to review the online informed consent form and complete a baseline survey. Parental consent was obtained for minors. Then, the ego was scheduled for an in-person baseline anthropometric assessment before the entire ego-network group was assigned a group ID and randomized (as a group) in blocks of 10 to begin one of the two study conditions. A random number generator was set up with a minimum value of 1 and a maximum value of 10 where odd numbers were assigned to Diary+Game and even numbers were assigned to Diary until one of the two conditions reached 5 ego-network groups and the rest were assigned to the other condition. These steps were repeated as the group sample exceeded 10, 20, 30, etc.

Upon completion of baseline assessment milestones, participants were emailed a user name and password with user instructions and encouraged to log on to the WP website everyday (Multimedia Appendix 3). Additional alters could be added to the ego-network group upon successful completion of phone screening, online informed consent, and baseline survey. After each ego completed first FU anthropometry and online survey, the entire ego-network group was switched to the other condition with email notification. First FU occurred between weeks 5 and 8 of the study and second FU occurred approximately between weeks 10 and 13.

Incentives were provided after completion of each data collection milestone—$10 for assessment at baseline, $10 for first FU, and $25 for second FU. All egos and up to their first 5 alters were mailed checks and minors were mailed gift certificates. This study procedure (Figure 2) was approved by the Institutional Review Board at USC.

Main Outcome Measures

The main outcome variables for this study included self-reported exercise frequency of all participants and anthropometric measures of all egos. PA was measured using one item that asked, "on average, how often do you exercise (minutes per day, days per week)" as used in previous studies [30]. Egos'

anthropometric data included BMI, fat percentage, and fat mass, collected by trained staff at the Center for Work and Family Life or at the participants' office, using a body composition analyzer (Tanita TBF-215GS, TBF-300A, Japan) and a standardized protocol.

Statistical Analysis

Means were reported first by survey wave and condition (Diary vs Diary+Game) to establish data trends. *T* tests comparing baseline and FU scores were conducted to determine if the interventions changed PA and body composition. Random effects lagged regression models were used to determine if changes were influenced by individual participants or study characteristics. A variable indicating the order of study condition (Diary or Diary+Game first) was included in the analyses to determine if the effects were sensitive to the specific starting condition of the ego-network groups. All analyses were completed using STATA version 11.1 (StataCorp LP, Texas, USA) with alpha set at $P \leq .05$ for significance tests on PA and $P \leq .10$ for significance tests on egos' BMI, fat percentage, and fat mass.

Power Analysis

Using a general power equation with standard assumptions and reaching a medium effect size [31,32], we calculated that we would need 30 groups per condition to detect significant changes in PA with the *P* value set at .05. As shown in Figure 1, our sample size and attrition rate did not meet the expected estimates. Therefore, these results should be interpreted with caution.

Figure 1. CONSORT 2010 flow diagram. Of these 54 ego-networks, 12 groups (28 people) failed to complete all survey measurements and were dropped from the analyses (n=142, 22.3% attrition). In addition, 27 participants dropped out from the study, leaving a final analytic sample of 87 individuals from 41 groups (n=142, 38.7% attrition).

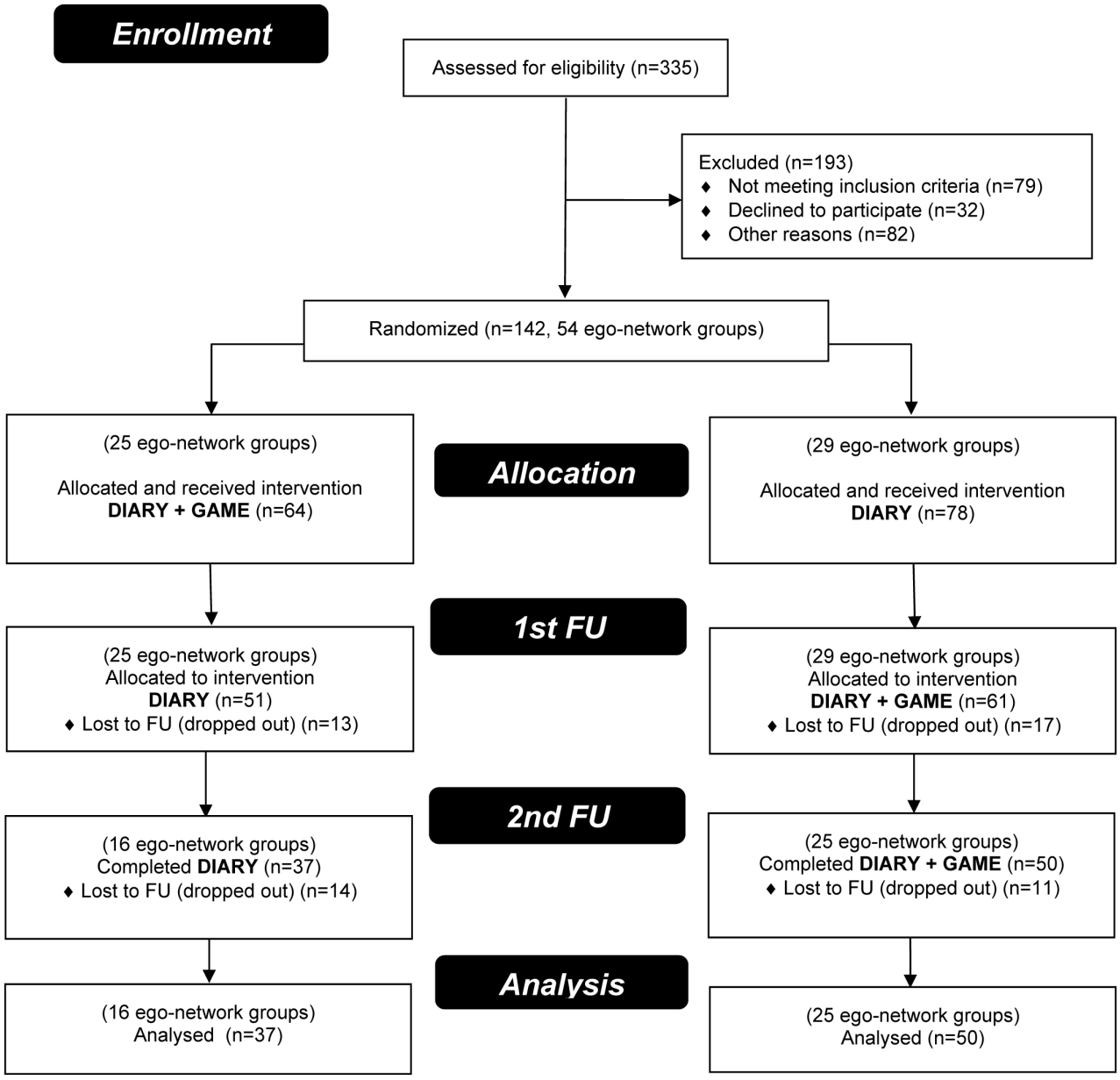
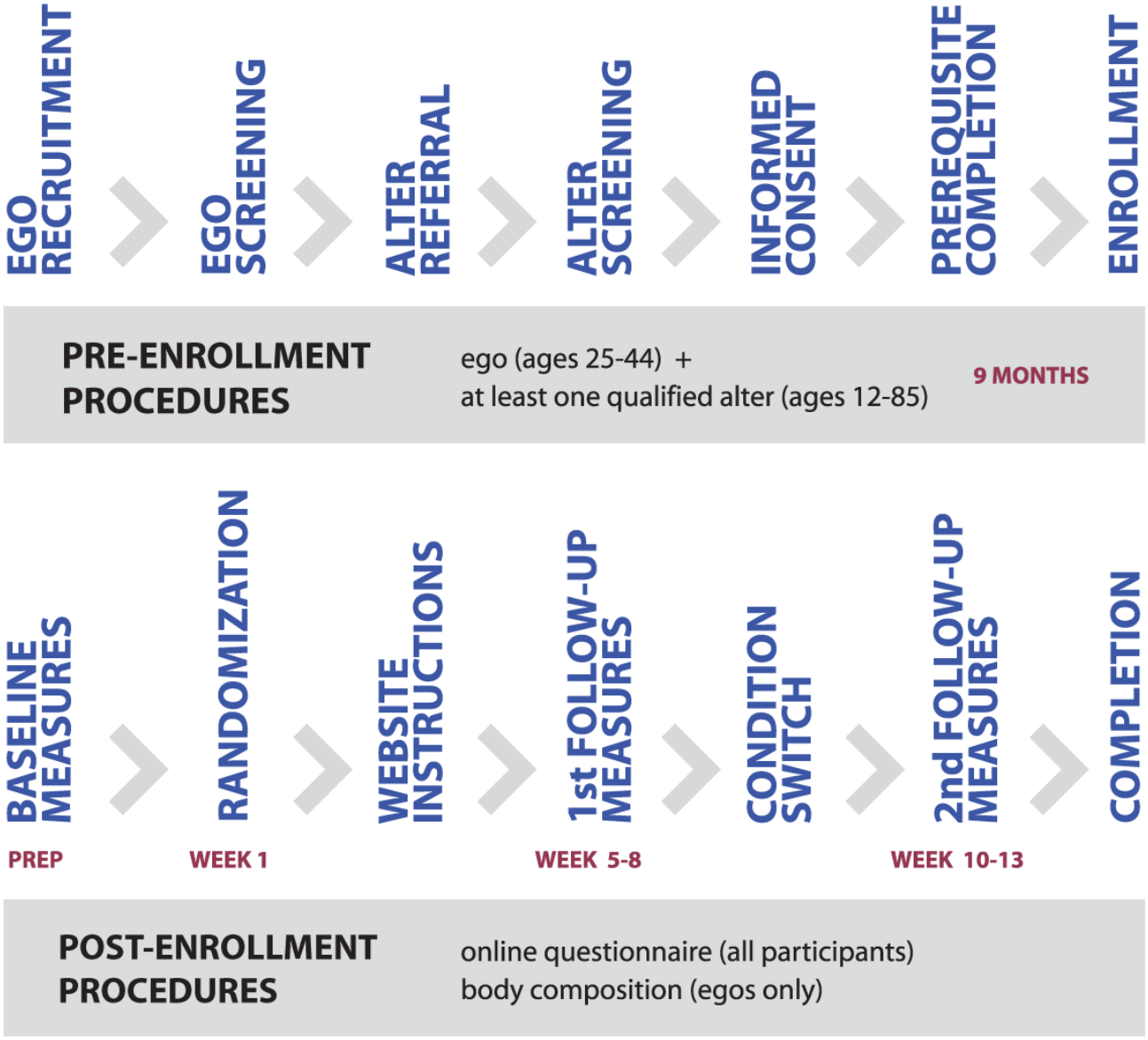


Figure 2. Pre-enrollment and post-enrollment study procedures.



Results

Participant Demographics

The initial sample included 54 egos and 88 alters that added up to a total of 142 individual participants in 54 ego-network groups at baseline (Figure 1). Egos recruited an average of 1.63 alters to be their "wellness partners". The minimum and modal group size was 2 (63%) with 13 groups including 3 people (24.1%) and maximum group size was 8. Over the course of the study, 49 people dropped out, and 6 people were excluded due to technical errors, leaving an analytical sample of 87 individual participants in 41 ego-network groups.

Table 1 reports the sociodemographic characteristics and descriptive statistics for the entire sample, participants lost to FU, participants lost to technical error, the analytic sample, and its breakdown by condition. In the entire sample, there were more female participants (95/142, 67.6%), more college graduates (103/142, 72.5%), and ethnic diversity (approximately 25/142, 18% were Asian or Asian American, 40/142, 28% were Hispanic/Latino) with an average age of 35.6 years. Participants who dropped out at FU were significantly more likely to be alters and have higher estimated BMI at baseline than those who completed the entire study. Comparisons on the analytic sample between conditions (Diary vs Diary+Game first) suggested that participants in both conditions were similar except that those in the Diary+Game first condition were younger (32.0 vs 38.7 years) and had a younger group average age (32.4 vs 38.9 years) than those in the Diary first condition. There were no statistically significant differences between egos and alters on these characteristics though alters were slightly more likely to be male, White, older, and less educated (results not shown).

Table 1. Sociodemographic characteristics of study participants by condition.

	Total	Lost to FU	Analytic sample	Diary first	Diary+Game first
Number of participants	142	55	87	49	38
Male, n (%)	46 (32.4)	17 (30.9)	29 (33.3)	14 (28.6)	15 (39.5)
College graduate, n (%)	103 (72.5)	35 (63.2)	73 (83.9)	39 (79.6)	34 (89.5)
Asian ethnicity, n (%)	25 (17.6)	5 (9.1)	20 (23.0)	9 (18.4)	11 (29.0)
Hispanic ethnicity, n (%)	40 (28.2)	20.2 (36.4)	20 (23.0)	10 (20.4)	10 (26.3)
Mean age (SD) years	35.56 (9.51)	35.24 (10.05)	35.80 (9.21)	38.69 (9.21)	32.00 (7.82)
Alters, n (%)	89 (62.7)	42 (76.4)	47 (54.0)	25 (51.0)	22 (57.9)
Ego-network characteristics					
Group size	3.11	3.07	3.14	3.14	3.13
Mean group age in years (SD)	35.56 (5.72)	34.8 (6.04)	36.1 (5.5)	38.9 (6.6)	32.4 (4.2)
Outcomes					
Mean days of PA per week (SD)	2.49 (1.87)	2.35 (1.86)	2.57 (1.89)	2.59 (1.83)	2.55 (1.98)
Estimated baseline BMI	26.97 (6.00)	29.06 (7.82)	26.30 (5.17)	26.52 (4.97)	26.02 (5.47)

User Logins

The WP server kept track of user activities. Overall, participants were given access to the intervention for 10-13 weeks. Our server data suggested that among participants in the analytical sample, in general, they accessed the WP website every other day, with the number of total logins ranging from 1-102 (mean 38.00, SD 22.31), the number of days they logged in ranged from 1-81 days (mean 32.75, SD 18.32), and the most popular times of the day they logged in were 9 am to 12 noon (mean 8.68 times), 6 pm to 9 pm (mean 7.32 times), and 9 pm to 12 midnight (mean 7.11 times).

Intervention Outcomes

Over time, mean number of self-reported days of exercise per week at baseline, first FU, and second FU were: 2.57, 3.21, and 3.23, respectively.

These overall trends, however, mask differences by condition (Diary vs Diary+Game first), and by participant status (ego vs alter). Figure 3 and Table 2 show self-reported exercise frequency at baseline, first, and second FU by study condition. In both conditions, there was an increase from baseline to first FU, yet the increase was lower in the Diary first condition (0.44 days vs 0.88 days per week). The Diary+Game first condition reported lower baseline exercise frequency (2.55 days per week) and higher exercise frequency at FU (3.43 days per week). Participant status may have influenced increase in PA, as shown in Table 2 and Figure 4. Increases were similar for egos and alters in the Diary first condition, and there was a trend for greater increase in the alters in the Diary+Game first condition. These differences did not attain statistical significance in the analysis of variance (F_2=2.56, P=.08).

Table 2. Self-reported days per week exercised by study condition and participant status.

	Baseline Mean (SD)	1st FU Mean (SD)	2nd FU Mean (SD)
Total	2.57 (1.92)	3.21 (1.74)	3.23 (1.68)
Diary → Diary+Game			
Total	2.59 (1.83)	3.03 (1.64)	3.07 (1.55)
Egos	2.64 (1.96)	3.04 (1.52)	3.04 (1.57)
Alters	2.54 (1.73)	3.02 (1.78)	3.10 (1.55)
Diary+Game → Diary			
Total	2.55 (1.98)	3.43 (1.87)	3.43 (1.89)
Egos	2.81 (2.14)	2.75 (1.84)	3.06 (2.17)
Alters	2.36 (1.89)	3.93 (1.76)	3.70 (1.65)

A random effects regression model was calculated using the ego-network group (the ego and their alters) as the random effects and sociodemographic variables (sex, education, ethnicity, age, estimated BMI, mean group age, and SD group age) were entered as controls, which may also mask intervention effects. The results in Table 3 represent unstandardized random

effects coefficients indicating the amount of change in self-reported PA for each unit change in the corresponding independent variable. For example, a one unit change in self-reported PA at baseline is associated with a 0.61 increase in self-reported PA at first FU. The first set of coefficients include only main effects, the second column (for each follow up period) report the main effects and include the interaction term of being an alter and being in the Diary+Game condition first.

As expected, baseline exercise frequency was strongly and significantly associated with exercise frequency at both first and second FU. The only significant predictor of increased self-reported PA at first FU was group age variation, indicating that groups composed of people of varying ages were more likely to increase their PA than those with less variation.

Table 3. Random effects regression coefficients on number of days per week exercised at FU.

	Number of days exercised 1st FU Regression coefficient (*P* value)		Number of days exercised 2nd FU Regression coefficient (*P* value)	
	Main effects only	Interaction included	Main effects only	Interaction included
1st FU	NA	NA	0.52 (<.001)	0.49 (<.001)
Baseline	0.61 (<.001)	0.64 (<.001)	0.35 (<.001)	0.38 (<.001)
Diary+Game first	0.55 (.08)	-0.30 (.40)	0.23 (<.35)	0.01 (.89)
Male	0.45 (.11)	0.37 (.14)	-0.19 (.45)	-0.19 (.16)
Education	0.59 (.09)	0.52 (.07)	0.24 (.25)	0.24 (.61)
Asian ethnicity	-0.40 (.12)	-0.35 (.15)	0.20 (.27)	0.20 (.36)
Hispanic ethnicity	0.42 (.31)	0.37 (.37)	0.79 (.004)	0.78 (.004)
Age	0.03 (.34)	0.05 (.09)	0.04 (.017)	0.04 (.011)
Alter (vs ego)	0.68 (.035)	-0.15 (.65)	0.18 (.47)	-0.03 (.93)
Ego-network characteristics				
Group size	-0.03 (.76)	-0.03 (.72)	-0.04 (.25)	-0.05 (.25)
Mean group age	-0.01 (.70)	-0.02 (.57)	-0.02 (.33)	-0.03 (.30)
Group age SD	0.07 (.012)	0.06 (.023)	0.01 (.53)	0.01 (.54)
Outcome				
Estimated baseline BMI	-0.04 (.26)	-0.04 (.18)	0.01 (.79)	0.0 (.88)
Condition by status				
Diary+Game alter interaction	not applicable	1.74 (.009)	not applicable	0.48 (.26)
Adjusted R^2	57%	63%	79%	79%

To test the combined effects of study condition and participant status, an interaction term of condition (Diary+Game first) and being an alter (rather than an ego) was constructed. Model estimates showed that the covariates remained mostly unchanged and the interaction term was statistically significant indicating that alters in the networks that started with the Diary+Game condition increased their self-reported PA significantly compared to egos and those in the Diary first condition.

Whether the changes in self-reported behavior translated into changes in anthropometric measures (ie, BMI, fat percentage, fat mass) for the egos was also examined. Anthropometric measures were only available for egos, and of the 40 egos, 34 had measurements at all 3 waves paired *t* tests on 3 measures of adiposity were conducted jointly and separately by condition, and given the smaller sample size, *P* values less than .10 were considered significant. Table 4 shows that, overall, there was a significant decrease in BMI from baseline to first FU, which was driven primarily by a decrease in BMI for the Diary+Game first condition. Overall, neither fat percentage nor fat mass decreased statistically, although there was a trend towards significant decreases in both fat percentage and fat mass in the Diary+Game first condition. These anthropometric measures showed a decrease in BMI and body fat for egos from baseline to first FU for those who received the Diary+Game first. Anthropometric measures at the second FU did not change for the egos.

Table 4. Anthropometric measures by study condition.[a]

	Baseline	1st FU	Difference	*P* value	Baseline	2nd FU	Difference from 1st FU	*P* value
N	38	38			33	33		
BMI								
Total	28.02	27.83	-0.19	.02	28.09	27.99	-0.10	.23
Diary → Diary+Game	28.02	27.86	-0.16	.10	28.05	27.94	-0.10	.28
Diary+Game → Diary	28.03	27.77	-0.26	.07	28.16	28.05	-0.10	.32
Fat percentage (pounds)								
Total	30.95	30.84	-0.12	.40	30.63	30.51	-0.12	.39
Diary → Diary+Game	30.70	30.94	0.25	.64	30.27	30.54	0.27	.66
Diary+Game → Diary	31.34	30.67	-0.67	.11	31.13	30.49	-0.64	.12
Fat Mass (pounds)								
Total	54.00	53.51	-0.49	.27	53.58	52.97	-0.61	.25
Diary → Diary+Game	54.17	54.21	0.05	.52	53.53	53.48	-0.05	.48
Diary+Game → Diary	53.74	52.43	-1.31	.09	53.66	52.29	-1.37	.16

[a] N=38, Diary → Diary+Game, n=23; Diary+Game → Diary, n=15; N=33, Diary → Diary+Game, n=19; Diary+Game → Diary, n=14.

We also compared egos' and alters' self-reported health status by examining responses to one question at baseline, "in general, would you say your health is…" (1 = excellent and 5 = poor). Alters tended to report significantly better health status than egos (2.48 vs 2.81; $F_{1,140}$=3.84; P=.052).

Figure 3. Exercise days per week at baseline, first, and second FU overall (total) and by Diary first versus Diary+Game first. The exercise frequency increase was greater in the Diary+Game first condition.

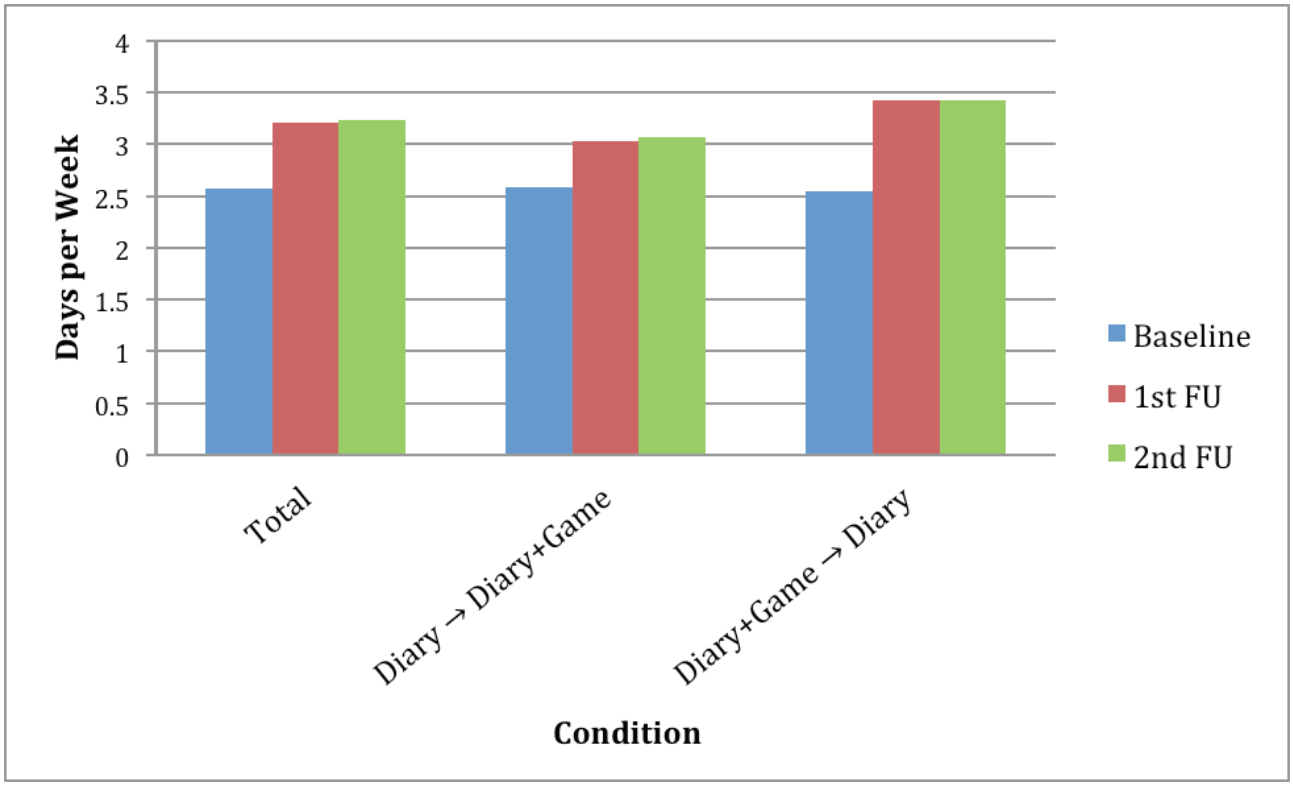
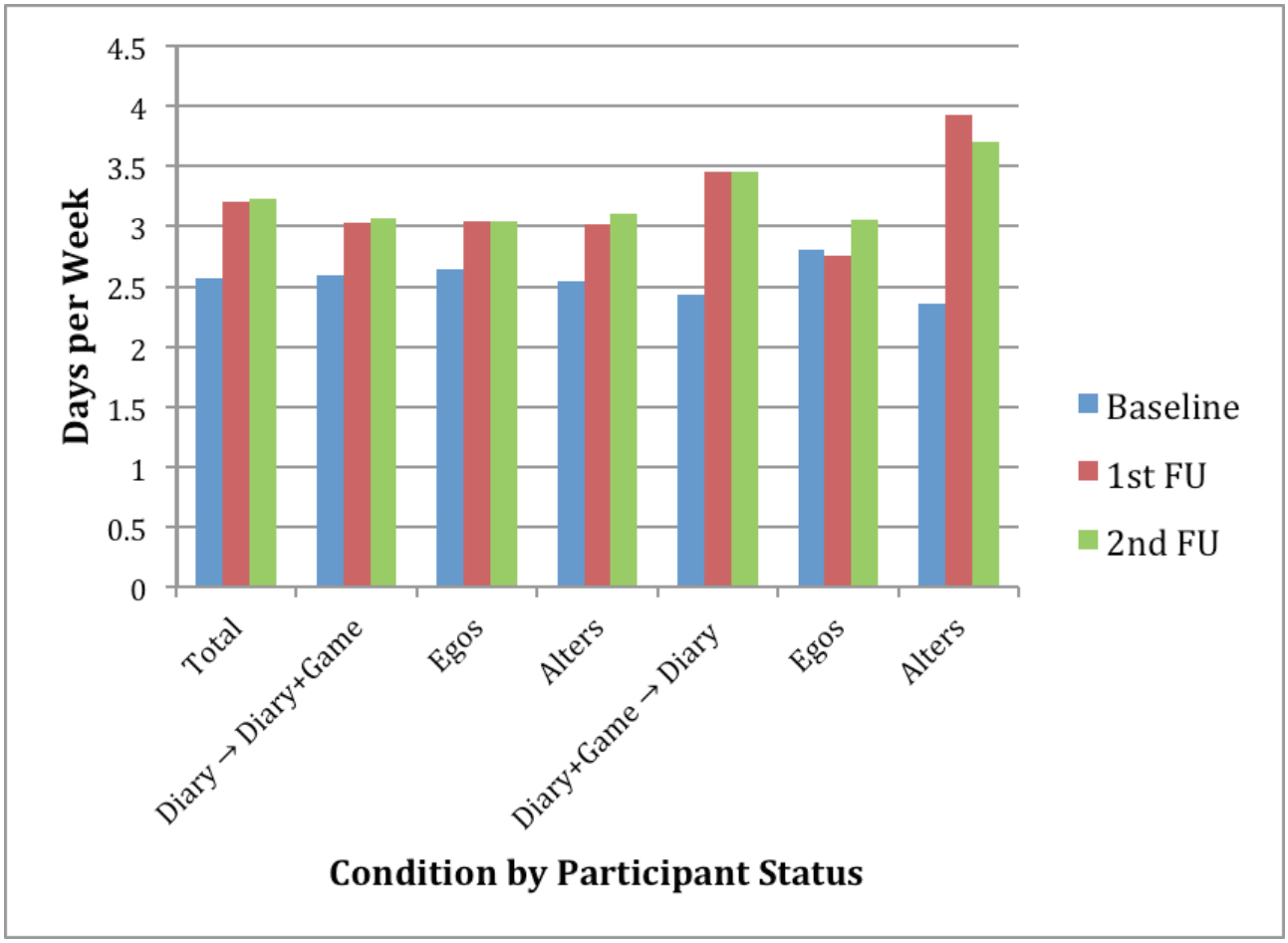


Figure 4. Exercise days per week at baseline, first, and second FU overall (total), by study condition (Diary first vs Diary+Game first), and by participant status (ego vs alter). The exercise frequency increase was greatest for alters in the Diary+Game first condition (1.57 days per week).



Discussion

Major Findings

To our knowledge, this is the first study to design, develop, and evaluate a Web-based PA diary intervention for adults that focused on the effects of social gaming. The concept of using game mechanics for motivating real world behaviors is now known as "gamification" [33]. We used a rigorous procedure for rolling recruitment and enrollment and collected data from different sources. Our findings demonstrated the potential of combining influence from close social ties and social gaming practices to promote an active and healthy lifestyle. During the course of a year, 87 middle-aged adults along with their family and friends formed 41 ego-network groups and participated in the WP program. The results showed modest, but statistically significant increases in self-reported PA, especially among alters, ego-network groups of larger age variation, and participants in Diary+Game first condition. Overall, the decrease in egos' BMI was statistically significant from baseline to first FU, with larger effects for those in the Diary+Game first condition. Interestingly, this effect did not weaken or improve at second FU, suggesting that the second condition served to maintain weight loss regardless of condition. The decreases in egos' fat percentage and fat mass were not statistically significant overall from baseline to first FU, although there was a trend for significance for those in the Diary+Game first condition. Overall, the intervention effects were stronger in the first period, with the second period serving as a maintenance phase.

The greater effectiveness of the social gaming features among alters is an intriguing finding. Alters were not different from each other on demographic characteristics. Their increased PA may have been prompted by a desire to have their egos look good in the study. Alternatively, they may have genuinely been more motivated to increase their PA because their family or friends recruited them. A third possibility is that the egos selected the alters purposely as someone who either would, or needed to, change their own behavior. However, the finding that alters reported significantly better perceived overall health than egos suggests that although individuals recruited others who were similar on sociodemographic characteristics, they may have reached out to "healthier" friends and family who could "help" them rather than try to positively influence others themselves. This pattern may have implications for recruitment of PA studies that have a social networking component.

The effectiveness did not vary by sociodemographic characteristics, indicating that the intervention was just as effective among younger and older participants, those of different ethnicities, with different educational levels, and different genders. This indicates that the social gaming features had broad appeal among this selected but varied population. This is encouraging considering the rudimentary nature of the game mechanics and interface. Interactive entertainment

applications can be costly to develop and this study demonstrated that even basic features could provide behavior modification potential for increasing PA.

Limitations

Technical Problems

Any new technology-based innovative interventions will have to face technical challenges. Engagement and retention of participants in this study may have been influenced by software problems and limitations they encountered. A number of projected features including a Twitter-enabled reporting function were not deemed stable enough for the main study after beta testing. Some software problems were known from beta testing, such as slow loading. Some participant activities did not get logged on the WP website due to a persistent random software bug that could not be corrected while the study was in progress. During one particular week, no email reminders were sent out to the participants. Upon quality assurance review of data, we discovered that the conditions of a few ego-network groups were not switched after first FU, and were excluded from the analytical sample (Figure 1).

Game Design

An additional limitation of the study related to accumulation of points earned from exercise in the Game+Diary version of the software. Participants could report an infinite number of PA or setbacks per day, but they were awarded points only for the first report within a 24-hour period. Several participants voiced frustration about this as a usability problem within the first few weeks of the study. We had not anticipated that participants would login more than once per day to report. We revised the reward schedule to 12 hours while the study was ongoing. This means that some of the participants earlier in the study received fewer points and may have not enjoyed the experienced as much as later participants. No other revisions were made to the point system as seen in (Table 5), which was not disclosed to participants.

Table 5. Wellness Partners Game+Diary point reward system.

	Number of participants	>15 mins	<15 mins	<30 mins	<45 mins	<60 mins	<75 mins	<90 mins
Points awarded for individual (solo) activities								
Light	1	1	3	5	7	8	9	9
Medium	1	1	8	10	12	15	17	17
Heavy	1	1	12	15	18	21	24	24
Points awarded for group activities (given to all reported activity participants)								
Light	2	1	1	3	2	2	2	2
	3	2	2	4	3	3	3	3
	≥4	3	3	5	4	4	4	4
Medium	2	1	1	2	2	2	1	1
	3	2	2	3	3	3	1	1
	≥4	3	3	4	4	4	1	1
Heavy	2	1	1	3	3	2	1	1
	3	2	2	4	4	3	2	2
	≥4	3	3	5	5	4	3	3
Points awarded for player activity posting								
First activity ever					5			
Second activity of the day					2			
First setback of the day					1 (0 points thereafter)			

We did collect feasibility data in this study, which includes FU survey questions on usability and evaluation of various features in each version of the intervention, user technology literacy (eg, prior gaming experience and participation on social networking websites), daily software bug reports, and 20 semi-structured, in-depth interviews [34]. However, here we focus on reporting the intervention and research design as well as major findings in the evaluation in this article and provide detailed information and analysis of feasibility data in a separate paper with insights for future development of such applications.

Outcome Measurement

Another limitation of this study is the use of a single self-report item measure of PA, which did not include accelerometry. Given limited resources at the time of study design, we determined that self-reported PA combined with objective measures of outcome, such as BMI, fat percentage, and fat mass would be adequate for this interventional pilot study.

Directions for Future Research

A future version of this study would include a number of revisions in both versions of the intervention and study

procedures. The first proposed revision relates to mobile access. Due to the exploratory nature of the intervention and the wide variety of socioeconomic characteristics of the intended audience, it was determined that the lowest common denominator technology would be a computer with a Web browser that participants could access at least once per day at home or at work. The Diary version of the intervention was compatible with mobile phones that had full Web browser support and the Diary+Game version was only compatible with Flash-enabled mobile phones. Given current smartphone ownership and social networking website diffusion, a revision of the software would be developed as a mobile app as well as a website to provide participants easy access.

The second revision would be the study design. This study used a crossover design without a washout period. Ego-network groups switched conditions within 24 hours of egos completing their first anthropometry FU. Although a washout period is common for pharmaceutical studies, this study did not have a washout period for several reasons. One secondary objective for this study was to determine whether a simple game could help jumpstart PA self-reporting and/or make it less tedious. Observing the immediate effects of ending the game was therefore important. In future analyses, researchers might also compare participants' satisfaction with the website versions and see whether greater affinity for either version (with or without game features) resulted in changes in usage behavior and/or changes in PA or other measures. For example, participants may report dislike of a version, yet they may benefit from adherence to it and not realize it is working for them until the program is swapped for something else. In addition, this study focused on the evaluation of the effectiveness of social gaming features as opposed to social networking only. Future studies may consider adding a control group with no intervention, or a wait list control group.

The third revision relates to the research procedure. A fully powered study based on the criteria described under the section Power Analysis would have to address both adequate enrollment and strategies for minimizing attrition. Given budgetary constraints, a manual rolling recruitment and data collection process was designed and adopted in this study. It was complicated to manage and required too many steps, which was a burden for study coordinators and potential participants. For example, egos whose alters delayed contacting us may have experienced higher frustration, which contributed to dropout rates. Future attempts of a similar approach could benefit from an automated content management system for participant recruitment, screening, and frequent reminders to egos about inviting unlimited alters.

The fourth proposed revision is on the objective measurement. Scheduling in-person anthropometric measurements was another challenge to participant retention. Since switching of the condition followed the egos' schedule of data collection, if an ego delayed completion of anthropometry or the online survey, the group would stay longer in their initially assigned condition. Future studies should take advantage of the more widely available free accelerometer mobile apps and obtain anthropometric measures from both egos and alters rather than relying on self-reports.

Finally, the fifth revision is regarding sampling. Implementing the study in a community setting, rather than a workplace setting, could be more convenient for some participants. Conducting the study with a population sample, rather than an organizational one, would provide even greater generalizability.

Conclusion

WP was designed as a Web-based PA promotion diary with social gaming features for adults. The intervention design requires an iterative process to ensure the quality of basic features. Rigorous research design and study procedure are needed to implement and evaluation the intervention. The game features included in the Diary+Game version of WP did not have a great variety or superb sophistication, greater depth and length of play would be required to produce stronger effects and sustain long-term changes. However, our empirical findings suggest that the Diary+Game version had stronger effects on BMI and body fat, with a trend for increased PA. Results were modest, yet surprising, given the short study duration and the absence of a nutritional intervention. This suggests that interventions with social gaming features hold promise in the battle against obesity.

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Conflicts of Interest

Gotsis and Jordan-Marsh have received workshop travel support from Humana unrelated to this project. Gotsis and Spruijt-Metz have received travel support from Apple unrelated to this project.

Multimedia Appendix 1

Video documentation of Wellness Partners website (Game Version).

[MP4 File (MP4 Video), 97MB - resprot_v2i1e10_app1.mp4]

Multimedia Appendix 2

Art asset documentation of Wellness Partners (Game Version).

[PDF File (Adobe PDF File), 942KB - resprot_v2i1e10_app2.pdf]

Multimedia Appendix 3

Documentation of instructions emailed to Wellness Partners study participants with their username and password. Version of instructions and version of website participants received access to was determined by random assignment of ego-network groups.

[PDF File (Adobe PDF File), 138KB - resprot_v2i1e10_app3.pdf]

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Abbreviations

BMI: body mass index
FU: follow-up
PA: physical activity
USC: University of Southern California
WP: Wellness Partners

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Original Paper

Development and Formative Evaluation of a Web-Based Self-Management Exercise and Diet Intervention Program With Tailored Motivation and Action Planning for Cancer Survivors

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Abstract

Background: Most dietary and exercise interventions developed to date for cancer survivors have employed intensive clinic-based face-to-face counseling sessions. However, when the clinic-based face-to-face intervention ends, the participants cannot receive feedback from the experts, and the motivation for regular exercise and diet practices decreases. One way to overcome the shortcomings of clinic-based face-to-face intervention is to employ the Internet to this end. To maximize effectiveness when providing Web-based interventions, action planning should be able to start at the right time, education should be tailored to motivational readiness, and self-efficacy should be enhanced at appropriate intervals.

Objective: The aim of this study was to develop a Web-based self-management diet and exercise intervention program with the aid of the transtheoretical model (TTM) and to conduct formative evaluations.

Methods: The Web-based self-management exercise and diet intervention program was developed employing a 5-phase system development life-cycle (SDLC) method. The 5 phases were 1) identification of user requirements, 2) system design, 3) system development, 4) system evaluation, and 5) system application. An expert group composed of 3 content experts, a Web developer, and 2 Web designers, evaluated the usability and accuracy of the content. The program was evaluated by 30 breast cancer survivors for perceived ease of use.

Results: The Web-based self-managed exercise and diet intervention program contained 5 components differing in screen layout. These components are introduction, assessment, education (tailored information provision), action planning (goal setting, scheduling, keeping a diary), and automatic feedback. Education, action planning, and automatic feedback were tailored to each participant through the assessment. The processes of change, self-efficacy, and decisional balance, which are the principal strategies encouraging behavioral change according to the TTM theory, were reflected in the education, and self-efficacy was also reflected in the automatic feedback. After iterative testing by experts on problems that arose in terms of usability and content accuracy during system operation, the perceived ease of use of the program was evaluated by 29 breast cancer survivors. The end users rated the program as being easy to understand and use (a total usability score of 81.3 points). In addition, program feasibility was evaluated using the percentage of patients (27/30, 90%) who consistently used the program.

Conclusions: The use of Internet technology allowed immediate and easy access to interventions, real-time monitoring of progress, online education, tailored action planning, and tailored short message services using mobile phones.

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KEYWORDS

Internet; health planning; exercise; diet; self-care; wellness programs

Introduction

Survival rates of cancer have improved steadily over the past 30 years [1]. This trend toward improved survival appears likely to continue. Such increases in the number of cancer survivors indicate that quality of life (QOL) issues among survivors must be addressed.

One common health problem in cancer survivors at diagnosis, during treatment, and after treatment is being underweight or overweight. Substantial weight loss has been documented in more than 50% of patients at diagnosis [2]. Symptoms including anorexia, early satiety, changes in taste and smell, and disturbances of the gastrointestinal tract are common side effects of cancer treatment, and such symptoms lead to substantial weight loss [3]. Also, many cancer survivors are overweight or obese at diagnosis. Weight gain (ie, sarcopenic obesity) can be a complication of cancer treatment [4] and is commonly observed during or after treatment of various cancers [3]. In particular, weight gain after cancer diagnosis increases the incidence of subsequent chronic disease, such as cardiovascular disease, diabetes, hypertension, secondary cancers, and cancer recurrence [5]. Both being underweight and overweight negatively affect health related QOL (HRQOL)[6] and survival [7]. For these reasons, maintaining a healthy weight is one of the top priorities when addressing the healthcare needs of cancer survivors [3].

Regular exercise and a balanced diet are essential for healthy weight management. Most dietary and exercise interventions developed to date have employed intensive clinic-based face-to-face counseling sessions [3]. Although the efficacy of such interventions is apparent immediately after delivery, once sufficient time has elapsed, the effects of the intervention cannot be found [8-11] or sustained [12]. The reason is that when the clinic-based face-to-face intervention ends, the participants cannot receive feedback from the experts, and the motivation for regular exercise and diet practices decreases [12]. In addition, the location of the clinic, travel time, and transportation issues are substantial barriers to the successful implementation of clinic-based face-to-face programs [13].

One way to overcome the shortcomings of clinic-based face-to-face intervention is to employ the Internet to this end. To maximize effectiveness when providing Web-based interventions, timely feedback on progress toward desired outcomes should be provided [14], action planning should be able to start at the right time [15], education should be tailored to motivational readiness [16], and self-efficacy should be enhanced at appropriate intervals [17]. The transtheoretical model (TTM) [18] integrates the concepts of self-efficacy and motivation with strategies including tailored feedback and action planning, and arranges these concepts and strategies to guide timely intervention. Therefore, it seemed appropriate to develop a Web-based self-management program using the TTM. The program sought to promote regular exercise and the adoption of a balanced diet to facilitate weight management.

Within the background, the overall aim of this study was to develop a Web-based self-management exercise and diet program featuring the delivery of education, the development of the capacity to plan, automatic feedback employing TTM-based strategies, and to evaluate whether the program was feasible.

Methods

Overview

The Web-based self-management exercise and diet intervention program was developed between February 1 and September 30, 2011, employing a 5-phase system development life-cycle method, which included identification of user requirements, system design, system development, system evaluation, and system application.

Phase I: Identification of User Requirements

System requirements included content and functionality. The content requirements of the Web-based self-management exercise and diet intervention program, called Health Planner, was determined via a review of the literature on the diet and exercise requirements of cancer patients after primary treatment. In addition, the development of Health Planner had been referenced to the prior Web-based application, Health Navigation [19], and the this study was part of a larger study—the TTM-based health management program for cancer survivors, called Leadership and Coaching for Health (LEACH). These studies might be applied to empower patients' ability to take care of themselves in the chronic care model [20]. For LEACH, interviews were conducted from September 2010 to March 2011 using semi-structured questions to seek case information on the healthy habits (ie, positive mindset, regular exercise, healthy diet, regular checkups, no smoking, not overworking), leadership, and commitment possessed by 46 cancer survivors (those who survived more than 5 years after diagnosis). Of the brief notes derived from the interviews, content on exercise and diet habits was extracted and reflected in Health Planner. Before each interview, each participant was informed as to the aim of the project. With semi-structured interviews [21], participants were encouraged to suggest, based on personal experience, information that should be provided to cancer patients. We prioritized information derived from cancer survivors, and selected content items after a consideration of the relevance of such items to our aim of providing effective weight management techniques to cancer survivors.

The functional requirements of the Web-based self-management exercise and diet intervention program were assessed by a review of existing Web-based health management programs for cancer survivors, and were also informed by TTM-based

strategies (ie, functions such as stage-matched education, feedback, and action planning).

Phase II: System Design

During system design, the content and function of the program were clearly defined with reference to the scope and the objectives. This was achieved by the selection of requirements identified in the first phase. Such clearly defined content and functional requirements were incorporated into the system with the aid of TTM theory. Screen layouts were designed to encompass these; all on-screen were designed with these principles in mind. To render visual communication effectively, and to provide users with a clear and consistent conceptual structure, the user interfaces were designed to be consistent and to be easily navigable.

Phase III: System Development

The system was developed on Microsoft Windows (Microsoft, Washington, DC, USA) the Web server application Apache Tomcat 6.0 (Apache Software Foundation, Forest Hill, MD, USA), and the database management system Oracle 10g (Oracle, Redwood Shores, CA, USA) environment. The program was written using Java (Oracle, Redwood Shores, CA, USA) and the JSP Standard Template Library (Sun Microsystems Inc, Santa Clara, CA, USA). Photoshop 8.0 (Adobe Systems, San Jose, CA, USA) and Flash 8 (Adobe Systems, San Jose, CA, USA) were used for Web page design. A short message service (SMS) module was integrated into the program.

Phase IV: System Evaluation

In this phase, the usability and accuracy of the content were evaluated by an expert group, composed of 3 content experts (a nutritionist, an exercise physiologist, and a clinical nurse, all of whom had PhDs), a Web developer, and 2 Web designers. Each component of the program, each element of the content, and all design features were repeatedly tested several times to determine whether any usability problem persisted, whether the content was accurate, if the program had been appropriately modified, and whether the group feedback had been incorporated.

The perceived ease of use of the program was evaluated by 29 breast cancer survivors. Breast cancer patients who had received curative breast cancer surgery with histologically confirmed stage 0-3 cancer were recruited consecutively from participating cancer registries of the 4 study hospitals. These 29 end users completed questionnaires exploring perceptions of the program [22,23]. The scores of items couched in negative terms were reversed; higher scores thus reflect a greater perceived ease of use. Cronbach alpha coefficient was 0.87. In addition, program feasibility was evaluated using the percentage of the patients who consistently used the program for 12 weeks.

Phase V: System Application

The system developed has been applied to the experimental group of the other interventional study to test program efficacy. The protocol of the intervention study is shown in Multimedia Appendix 1.

Results

Identifying User Requirements

The content requirements of the Web-based self-managed exercise and diet intervention program were identified by interviewing one key group of cancer patients (who survived more than 5 years after diagnosis) and by reviewing the literature.

Cancer survivors who were questioned about their habits regarding healthy diets reported that they wish to know what to eat and what not to eat. The cancer survivors described the difficulties they faced in maintaining a healthy diet that included at least 5servings of fruits and vegetables (F&V) per day due to lack of preparation time, taste concerns, and fear of pesticide exposure. Several survivors were skeptical about dietary recommendations because information from mass media and research studies often conflicted. However, because most believed that consumption of more F&V afforded overall health benefits, such informational conflicts did not deter the adoption of balanced diets. Some cancer survivors emphasized that it was very difficult to become motivated to change their diet to include more healthy foods. Participants gradually changed their diet over time. Some reported that tight schedules prompted them to eat out more often than they would prefer. They also reported difficulties finding healthy foods in restaurants. A few survivors commented on the high cost of organic vegetables and that F&V spoiled quickly. Even though cost and spoilage were thus identified as barriers, F&V were still consumed.

The main concerns for cancer survivors related to exercise were whether being overweight increases the risk of cancer recurrence, how to exercise during treatment and recovery, and what kinds of special precautions should be taken when exercising. Many women reported that it was difficult to schedule exercise time. A few mentioned that they had followed a routine at one time, but had stopped because cancer treatment had interrupted it or because they lacked an exercise partner. Several barriers rendering inadequate exercise were identified. These included side effects (especially fatigue) of cancer treatment, not having a local gym, and not living near a park. Bad weather sometimes prevented exercise. Some women commented that it was difficult to feel motivated to exercise. Encouragement from friends, or a few words from their doctors, made lasting impressions on them. Participants who discovered a sense of increased energy and a feeling of well-being when exercising were more motivated to maintain physical activity programs. Some female survivors claimed that it was difficult to exercise, particularly when it was dark outside.

Program content requirements obtained by reviewing literature included the need to improve exercise and dietary behavior in cancer survivors [24], the importance of healthy weight management [25,26], barriers to regular exercise and a balanced diet [27], considerations when planning exercise and diet [3], outcomes (such as recurrence, QOL, and survival) associated with the performance of regular exercise and a balanced diet [27,28], exercise and dietary guidelines for cancer survivors [29], and maintenance of regular exercise and balanced diet programs [24].

The functional requirements of the Web-based self-management exercise and dietary intervention program identified by a review of existing Web-based health management programs for cancer survivors were provisions of information, feedback, and evaluation. The functional requirements obtained from a consideration of TTM-based strategies were tailored education, action planning [15,30,31], automatic feedback [14], and comparison between the current status and recommended goal levels of exercise and diet [32].

System Design and Development

Overall

After clearly defining the content and functional requirements within the scope and objectives of the program, they were arranged and refined with the aid of the TTM theory. The Web-based self-managed exercise and diet intervention program contained 5 components differing in screen layout, which includes the introduction, assessment, education (tailored information provision), action planning (goal setting, scheduling, keeping a diary), and automatic feedback. That is, the program was designed to deliver education, action planning, and automatic feedback relevant to each of the stages of change. Education, action planning, and automatic feedback were tailored to each participant through the assessment. The processes of change, self-efficacy, and decisional balance are the principal strategies encouraging behavioral change according to the TTM theory and were reflected in the education [33-35]. Self-efficacy was also reflected in the automatic feedback. The details of each component of the program are as follows.

Introduction

The introduction informed participants of the overall background for developing Health Planner, the usage of the program, and the importance of exercising regularly and eating properly in maintaining good health for cancer survivors.

Assessment

The assessment section allowed participants to input their physical activity level, body weight, and stage of motivational readiness. All participants were screened for any contraindications to exercise using the physical activity readiness questionnaire [36] during assessment. Using algorithms based on input data, each patient could access tailored information appropriate to each stage of change, and was prescribed the appropriate number of portions of 6 food groups given their physical activity level and body mass index (BMI, measured on a daily basis).

Education

Each participant was scheduled to be online for 5-10 minutes each week. The educational content was divided into 5 modules based on the current stage of motivational readiness of each patient through assessment [18]. For patients in the precontemplation stage, education focused on raising consciousness, dramatic relief, environmental reevaluation, and increasing the number of pros. For patients in the contemplation stage, education focused on self-reevaluation, increasing the number of pros, decreasing the number of cons, and building self-efficacy. For patients in the preparation stage, education focused on self-liberation, and remembering and increasing the number of pros. For patients in the action and maintenance stages, education focused on reinforcement, assisting with relationships, counter-conditioning, stimulus control, and management of temptation.

Action Planning

Components

The action planning included setting a recommended goal, planning, keeping a diary, and comparing between current and recommended levels of exercise and diet. Each participant was encouraged to actively plan their exercise behavior in line with the American Cancer Society (ACS) guidelines for cancer survivors [24], and to achieve an excellent dietary score (measured using the Korean version of the Diet Quality Index). The details of exercise and diet planning delivered via Health Planner are as follows.

Exercise Planning

The goal of exercising was to perform at least moderate-intensity aerobic exercise for at least 30 minutes on at least 5 days each week (to yield 12.5 metabolic equivalents of energy expenditure, in line with ACS guidelines for cancer survivors) [24]. Health Planner generated a tailored plan for each participant through assessment. If a patient had no history of exercise prior to cancer treatment, exercise was gradually introduced [3]. Planning regular exercise was set to start at the preparation stage. The exercise was to be aerobic in nature, and the specific type of exercise was based on individual patient preference. The type, intensity, duration, and frequency of exercise could be self-adjusted as necessary depending on patient age, history of exercise, and subjective experience of tiredness. Exercise plan was implemented as an event on a calendar.

Dietary Planning

The goal of dietary planning was to achieve an excellent dietary quality score (measured using the Diet Quality Index [37]). The aims included an energy level derived from fat of ≤20%, an energy level derived from saturated fat of ≤6%, cholesterol ≤300 mg/day, an energy level derived from carbohydrates of ≤65%, an intake of vegetables and fruit of ≥7 servings/day, a protein recommended dietary allowance of 75-125%; a calcium recommended dietary allowance of 75-125%; and a sodium intake of ≤3500 mg/day. Dietary planning was based on individual BMI values, ideal body weights, and daily calorific requirements. Each patient was educated in terms of the recommended daily number of portions from the 6 food groups (grain, meat/fish/eggs/beans, vegetables, fruit, milk and dairy products, and fats and oils) as suggested by the Korean Nutrition Society (2010). All participants were encouraged to achieve a balanced diet.

Participants recorded the daily number of portions of 6 food groups consumed in a dietary diary and daily exercise behavior (type, intensity, and duration) in an exercise diary. These data were used to give automatic feedback on progress toward goal attainment (the SMS module was employed toward this end). The data were also presented visually where a graph compared the actual amount of exercise done, dietary intake, and the behaviors to what were recommended.

Automatic Feedback

Participants were asked to input, on a daily basis, the number of portions from the 6food groups consumed and the details of their exercise behavior (type, intensity, and duration of exercise) as shown in the exercise and dietary diaries. This information was used to provide feedback on progress toward goal attainment in the SMS module. Comparisons of the daily number of portions from the 6 food groups consumed with the recommended number, and of the weekly energy expenditure on aerobic exercise with the exercise goal identified patients who attained goal behaviors. These patients were given immediate reinforcement via positive automated messaging. Patients who did not attain goal behavior were encouraged to restart active exercise or to increase their dietary efforts. Such patients were encouraged to increase their level of physical activity or to attain a balanced diet by increasing F&V intake or moving to a low-carbohydrate or low-fat diet.

The protocol on the interventional goal, principal strategies, content theme in the educational component, and functions used for delivering interventions at each stage of change are briefly summarized in Table 1.

System Evaluation

In this phase, experts who had participated in the system design and development were contacted again and asked to advise on problems that arose in terms of usability and content accuracy during system operation. For example, the confusing array of content was rearranged to ensure consistency and relevance. Input speed was improved. The functions (ie, keeping a diary, setting a weekly exercise goal, measuring weekly body weight for a revised diet prescription, measuring the stage of change, SMS-based feedback) that depend on the stage of change and timing were modified to activate at an appropriate stage or timing. Images of various food servings were added and an example of the written 3-day dietary recall report was included. The number of pop-ups (negatively affecting concentration) was reduced. Tasks that were shown as incomplete on the calendar were identified. An SMS alarm was added to inform patients of the weekday on which education would be given. In addition, various bugs and errors were corrected. After iterative testing, the program was modified and installed on a server. Patients could access Health Planner from a home computer using an Internet browser.

The characteristics of end users participating in the usability evaluation are shown in Table 2. The end users rated the program as being easy to understand and use (a total usability score of 81.3 points, Table 3). In addition, program feasibility was evaluated using the percentage of patients (27/30, 90%) who consistently used the program for 12 weeks.

Table 1. Protocol of the Web-based self-management exercise and diet intervention program.

Stage of change	Interventional goal	Principal strategies (process of change, self-efficacy, decisional balance)	Content theme in the educational component	Functions used for delivering interventions
Precontemplation	Increase awareness of the need to change exercise and dietary behavior	Consciousness-raising Dramatic relief Environmental reevaluation Increase the pros	Effect of exercise and a balanced diet on health Specific reasons for not considering exercise or use of a balanced diet Risks associated with a sedentary lifestyle and an unbalanced diet	Weekly Web-based tailored education (5-10 minutes daily).
Contemplation	Motivate and increase confidence in the ability to change; build motivation for change	Self reevaluation Increase the pros/decrease the cons Build self-efficacy	Specific benefits of exercise and use of a balanced diet; barriers toward such achievements Solutions to overcome the specific barriers to exercise and use of a balanced diet Contemplation of improved health following exercise and use of a balanced diet	Weekly Web-based tailored education (5-10 minutes daily)
Preparation	Develop and negotiate a plan for exercise and use of a balanced diet	Self-liberation Remember the pros Increase self-efficacy	Recalling the effects of exercise and a balanced diet on health Individualized exercise and dietary prescription and creation of specific aims of exercise Keeping and monitoring of a daily exercise and dietary diary Planning gradual progress in terms of exercise Exercise planning in line with ACS	Weekly Web-based tailored education (5-10 minutes daily) Use of an exercise and diet diary Weekly planning exercise and diet
Action Maintenance	Reaffirm the commitment to exercise and to use of a balanced diet Develop strategies to prevent relapse	Reinforcement management Assisting with relationships Counter-conditioning Stimulus control Managing of temptation	Evaluation of current exercise and dietary pattern Self-reward for regular exercise and use of a balanced diet Recall of the specific aims or reasons for performing regular exercise and using a balanced diet Substitution of exercise for sedentary behavior and a balanced diet for one that was unbalanced Social and/or family support to help maintain exercise and dietary programs Avoidance of stimuli and other triggers provoking inactivity or use of an unbalanced diet Individualized exercise and dietary prescription detailing the specific aims of exercise Keeping and monitoring of a daily exercise and dietary log Planning gradual progress toward more exercise Exercise planning in line with ACS	Weekly Web-based tailored education (5-10 minutes daily) Use of an exercise and diet diary Weekly planning of exercise and diet Daily or weekly feedback on progress toward goal attainment Comparison of the current status and the goal levels of exercise and diet

Table 2. Characteristics of end users participating in the usability evaluation.

Characteristic	Participants N=30 n (%)
Age in year	
Mean (SD)	41.5 (6.3)
Educational level	
High school	7 (23)
College or beyond	23 (77)
Marital status	
Married	27 (90)
Not married	3 (10)
Time elapsed since treatment, days	
Mean (SD)	161.6 (107.8)
Range	26–349
Surgery type	
Breast-conserving	20 (67)
Mastectomy	10 (33)
Receiving chemotherapy	
No	4 (13)
Yes	26 (87)
Receiving radiotherapy	
No	3 (10)
Yes	27 (90)
Clinical stage	
Stage 0	2 (7)
Stage I	12 (40)
Stage II	13 (43)
Stage III	3 (10)

Table 3. Usability evaluation of health planner by end user responses.

	N=30 Mean (SD)[a]
Items	
1. I thought this program was easy to understand.	5.9 (1.4)
2. I could complete the tasks that were asked of me in this program.	5.7 (1.4)
3. I found this program confusing.	1.5 (1.1)
4. I thought that this program was easy to use.	5.9 (2.0)
5. I would choose to use this type of program in the future to complete an intervention that aims to improve my health.	6.5 (1.5)
6. The program was too complex.	2.2 (1.3)
7. I would need help from a technical support person to be able to use this program.	1.3 (1.8)
8. The program ran smoothly.	6.0 (1.7)
9. The program was inconsistent (there were parts of the program that seemed out of place).	2.0 (1.3)
10. I think that most people would learn to use this program quickly.	5.7 (1.3)
11. Using this program felt awkward to me.	1.9 (1.4)
12. I felt very confident using this program.	6.0 (1.8)
13. I needed to learn a lot of things before I could get going with this program.	2.4 (1.6)
Total Usability Score [b]	81.3 (20.2)

[a]Responses were on a 7-point scale, ranging from 1 (strongly disagree) to 7 (strongly agree).

[b]This is a composite of the responses to all usability questions (a 100-point score); higher scores indicate greater perceived usability.

Discussion

There is a widely recognized need for interventions to increase healthy behaviors for cancer survivors. However, the effectiveness of traditional interventions remains unclear due to low accessibility and non-persistent feedback. We developed the Web-based self-management exercise and dietary intervention program aiming to increase exercise and improve dietary behavior among cancer survivors. The program has several notable features. Critically, we embraced action planning when considering exercise and dietary behavior. The Web-based self-management exercise and diet intervention program managed day-to-day health behavior via action planning. Practical and specific action planning and scheduling promotes the initiation and maintenance of healthy behavior by identifying and filling intention-behavior gaps [15].

The program provided timely reinforcement via daily delivery of positive automated messages. The tailored feedback-based intervention may provide relief to survivors in that someone (or something) close to the patients is managing their health [38], motivating the patients to achieve and maintain goal behaviors at the recommended levels. Earlier work suggested that maintenance of healthy behavior is greatly assisted by the provision of appropriate feedback on progress toward desired outcomes [14]. The tailored reaction might stimulate self-regulatory behavior through making self-judgments on progress toward desired exercise and diet behavior [39].

The patients' needs were reflected in the program through interviews with the patients, and the identified user requirements were combined with technologies to implement TTM theory-based functions. Our Web-based self-management program, featuring the use of TTM theory may not only trigger the required behaviors, but may assist in sustaining such long-term behaviors [12,16]. Self-regulation strategies, including diary keeping, an emphasis on goal-setting, and feedback on progress may increase motivation and perceived self-efficacy [33].

A review of previous studies identified the possibility that the TTM could be applied to a Web-based program seeking to encourage healthy behavioral changes. The potential of TTM theory has been recognized in previous studies for application in Web-based physical activity intervention [40], but not for Web-based diet programs. Individual exercise regimens were prescribed using TTM theory, with reference to stages of change, in an interventional Web-based program developed for patients with type 2 diabetes [40]. Program clarity, simplicity, recommendations, accuracy, consistency, and efficiency were rated as acceptable. In another study, a Web-based TTM-based program was developed to promote physical activity in the general female population [41]. The program was a full success, having promoted self-efficacy, physical activity, and exercise. To date, however, no Web-based program aimed at such lifestyle modifications in cancer survivors is yet available.

Previous findings of Web-based lifestyle intervention trials remain controversial. Delivery of theory-based messages via the Web enhanced lifestyle modifications [19,40,42]. However, a Web-based program that apparently failed to trigger lifestyle changes lacked a theoretical basis, had low utilization, and did not suit participants' needs [43]. This program rated high

utilization. It might be due to the strategies of daily feedback and action planning. The diagnosis of cancer also provides a teachable moment when the patients' motivation for lifestyle change is especially high [44].

In conclusion, a Web-based program targeting change in exercise and dietary behaviors was feasible when TTM theory was used to inform program strategy. The use of Internet technology allowed immediate and easy access to interventions, real-time monitoring of progress, online education, tailored action planning, and tailored SMS using mobile phones [45]. Most healthcare providers in busy clinical settings rarely find time to counsel patients on health management. Given that the number of cancer survivors is increasing, targeting of such high-risk groups can potentially achieve positive and widespread public health outcomes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The protocol of the trial.

[PDF File (Adobe PDF File), 17KB - resprot_v2i1e11_app1.pdf]

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Abbreviations

ACS: American Cancer Society
BMI: body mass index
F&V: fruits and vegetables
HRQOL: health related quality of life
LEACH: Leadership and Coaching for Health
QOL: quality of life
SMS: short message service
TTM: transtheoretical model

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Original Paper

Designing iCanFit: A Mobile-Enabled Web Application to Promote Physical Activity for Older Cancer Survivors

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Abstract

Background: Most older cancer survivors (OCS) do not engage in regular physical activity (PA) despite well-known health benefits. With the increased use of mobile technologies among older adults, mobile tools may be an effective method to deliver PA promotion programs for OCS.

Objective: To document the process of designing an OCS-friendly mobile-enabled Web application of PA promotion program.

Methods: Mixed methods encompassing group discussions, individual interviews, and brief surveys with community leaders, OCS, cancer care providers, and software professionals were used in this formative research.

Results: The varied stakeholders welcomed the idea of developing an online tool to promote PA in OCS. Our formative research revealed several major barriers to regular PA including limited access to senior-friendly PA resources, lack of motivation and social support, and insufficient knowledge and skills on building safe and appropriate workout plans. This feedback was incorporated into the development of iCanFit, a mobile-enabled Web application, designed specifically for OCS. The iCanFit online tools allow users to locate PA resources, set and track goals for PA, network with peer OCS in a secure online space, and receive practical and evidence-informed healthy tips.

Conclusions: Our mixed-method formative research led to the design of iCanFit protocol to promote PA and well-being of OCS. The involvement of stakeholders is critical in the planning and design of the mobile application in order to enhance program relevance, appeal, and match with the needs of target users.

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KEYWORDS

older cancer survivors; physical activity, survivorship, mHealth, website design; user-computer interface; protocol development; formative research

Introduction

Early detection and improved treatment for cancer has resulted in approximately 13 million survivors in the Unites States today. It has been estimated that these numbers will increase by nearly a third to 18 million by 2022 [1]. Most cancer survivors are 60 years of age or older, and the population of older cancer survivors (OCS) is increasing, resulting in many challenges

associated with the continuity of care and resultant quality of life [2,3]. Countering these challenges, numerous studies point to the physiological and psychosocial benefits of physical activity (PA) for cancer survivors [4,5]. These benefits include improved physical endurance, capacity and strength, higher immune function and hemoglobin concentration, decreased risk of cancer recurrence, and improved quality of life as indicated by decreased fatigue and depression [6-10]. Several guidelines on PA for cancer survivors have been recently issued, recommending cancer survivors to engage in low to moderate impact PA regularly, specifically, at least 30 minutes of exercise a day for 5 days a week [11,12].

Despite the recognized importance of PA for cancer survivors, evidence suggests that the level of adherence to PA guidelines among cancer survivors is very low. Smith and Chagpar reported that only 4.6% of breast cancer survivors followed PA guidelines, compared to 12% of women without breast cancer [13]. The majority of cancer survivors are not participating in the recommended levels of PA, resulting in a greater disease risk and health care costs [14]. In a review of existing programs to promote PA among cancer survivors, Schmitz and colleagues observed that most existing programs are limited to walking only, and that there is a lack of diversity in types of PA for cancer survivors [15]. In addition, most existing studies of interventions to increase PA have relied on individual or small group counseling approaches, typically offered by nurses or health educators. Such face-to-face approaches, although promising, have encountered problems of high personnel cost and limited reach. Thus, a critical need exists for more cost-effective strategies to reach a large number of OCS with effective strategies for promoting PA [12,16].

In the exploration of interventions to promote PA among OCS, mobile technologies are gaining increased attention across all age groups. As of 2012, about 88% of US adults and nearly 70% of people older than 50 accessed the Internet. 85% of US adults owned cell phones, of those, 53% owned smartphones [17]. Approximately 70% of adults over 50 owned a cell phone, and more than 42% owned a laptop or tablet computer [18]. The percentage of older smartphones or mobile computer owners is expected to accelerate in the coming years. Further, recent surveys by National Cancer Institute indicated that more than 60% of cancer survivors access the Internet; and once online, they are more likely to use it for health-related purposes than general users [19, 20]. Among cancer survivors, the Internet has become the second most used resource for finding health-related information (the primary resource was physicians) [21,22]. The ubiquity of Internet access in the US and the rapid penetration of smartphones and tablets suggests the feasibility of using mobile technologies to promote PA among OCS. In a recent review of existing Web and mobile applications for PA promotion, we found that most websites or applications were designed for general and younger populations. Few online PA programs were designed for cancer survivors, not to mention OCS. The purpose of this article was to describe a formative study we conducted to inform the design of a mobile or Web application for the purpose of promoting PA among OCS.

Methods

Overview

A multidisciplinary research team from Communities of Texas: Cancer • Activity • Research • Education • Support (CTxCARES) program representing public health, medicine, health education, and technology development worked collaboratively to design the formative research protocol. A mixed-method approach was used to collect data to inform the structure and content of the mobile or Web application. Our team met regularly to discuss the data collected from field, enabling prompt feedback for project development and refinement. Data collection in formative research spanned from November 2011 to September 2012. We held group discussions with community leaders, individual interviews with cancer care providers, and conducted a brief survey and interviews with OCS. Table 1 lists all the data collection methods utilized. The study protocol was approved by the Institutional Review Boards at the Texas A&M University and Scott & White Healthcare.

Table 1. Data sources of formative research in the iCanFit program.

Data collection method	Participants	Recruitment venues	Data collection mode
Group discussion	Community leaders (n=20)	Community centers	Face-to-face
Individual interview	Cancer care providers (n=14)	Conferences, clinics	Face-to-face, phone
Individual interview	Older cancer survivors (n=20)	Communities, clinics, cancer-related events	Face-to-face, phone
Questionnaire	Older cancer survivors (n=92)	Communities, cancer-related events	Paper-pencil

Group Discussions with Community Leaders

The CTxCARES program has collaborated with local cancer communities and senior communities for several years, leading to established relationships. At the planning stage of the project, we communicated about our intention to develop a mobile or Web application for OCS to local senior and cancer community leaders and obtained their support. In our formative research, we had 2 group discussions with local community leaders to get their input on the feasibility of a website to engage OCS and promote their PA. The discussions took place in informal expanded meetings of community organizations in which community leaders and members were present. These discussions were not taped, but detailed notes were taken during and after the meeting.

Interviews with Cancer Care Providers

We also interviewed practicing cancer care providers who have patients either in active cancer treatment or are cancer survivors. The provider's interview guide was developed based on the literature review and informal discussions with community leaders. The guide focused on: (1) perceptions on OCS' barriers to regular PA, (2) current counseling of PA with OCS, (3) suggested contents of a mobile or online program, and (4) strategies to disseminate the program after piloting. The interview guide was piloted with 2 physicians before field use. A total of 14 cancer care providers were recruited during a large state cancer conference, representing surgeons, oncologists, family physicians, internists, health educators, and counselors. One-on-one interviews ranging from 20-45 minutes were conducted in a private space. All conversations were audio-taped and transcribed verbatim.

Survey with OCS

We conducted a brief survey with OCS who were at least 60 years old, had a cancer diagnoses, and had completed initial treatment. Surveys were distributed at local health fairs and cancer survivors' events. Participants reported on their Internet and cell phone use, current PA behaviors, access to health information, and attitudes toward mobile-based PA promotion program. It took the OCS approximately 10 minutes to complete the brief paper-pencil survey. A total of 92 OCS (mean age 62) provided oral consent and completed the survey. All survey data were entered into SPSS 16.0 (SPSS Inc, Chicago, IL, USA).

Interviews with OCS

Our third strategy was to conduct in-depth individual interviews with OCS. We developed an interview guide for OCS based on the brief survey with OCS and the in-depth interviews with cancer care providers. The interview guide consisted of the following domains: (1) current PA including type, intensity, duration, and frequency, (2) barriers to regular PA, (3) preferred PA and facilitators to regular PA, (4) attitudes toward an online or mobile PA promotion program, (5) suggestions on content and features of the mobile program, and (6) suggestions on program implementation and evaluation. A total of 11 OCS in Central Texas were recruited through community outreach strategies. The interviews were conducted face-to-face or over the phone, lasted 25-45 minutes, and were audio-taped. Each participant provided consent and received a $15 gift card.

Data Analysis and Interpretation

The data collected in the formative research included: (1) notes from the research team's regular meeting discussions, (2) detailed notes from discussions with community leaders, (3) transcripts from interviews with cancer care providers, (4) survey data from OCS, and (5) transcripts from interviews with OCS. Quantitative data were saved in SPSS and descriptive statistical methods were used to analyze frequency of key variables. Qualitative data were saved in Microsoft Word; thematic content analysis was used to identify the major themes and key exemplary quotes [23]. Findings from each data set were used to inform analysis and interpretation of other data sets. The data analysis was iterative and continued throughout the formative research; the findings were used to inform the design, content, and structure of the iCanFit mobile-enabled Web application.

Results

Feasibility of Mobile PA Promotion Program for OCS

The survey and interviews with OCS and discussions with community leaders revealed the current online behaviors of OCS. Most of OCS accessed the Internet, and the Internet was a major source of health information for the participants. For example, more than 80% of OCS in our interviews indicated that they would participate in an online PA promotion program or OCS support program. OCS also suggested that compared to younger people, they had shorter online duration and that they were more likely to visit the same authoritative sites. Less than 10% of OCS accessed the Internet through their cell phones frequently, but many had tablets such as iPads and many accessed the Internet through their mobile devices.

> *I use Internet many times a day, and I search for health information for myself and my family. I search the Internet using both my desktop and my iPhone…People have misconceptions about seniors using mobile technologies, many of us are computer savvy.* [61 year old OCS]

Some OCS, especially those over 75 years old, reported less use of Internet themselves, but they relied on their families to access the Internet and obtain health information. More than 80% of the OCS we talked to have easy access to health information and could easily obtain this information from the Internet.

Barriers to PA Among OCS

The interviews with cancer care providers indicated that most of them were aware of regular PA as part of healthy living for cancer survivors, but very few discussed PA with their survivor patients. Care providers identified the lack of motivation to carry out PA from survivors as the major barrier to regular PA. For example, a physician related, "If they want to do it, they'll do it. If they don't, they won't." Most cancer care providers listed time constraint as a major barrier to discussing PA with their cancer survivor patients. As one physician indicated, "The conversation doesn't get that in-depth because we have so many other issues to discuss."

The interviews with OCS confirmed that most did not participate in regular PA. Four personal and structural level barriers to PA were identified. First, some survivors were not aware of the benefits of PA.

> *For myself, since I got colon cancer, I became more cautious with what I eat. I see nutrition is more important for me…Physical activity? I do some yard work, and when I shop in Wal-Mart, I walk fast with my shopping cart* [60 year old OCS]

Second, some understood the importance of regular PA, but lacked motivation to be more physically active.

> *After all the treatments, I just want to go back to my normal life. I know exercise is good for health, but it is probably the last thing in the mind now. I just want*

> *to get back to normal, rather than an enhancement or set up new goals.* [67 year old OCS]

Third, many OCS had limited access to information on local, senior-friendly PA programs and resources. They expressed frustration in finding senior-friendly PA resources.

> *There is a senior center here in [omitted], but I've been there and looked into their exercise room and it's about twice the size of my hall bathroom; and it is so confined that I am not inspired to get in there and do anything.* [70 year old OCS]

Another OCS who had tried some programs said, "It did help a little but I quit going because they did not treat me as an individual but they just do everybody in mass." In addition, since PA was rarely discussed in their visit with health care providers, OCS did not know how to set up individualized plans that fit their health and needs. Fourth, some OCS did not have enough social support, especially peer support, to engage in regular PA. For instance, some OCS commented, "I am basically lazy…and I need somebody to crack the whip…If I had an exercise partner, I may go more often." Our brief survey with OCS suggested that only a small number of OCS were part of the online cancer support groups but most were willing to join one.

Key Functions and Structure of the Online PA Promotion Program

In addition to identifying barriers to regular PA, our participants of community leaders, cancer care providers, and OCS also provided suggestions on how to design the online program to address these barriers. Their input was incorporated into the design of a mobile-enabled Web application called iCanFit. The reason for a Web application instead of a mobile application is to fulfill the goal of making iCanFit accessible through all mobile devices with Internet connections. Most mobile applications are limited to certain devices or platforms. For example, iPhone apps will not work on Android phones. Our mobile-enabled interactive website allows seniors to access the program through their various mobile devices with minimal restrictions.

Table 2 lists input from stakeholders on the barriers and corresponding functions on the Web application to address stakeholder feedback. The interactive iCanFit has the following 6 major functions addressing the needs and barriers to regular PA in OCS:

1. "Locator", a function that allows easy search for local resources of PA, including parks, facilities, and programs. Users can set their preferences for searching, for example, indoors, free, group activity, etc.

2. "Goals", a function that allows users to set long- and short-term goals of PA. They can track their PA by entering their weekly PA. The iCanFit system will provide tailored feedback on their progress and suggestions on changing on short-term goals. iCanFit sends weekly reports to the users tracking their goals and providing tailored tips and kudos. Those who met their goals were congratulated by a virtual coach and those who did not meet their goals received motivational messages from the virtual coach.

3. "Community", a function that offers social support through virtual networking. Users are able to create a profile, post images, and start and follow discussions and to connect with peers users. Users are also able to create a profile, post images, and start and follow discussions and to connect with peers users. Those who exceed the short-term PA goals will also be recognized and congratulated in the online community.

4. "Healthy Tips", a function that sends regular health tips to users. These consist of tips for seniors to make small changes in daily life and make incremental progress toward an active and healthy living.

5. "Library", is a function that provides convenient access to authoritative health information. In addition to links to major senior health and cancer survivor organizations, this function also allows keyword search for specific health information.

6. "Support", is a function where users can seek help and technical support when using iCanFit programs.

We included some screen shots to help visualize how iCan Fit works. Figure 1 depicts iCanFit homepage on a desktop, Figure 2 displays the key functions of iCanFit on a laptop, and Figure 3 shows iCanFit functions on an iPhone interface. In line with stakeholders' suggestions and the National Library of Medicine guidelines of "making your website senior friendly" [24], the iCanFit interface is simple with bigger icons, bigger fonts, more space between lines, and clear background in contrast with the main texts. The iCanFit protocol is currently being developed into active Web application.

Table 2. Proposed key iCanFit functions based on inputs from stakeholders.

Input	Proposed iCanFit function	Purpose
OCS: Limited safe and senior-friendly physical activity resources. CL: Lack of access to information on community resources and events.	Locator	• Allows easy search for local resources of PA, including parks, facilities, and programs • Users can set their preferences for searching, for example, indoors, free, group activity etc • Suggests a variety of types of PA
CCP: Insufficient time to discuss PA or make specific plans with patients. OCS: Need assistance in setting individualized plans.	Goals	• Allows users to set long- and short-term goals of PA. • Users can track their PA and iCanFit provides tailored feedback
OCS: OCS need social support, especially peer support to start and maintain regular physical activity. OCP: Social support is an important factor for OCS to stay physically active. CL: Online community can expand OCS social networks, especially for rural residents.	Community (Chatter)	• Offers social support with other OCS through virtual networking • Users can create personal profiles, post images, start and follow discussions
CCP: OCS lack motivation to stay physically active. OCS: Need constant reminders to continue the momentum. CL: Simple tips can make small changes, and small changes can add up.	Healthy Tips	• Sends regular practical, senior-friendly, evidence-based healthy tips specific to OCS
OCS: Many OCS are unaware of necessity and benefits of regular PA. CCP: Do not have enough time to carry out patient education.	Library	• Provides convenient access to authoritative health information • Provides links to major senior health and cancer survivor organizations

Figure 1. iCanFit webpage interface on a desktop computer.

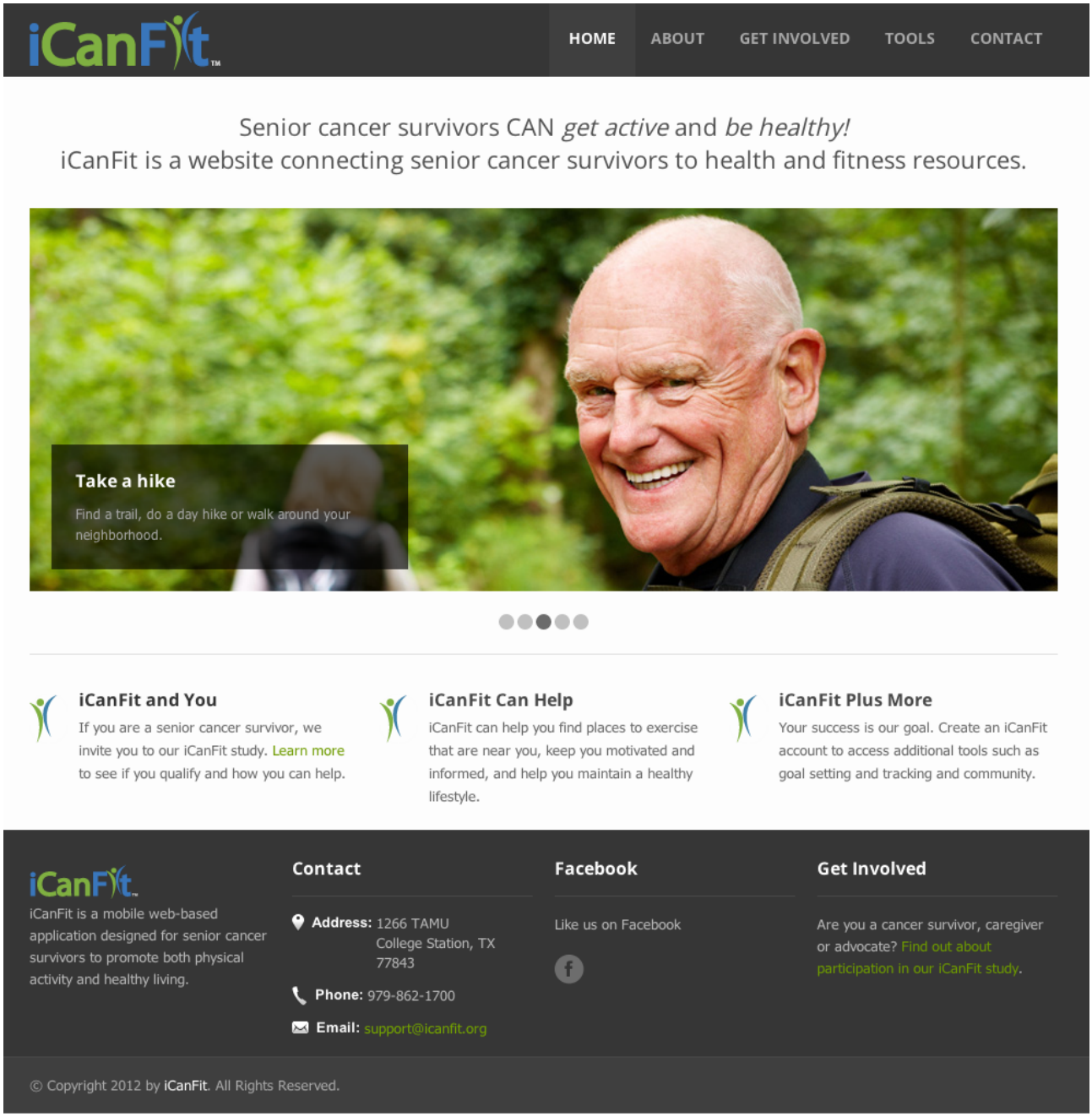

Figure 2. Major functions of iCanFit on desktop interface.

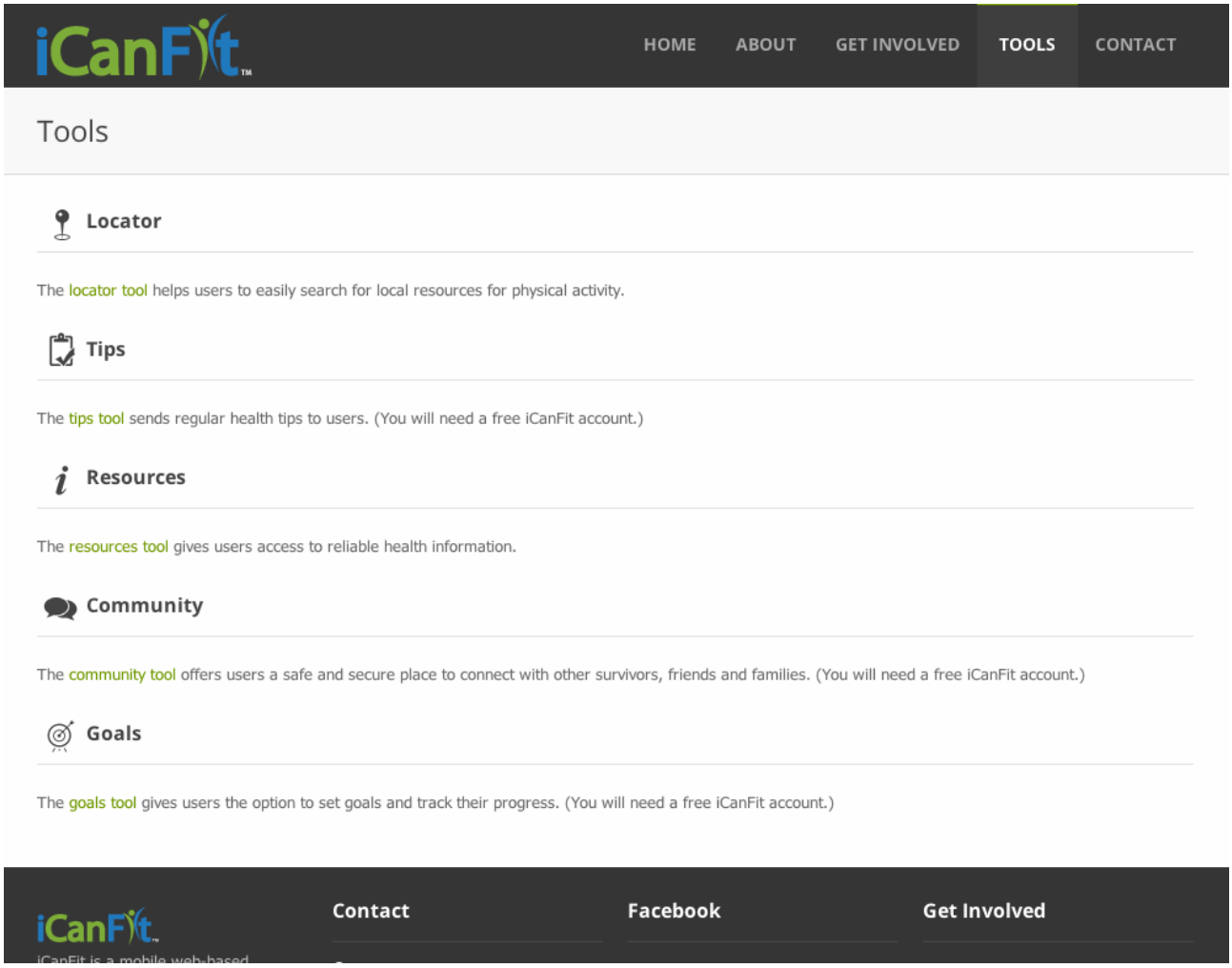

Figure 3. Major functions of iCanFIt on an iPhone interface.

Discussion

With the population of OCS expanding and few OCS having regular PA, a strong need exists for a cost-effective health promotion program targeting this population. Online access is increasingly common among older adults, and mobile use is also accelerating, thus offering a potential mode of widespread intervention delivery. A combination of Web and mobile technology that incorporates the best principles of chronic care management—including identifying patient preferences,

addressing barriers to lifestyle changes, enhancing self-management skills, providing coaching and feedback, and facilitating peer support—offers an excellent opportunity to meet this need [25,26].

Although the number of online health promotion programs is skyrocketing with demonstrated efficacy [27,28], very few programs are available for OCS. This study documents the process necessary to develop a PA promotion program for OCS. It has long been recognized that employing user-centered design and development process is essential for ensuring a quality user experience [29-31]. Our formative research has involved the key stakeholders from very beginning and throughout the phase of protocol development. The resulting iCanFit protocol addresses OCS' barriers to regular PA. It provides an engaging venue for achieving behavioral change through easy access to community resources, goal setting and reinforcement, and peer support. It is important that these functions are relevant to OCS and presented in a format that appeal to the intended audience.

Several limitations should be noted for this study. First, we had a relatively small sample size in both quantitative and qualitative data collection, which might introduce potential reporting bias. However, our participants were drawn from a diverse background and the data suggested saturation. Second, as our participants were recruited from communities in Texas, the findings may not be generalizable to OCS from other locations. We employed community outreach versus online recruitment because we needed to conduct an in-depth and sometimes repeated interviews with OCS to obtain their feedback. Third, our program only addressed 3 key barriers to regular PA identified by OCS and their care providers. Whether the program met their expectations and could promote regular PA and health outcomes requires a long-term study. We are now developing the iCanFit protocol to the active Web application. Once beta-testing is completed, we will conduct an efficacy trial to assess whether it can promote PA and other health outcomes of OCS.

The design of online health promotion programs, especially behavioral change programs, should reflect collaborative efforts between researchers, computer software designers, and key stakeholders. Through this formative research, we learned the importance of setting a realistic timeline and recruiting participants from diverse backgrounds. We also appreciate the value of a mixed-method study that involves key stakeholders to understand target users' needs and preferences in order to identify best strategies for program development and evaluation of this new mobile-enabled Web application.

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Conflicts of Interest

None declared.

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Abbreviations

CCP: cancer care providers
CL: community leaders
CTxCARES: Communities of Texas: Cancer • Activity • Research • Education • Support
OCS: older cancer survivors
PA: physical activity

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Original Paper

User Perceptions of a Dementia Risk Reduction Website and Its Promotion of Behavior Change

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Abstract

Background: Several modifiable health and lifestyle factors are consistently associated with dementia risk and it is estimated that significantly fewer people would develop dementia if the incidence of risk factors could be reduced. Despite this, Australians' awareness of the health and lifestyle factors associated with dementia risk is low. Within a national community education campaign, Alzheimer's Australia developed a dementia risk reduction website providing information about modifiable risk or protective factors for dementia.

Objective: This study aimed to assess the usefulness of the website content in improving knowledge and enabling adoption of recommended strategies, and to examine what additional resources consumers need.

Methods: Visitors to the website over a 3 month period were invited to complete an online survey, which asked them to rate their knowledge of dementia risk reduction before and after visiting the site, how important monitoring their health related behavior was to them before and after visiting the site, their current behavior related to health and lifestyle factors associated with dementia risk, their intentions to change behavior, and the usefulness of potential additional resources to help them do so.

Results: For this study, 123 Australian adults responded to the survey. 44.7% (55/122) were aged over 60 and 82.1% (98/119) were female. Respondents' ratings and comments indicated they generally found the content interesting, informative, and helpful to them. Respondents' ratings of their knowledge about the links between health and lifestyle factors and dementia risk significantly increased after visiting the website (P<.001). Their ratings of how important monitoring what they do in relation to their health and lifestyle factors were also significantly increased after visiting the website (P<.001). Average ratings for how well respondents felt they were doing at the time in relation to specific risk or protective factors were generally high, suggesting many website visitors already had high levels of health motivation and healthy lifestyle behaviors. 55.6% (45/81) said that after visiting the website their intention to make lifestyle changes was strong. Only 27.1% (22/81) said their intention to visit their doctor to discuss dementia risk reduction was strong. Potential additional resources that would help people assess and address their personal dementia risk factors were rated as more helpful than general information resources.

Conclusions: A dementia risk reduction website providing information about the current evidence and practical strategies was of interest and was useful to the Australian community. Benefits for visitors included increased knowledge and increased motivation to address relevant behaviors. Many visitors to the site were already health conscious, indicating that more needs to be done to get dementia risk reduction messages to the wider community. More interactive and personalized resources in future interventions may offer additional benefits to individuals.

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KEYWORDS

dementia; Alzheimer's disease; risk reduction behavior; health communication; evaluation studies

Introduction

Background

The prevalence of dementia worldwide is increasing with the ageing population. In Australia, it is projected to increase four-fold to around 1 million people by 2050 [1], with significant impacts on the health system and economy. While dementia remains incurable, preventative health approaches to address dementia risk factors offer some hope of reducing this impact. Efforts to provide a preventative health strategy for dementia are increasingly seen as worthwhile, and vital to curbing the growing number of people who are affected [2-6].

Several modifiable health and lifestyle factors are consistently associated with the risk of developing dementia from all causes, including Alzheimer's disease [7-9]. Midlife hypertension [10], midlife high total cholesterol [11], diabetes [12], midlife obesity [13], high saturated fat consumption [14], head injury [15], and smoking [16] are associated with greater risk of developing dementia. Odds ratios vary between studies and meta-analyses, but generally these factors are associated with 1.5-3 times increased risk of dementia. Regular physical exercise [17], mental and social activity [18,19], and higher fruit and vegetable and unsaturated fat consumption [14] are associated with reduced risk of developing dementia. These factors are typically associated with 30-70% reduced risk of dementia.

Preventative health approaches that facilitate lifelong mental, physical, and social activity, healthy eating and lifestyles, and prevention or control of vascular risk factors have the potential to reduce the number of people developing dementia [9]. Barnes and Yaffe recently estimated that 3 million cases of Alzheimer's disease could be prevented worldwide by reducing by 25% the incidence of 7 risk factors (diabetes, midlife hypertension, midlife obesity, depression, physical inactivity, smoking, and cognitive inactivity, [2]). Computer modelling based on population growth estimates and dementia prevalence data showed that significant impacts could be achieved by modifying the risk factor profile in the Australian population. For example, a decline in the physical inactivity rate by 5% every 5 years would reduce dementia prevalence by 11% in 2051 [20].

Despite this potential, most people have little knowledge about dementia risk factors [21]. A 2008 review of surveys revealed that, on average, 51% of Australians believed risk reduction is possible, while 20% believed nothing can be done to reduce dementia risk, and the remainder were unsure [21]. When asked how risk could be reduced, or when presented with possible reduction factors and asked which would reduce risk, mental activity was nominated by more Australians than any other strategy, followed by a healthy diet and physical exercise. The majority of people did not agree that reducing vascular risk factors (smoking, high blood pressure, and high cholesterol) could reduce dementia risk, highlighting a pressing need to educate the public that preventing or managing vascular risk factors can reduce risk of developing dementia in addition to heart disease and stroke [21].

Mind Your Mind

To improve public awareness, Alzheimer's Australia (Australia's national dementia association) developed a community education program about dementia risk reduction called Mind your Mind (MYM). The program provides information about health and lifestyle behaviors associated with lower risk of developing dementia. The 7 MYM "signposts" (body, brain, diet, habits, head, health checks, social life) deal with aspects of behavior related to modifiable risk factors for dementia. The program initially relied on community education forums and printed resources, but these have limited reach. To improve accessibility to MYM, the program now includes online resources as described in the Methods section below.

In developed countries including Australia, the vast majority of people are Internet users (in 2011 an estimated 89.8% of Australians were Internet users [22]). The use of the Internet for health information is increasing, in part because people like the convenience and anonymity it provides [23-25]. Web-based health information therefore has the potential to reach large audiences at low cost [26,27]. Web-based interventions are also found to be effective at increasing awareness and enabling healthy behavior changes. Many studies report positive changes in knowledge, attitude, awareness, and healthy behavior for participants using Web-based health interventions, suggesting that Web-based health resources are capable of promoting healthy lifestyles [28,29].

In 2010, a MYM website was launched [30]. By assessing user perceptions of this website, this study aimed to determine whether evidence-based advice provided online is effective in promoting the uptake of dementia risk reduction approaches by individuals. Specifically, the study aimed to evaluate the effectiveness of the information provided in improving knowledge about dementia risk factors and the lifestyle and health strategies that may reduce risk, the effectiveness of the information provided in motivating and enabling individuals to adopt healthy behaviors, and what additional resources might assist individuals in adopting dementia risk reduction behaviors.

Methods

The MYM Website

The MYM website was developed to provide the Australian community with accessible and engaging information about the current evidence for lifestyle and medical factors associated with dementia risk. Figure 1 shows a screenshot of the MYM website home page. Table 1 describes the website sections and their contents at the time of this study. The main section of the website described the modifiable risk or protective factors associated with dementia, grouped under the 7 MYM signposts. For each factor, the current state of evidence was described in lay language and the strength of the evidence was rated using a 5-star system, and practical advice and links to relevant resources were provided. In developing the site content, Alzheimer's Australia reviewed relevant literature, and used external experts' advice on the recommendations being made regarding dementia risk reduction. The content was designed to be understood by Australian adults with average literacy and was not personalized for particular groups with differing levels

of prior knowledge. Feedback from Alzheimer's Australia staff and consumer advisors about the appropriateness of the content for the general public was incorporated into the final content design.

The Survey

An online survey was developed using SurveyMonkey [31]. Feedback from Alzheimer's Australia staff and consumer advisors was incorporated into the final survey design. At the commencement of the study, a brief notice and link were provided on the MYM website homepage to a dedicated internal page that provided detailed participant information and a link to the survey. Participants were instructed to read through the website before completing the survey, both on the information page on the website and on the survey itself, to minimize the chance of completing the survey without having viewed the website. The survey consisted of 48 items including demographics and questions about knowledge of dementia risk reduction before and after visiting the website, motivation to do something to reduce dementia risk before and after visiting the website, current behavior, intentions to change lifestyle behaviors to adopt risk reduction strategies, and what additional resources people feel they need to be able to improve their risk reduction behaviors.

Most items asked respondents to rate a specific attribute of the information provided on the website using a 5-point rating scale. Respondents were also able to enter additional comments. Where items asked respondents to rate attributes of the various sections of the website or of the information provided about specific risk or protective factors, respondents were instructed to select "not applicable" for any sections or factors they had not looked at. The survey also included open questions about what lifestyle changes respondents intended to make and what additional resources might help them.

Participants

Users of the website from April to June, 2011, were invited to participate in the study via an information page on the MYM website with a link to the survey. Eligible participants included adults 18 years of age and over residing in Australia. Participants were anonymous but the survey asked for demographic information including age, gender, place of residence, medical status, education, and occupation. 123 people responded to the survey, however not everyone completed all questions.

Data Analysis

For items rating attributes of the website using a 5-point scale, the mean rating across participants who provided a rating was calculated. Non-responders to individual questions were excluded from the analysis of those questions. *t* tests were conducted to examine differences in ratings between before and after visiting the website, for knowledge about the links between specific risk or protective factors and dementia, and for the importance of monitoring actions in relation to specific risk or protective factors. To correct for multiple comparisons, a significance level of $P<.001$ was applied.

Table 1. Description of the contents of each section of the MYM website.

Section	Contents
About dementia	what is dementia, symptoms, forms of dementia, risk factors
MYM	summary of evidence, practical advice, and links to resources for risk or protective factors: mental activity, diet, physical activity, social activity, blood pressure, cholesterol, diabetes, body weight, smoking, alcohol, head injury
Resources	downloadable information sheets, brochures and papers, frequently asked questions, quiz answers
Health professionals	downloadable guidelines and summary of evidence, resources for clinicians and patients for risk or protective factors: mental activity, diet, physical activity, social activity, blood pressure, cholesterol, diabetes, body weight, smoking, alcohol, head injury, depression
Research	dementia prevention research generally, current Australian research
Quizzes	three 10-question multiple choice quizzes on MYM, the brain, and music
Blog	brief articles on new research, publications, or resources

Figure 1. Screenshot of the Mind your Mind website home page.

Results

Participant Demographics

The majority of respondents were 50-69 years of age (see Table 2). There were 98/119 (82.4%) female respondents and 86/120 (71.7%) lived in urban areas. There were 32/117 (27.0%) respondents born outside Australia and 28/121 (23.1%) reported speaking a language other than English at home. Some form of post-secondary education was completed by 76/121 (62.9%) respondents, and 39/121 (32.2 %) respondents were retired. Reported current or previous occupations were grouped according to the Australian and New Zealand Standard Classification of Occupations [32] and 57/118 (48.3%) respondents worked in management or professional roles. Chronic medical conditions affecting day-to-day function were reported by 10/120 (8.3%) respondents, but none had dementia.

There were no significant differences between responders and non-responders to each section of the survey regarding age group (P>.009), gender (P>.3), highest education level (P>.7), occupation classification (P>.3), or language spoken at home (English or non-English; P>.4). Older respondents were more likely to drop out of the survey earlier and not complete all questions, but not significantly so. The P values shown are representative of the lowest significance obtained from 3 t tests for each variable. The variables were compared between responders and non-responders to the 3 sections of the survey that followed the first section on demographics. For questions relating to the sections of the website, P=.03 for age, P=.66 for gender, P=.99 for education, P=.37 for occupation, and P=.43 for language. For questions relating to the specific risk or protective factors, P=.009 for age, P=.52 for gender, P=.75 for education, P=.45 for occupation, and P=.91 for language. For questions relating to potential additional resources, P=.01 for age, P=.37 for gender, P=.74 for education, P=.36 for occupation, and P=.99 for language.

Table 2. Characteristics of respondents.[a]

Characteristic	n (%)
Age of respondents (N=122)	
18-30	10 (8.2)
31-40	14 (11.5)
41-50	12 (9.8)
51-60	31 (25.4)
61-70	40 (32.8)
71-80	13 (10.7)
>80	2 (1.6)
Highest level of education completed by respondents (N=121)	
Year 6	2 (1.7)
Year 8	3 (2.5)
Year 10	23 (19.0)
Year 12	17 (14.0)
Diploma	25 (20.7)
Bachelor degree	26 (21.5)
Postgraduate degree	25 (20.7)
Occupation classifications of respondents (N=118)	
Managers and self-employed	8 (6.8)
Professionals	49 (41.5)
Technicians and trade workers	5 (4.2)
Community and personal service workers	12 (10.2)
Clerical and administrative workers	31 (26.3)
Sales workers	4 (3.4)
Machinery operators and drivers	2 (1.7)
Labourers	1 (0.8)
Students and housewives	6 (5.1)

[a]N varied based on the number of respondents from 123 total participants who answered each question.

Reasons for Interest in the Website

Respondents were asked what made them interested in dementia risk reduction and visiting the website. Table 3 shows the numbers of respondents who selected given reasons. Being worried about their memory or thinking was the most selected reason. Respondents were also asked what they hoped to learn from the website. Table 4 shows the numbers of respondents who selected given topics. What to do to reduce dementia risk was the most selected topic.

Impressions of the Website and Content

Respondents overall impressions of the website were generally positive. Comments indicated that people found the content interesting, useful, and enlightening. For example, a female respondent past 70 years of age wrote,

> *Thank you for providing such a wealth of information on the subject. To have so much info on one site is fantastic.*

However, a few respondents commented that the layout of the site could be made more interesting or that there was too much text. As shown in Table 5, the average rating of interest and appeal for most sections was between 4 (quite interesting) and 5 (very interesting), with a mean rating across sections of 4.07 (SD 0.33). The “MYM” section was rated the highest and the “blog” the lowest.

Respondents found the website easy to navigate. As shown in Table 5, average ratings for ease of navigation for each section were between 4 (somewhat easy) and 5 (very easy), with an average of 4.28 (SD 0.05) across sections. Comments about the navigation suggested that some people, while not finding it difficult, found using the drop down menus to navigate to another page annoying.

Respondents generally reported that the information provided was helpful to them, with ratings for most sections between 4 (quite helpful) and 5 (very helpful), as shown in Table 5, and a mean rating of 4.05 (SD 0.25) across sections. The “about

dementia" section was rated the highest and the "blog" the lowest. Two people who felt they already knew a lot about dementia through having affected family members said that the website was not so helpful to them.

Respondents generally found the information provided easy to read and understand. As shown in Table 5, ease of understanding of website sections was rated between 3 (just right) and 4 (somewhat simplistic), with a mean rating across sections of 3.34 (SD 0.07). As shown in Table 6, ease of understanding of the information provided on specific risk or protective factors was also rated between 3 and 4, with an average rating across factors of 3.39 (SD 0.02). The information on alcohol was rated the closest to "just right" at 3.35. Comments indicated a high degree of satisfaction with understanding the content provided. For example, a female respondent in her 70s wrote, "The website is very good to read and understand specially for the people with English as a second language [*sic*]". However, a male respondent in his 80s felt "the pertinent information is scattered around and not easily readable".

Impact on Dementia Risk Reduction Knowledge

As shown in Figure 2, average ratings of how much respondents knew about the links between specific risk or protective factors and dementia risk before reading the website were between 3 (a little) and 4 (quite a bit) for most factors. The average rating across factors was 3.20 (SD 0.25). Respondents rated their prior knowledge as lowest for diabetes (mean 2.81, SD 1.11) and highest for mental activity (mean 3.66, SD 0.90). Also shown in Figure 2, average ratings of how much respondents knew about the links between specific factors and dementia risk after reading the website were between 4 (quite a bit) and 5 (a lot), with an average rating across factors of 4.32 (SD 0.08). The largest improvement in knowledge was for diabetes (increase in mean rating of 1.41) and the smallest was for mental activity (increase in mean rating of 0.80). All factors showed significantly improved knowledge ($P<.001$) and the average increase in rating across factors was 1.12 (SD 0.02).

On average, respondents rated how much they learned from the website sections between 3 (something) and 4 (a fair bit), as shown in Table 5, with an average rating across sections of 3.75 (SD 0.17). Learning was rated highest for the "Research" section and lowest for the "Blog". Some respondents commented that they had previous knowledge of the topics and so personally did not learn a lot. One female respondent in her 70s commented that she felt "someone with not much knowledge about dementia would learn a fair amount about it", while a male respondent in his 60s felt that "most people will understand that they are actions which should be taken in any case for overall wellbeing".

Table 3. Proportion of respondents who selected the given reasons for their interest in the website (N=116).

Reason	n (%)
I care for someone who has dementia	15 (12.9)
I have a family history of dementia	31 (26.7)
I feel I am getting to the age when dementia could affect me	34 (29.3)
I am worried about my memory or thinking	36 (31.0)
I am worried about someone close to me	22 (19.0)
The website was recommended to me by someone else	33 (28.4)
The information is relevant for my work	12 (10.3)

Table 4. Proportion of respondents who selected the given options for what they hoped to learn from the website (N=116).

Topic	n (%)
How to slow the progress of dementia	61 (52.6)
Whether dementia can be prevented	46 (39.7)
Whether I am at risk of getting dementia	51 (44.0)
Whether someone close to me is at risk of getting dementia	21 (18.1)
How to improve my memory or thinking	72 (62.1)
What to do to reduce the risk of getting dementia	90 (77.6)

Table 5. Mean (SD) ratings for questions asked in relation to website sections.

Section	Overall impression[a]	Easy to understand[b]	Easy to navigate[c]	Helpful information[d]	How much did you learn?[e]
	n=88 mean (SD)	n=86 mean (SD)	n=85 mean (SD)	n=83 mean (SD)	n=84 mean (SD)
Whole website	N/A	N/A	4.23 (0.91)	4.13 (0.82)	3.72 (0.96)
Home page	4.02 (0.78)	3.35 (0.74)	N/A	N/A	N/A
About dementia	4.38 (0.81)	3.36 (0.74)	4.26 (0.86)	4.34 (0.75)	3.81 (0.94)
MYM	4.51 (0.70)	3.33 (0.77)	4.28 (0.85)	4.26 (0.82)	3.84 (0.99)
Resources	4.11 (0.90)	3.26 (0.71)	4.33 (0.81)	4.10 (0.86)	3.83 (0.95)
Health professionals	3.85 (0.92)	3.31 (0.76)	4.26 (0.83)	3.89 (0.98)	3.71 (0.92)
Research	4.21 (0.99)	3.29 (0.80)	4.34 (0.75)	4.05 (0.94)	3.93 (0.91)
Quizzes	4.09 (1.02)	N/A	N/A	N/A	N/A
Blog	3.43 (1.38)	3.47 (0.73)	N/A	3.59 (1.10)	3.41 (1.08)

[a]What is your overall impression of the various sections of the website: how interesting and appealing are they? 1=not at all; 2=not very; 3=somewhat; 4=quite; 5=very (interesting)

[b]Is the information provided in the various sections of the website easy to read and to understand? 1=very complex; 2=somewhat complex; 3=just right; 4=somewhat simplistic; 5=very simplistic

[c]Do you find the website and its sections easy to navigate? 1=very difficult; 2=somewhat difficult; 3=neither easy nor difficult; 4=somewhat easy; 5=very easy

[d]How helpful is the information provided on the MYM website to you? 1=not at all; 2=not very; 3=somewhat; 4=quite; 5=very (helpful)

[e]How much do you feel you learned from the MYM website? 1=nothing at all; 2=not very much; 3=something; 4=a fair bit; 5=a great deal

Table 6. Mean (SD) ratings for questions asked in relation to specific risk or protective factors.

Risk /protective factor	Current behavior[a]	Intention to change[b]	Was information easy to understand?[c]	How well did information equip you?[d]	Are practical tips relevant and useful?[e]
	n=67 mean (SD)	n=67 mean (SD)	n=66 mean (SD)	n=65 mean (SD)	n=65 mean (SD)
Alcohol	4.16 (0.86)	3.75 (1.05)	3.35 (0.73)	4.06 (0.76)	4.03 (1.0)
Blood pressure	4.21 (0.73)	4.08 (1.04)	3.37 (0.78)	3.92 (0.91)	4.20 (0.86)
Body weight	3.77 (0.97)	4.23 (0.86)	3.39 (0.77)	4.00 (0.90)	4.19 (0.77)
Cholesterol	3.85 (0.78)	4.14 (0.98)	3.40 (0.77)	4.11 (0.86)	4.21 (0.86)
Diabetes /blood sugar	4.17 (0.80)	4.03 (1.07)	3.41 (0.79)	4.17 (0.81)	4.15 (0.86)
Diet	3.83 (0.84)	4.18 (0.99)	3.38 (0.76)	4.08 (0.9)	4.20 (0.75)
Head injury	4.38 (0.68)	4.29 (0.76)	3.38 (0.76)	4.10 (0.84)	3.96 (1.02)
Mental activity	4.20 (0.78)	4.26 (0.96)	3.39 (0.78)	4.05 (0.90)	4.31 (0.81)
Physical activity	3.64 (0.95)	4.36 (0.82)	3.41 (0.78)	4.11 (0.87)	4.18 (0.79)
Smoking	4.74 (0.59)	4.47 (0.72)	3.40 (0.77)	3.90 (1.04)	3.63 (1.33)
Social activity	4.02 (0.83)	4.23 (0.83)	3.39 (0.78)	4.05 (0.82)	4.20 (0.86)

[a]How well do you think you are currently doing in relation to the factors listed? 1=very badly; 2=somewhat badly; 3=could do better; 4=pretty well; 5=very well

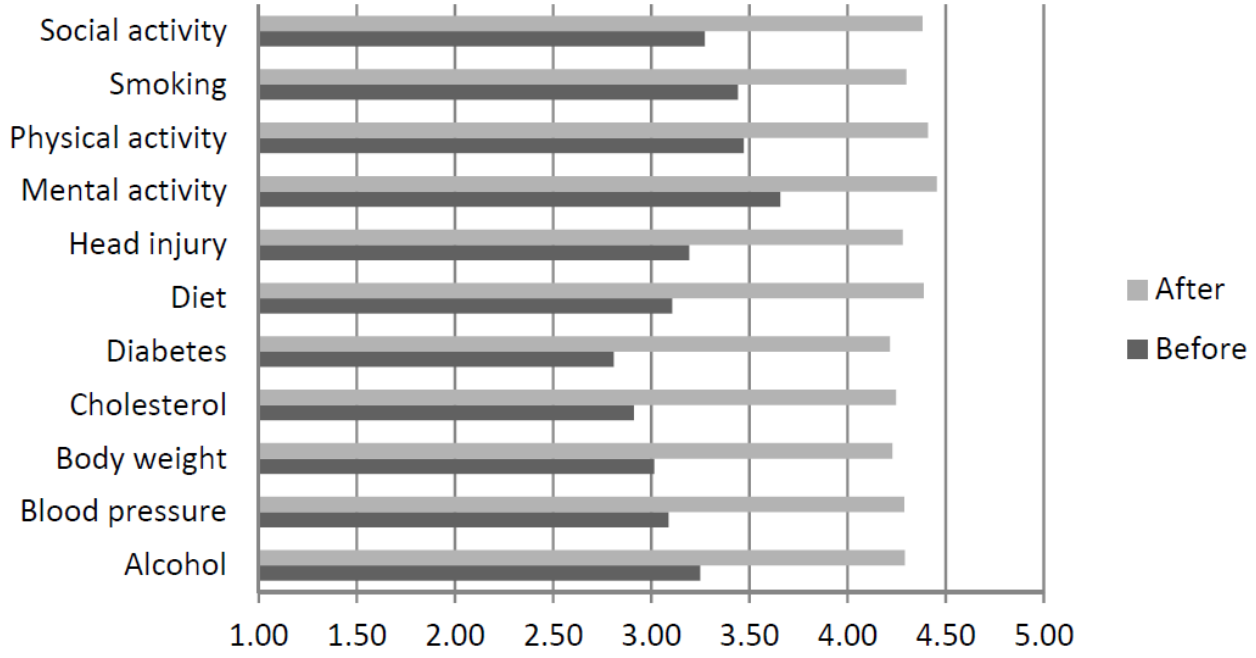
[b]How strong is your intention to make changes to improve what you do in relation to the factors listed? 1=very weak; 2=somewhat weak; 3=considering it; 4=somewhat strong; 5=very strong

[c]How easy to understand was the information provided for each of the factors listed? 1=very complex; 2=somewhat complex; 3=just right; 4=somewhat simplistic; 5=very simplistic

[d]How well did the information provided equip you to improve what you do in relation to the factors listed? 1=not at all; 2=not much; 3=a little; 4=quite well; 5=very well

[e]Are the practical tips, activities, strategies and resources provided for the factors listed generally relevant and useful to you? 1=completely useless; 2=somewhat useless; 3=a little useful; 4=somewhat useful; 5=very useful

Figure 2. Mean ratings of knowledge about the link between risk or protective factors and dementia risk before and after visiting the Mind your Mind website (n=68). Ratings: 1=nothing at all; 2=not much; 3=a little; 4=quite a bit; 5=a lot.



Impact on Dementia Risk Reduction Importance

As shown in Figure 3, average ratings of how important monitoring what they do in relation to specific risk or protective factors was to respondents before reading the website were between 3 (somewhat important) and 4 (quite important). The average rating across factors was 3.35 (SD 0.21). Respondents rated the importance of monitoring what they do as lowest for head injury (mean 3.03, SD 1.34) and highest for physical activity (mean 3.63, SD 1.22). Also shown in Figure 3, average ratings of how important monitoring what they do in relation to specific risk or protective factors was to respondents after reading the website were between 4 (quite important) and 5 (very important), with an average rating across factors of 4.28 (SD 0.15). The largest increase in rating of importance was for diabetes (increase in mean rating of 1.11) and the smallest was for smoking (increase in mean rating of 0.61). All factors except smoking (P=.02) showed significantly increased rating of importance (P<.001) and the average increase in rating across factors was 0.93 (SD 0.13). The information provided overall motivated 54/82 respondents (65.9%) to want to do something about reducing their dementia risk “quite a bit” or “a lot”. The mean rating for motivation was between “a little” and “quite a bit” (mean 3.66, SD 0.88).

Practicality of the Information Provided

The average rating of how well respondents (n=81) felt the information provided equipped them to do something about reducing their risk of dementia was 3.78 (SD 0.89), between “a little” and “quite well”. 56 (69.1%) said the information provided equipped them “quite well” or “very well”. Average ratings of how well the information provided for specific risk or protective factors equipped respondents to improve what they do in relation to the factors are shown in Table 6. Mean ratings were between 4 (quite well) and 5 (very well) for most factors, with an average rating across factors of 4.05 (SD 0.08). The lowest average rating was for smoking and the highest was for diabetes.

As shown in Table 6, respondents rated whether the practical tips, activities, strategies, and resources provided for specific risk or protective factors were generally relevant and useful to them between 4 (somewhat useful) and 5 (very useful) for most factors. The average rating across factors was 4.12 (SD 0.19). The usefulness of the tips for mental activity was rated highest and that for smoking was rated lowest.

Current Behavior

Average ratings for how well respondents felt they were currently doing in relation to specific risk or protective factors were between 3 (could do better) and 4 (pretty well) or 4 and 5 (very well), as shown in Table 6, with an average rating across factors of 4.09 (SD 0.31). Current behavior was rated highest for smoking and lowest for physical activity.

Intention to Change Behavior

Of the 81 respondents, 45 (55.6%) rated their intention to make lifestyle changes to reduce their risk of dementia as 4 (somewhat strong) or 5 (very strong), and 28 (34.6%) rated their intention as 3 (considering it). The mean rating was 3.68 (SD 1.01). Only 22 (27.1%) said their intention to visit their doctor to discuss dementia risk reduction was “somewhat strong” or “very strong”, and a 21 (25.9%) were “considering it”. The mean rating was 2.63 (SD 1.29). Of those who felt they needed to change, respondents on average rated their intention to make changes to improve what they do in relation to specific risk or protective factors between 4 (somewhat strong) and 5 (very strong) for most factors, as shown in Table 6, with a mean rating across factors of 4.18 (SD 0.19). Intention to change was rated lowest for alcohol and highest for smoking.

When asked to specify what changes they intend to make, 35 people provided a response. As shown in Figure 4, the most common intended change was to increase physical activity (23 respondents), followed by improving diet (15 respondents). Only one person said they intended to try to quit smoking, but among those for whom smoking was an issue, intention to change was rated very highly as stated above.

Additional Resources Needed

Respondents rated how helpful they felt 12 suggested resources would be to them, if provided in addition to the information on the website. As shown in Table 7, average ratings were between 3 (somewhat helpful) and 4 (quite helpful) or 4 and 5 (very helpful). An online assessment to identify personal risk factors was rated highest and regular reminders to see a general practitioner was rated lowest. Several respondents commented that an online assessment to determine your individual percentage risk could be confronting, and that assessing and providing information about risk factors was a better approach. Some commented that a personalized dementia risk reduction program would need to involve their doctor. Others commented that regular reminders might be seen as "information overload".

Respondents were asked an open question about what other information, advice, or resources they would like to see on the website and 18 people provided a response. Suggestions included opportunities to volunteer for research, information on local groups and clubs, diet and supplement information, personal stories, and information on other risk factors such as age and drugs. Respondents were also asked what else they needed to help them make changes in relation to specific risk or protective factors. The responses from 18 respondents are summarized in Table 8. Suggestions included fact sheets summarizing the important information and providing more tips to make it easier for people to take up the recommended strategies.

Figure 3. Mean ratings of importantance of monitoring behavior in relation to risk or protective factors before and after visiting the Mind your Mind website (n=67). Ratings: 1=not at all; 2=only mildly; 3=somewhat; 4=quite; 5=very (important).

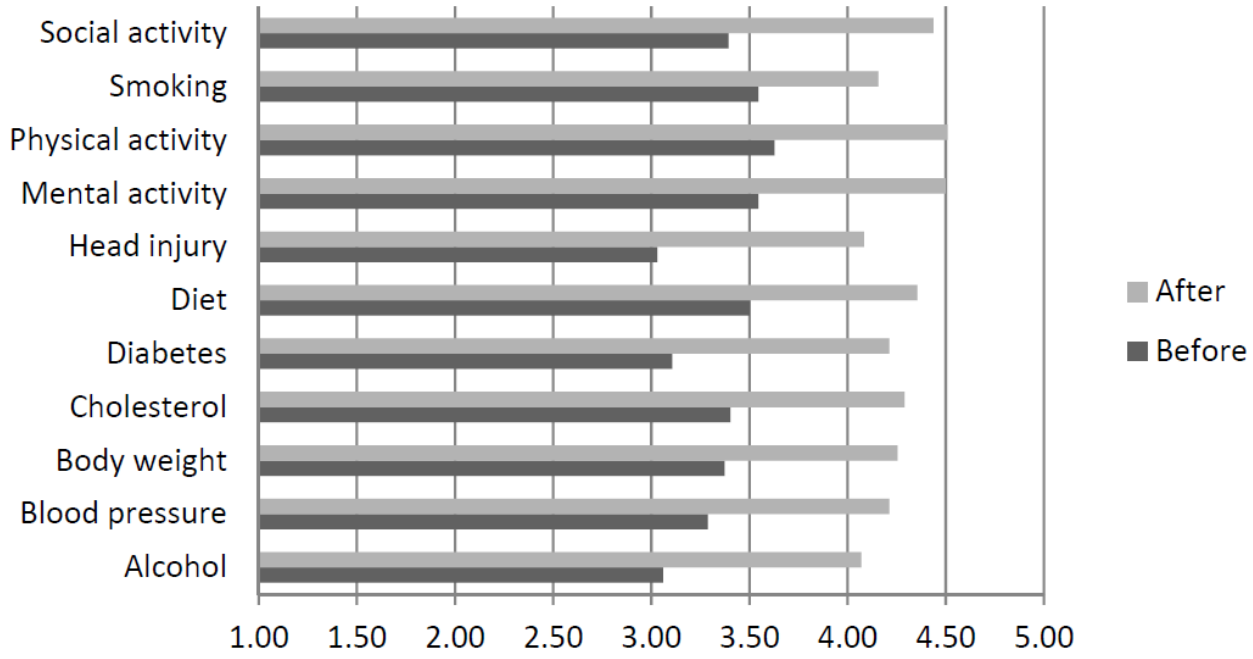


Figure 4. Number of respondents who stated intentions to make improvements in specific areas of behavior.

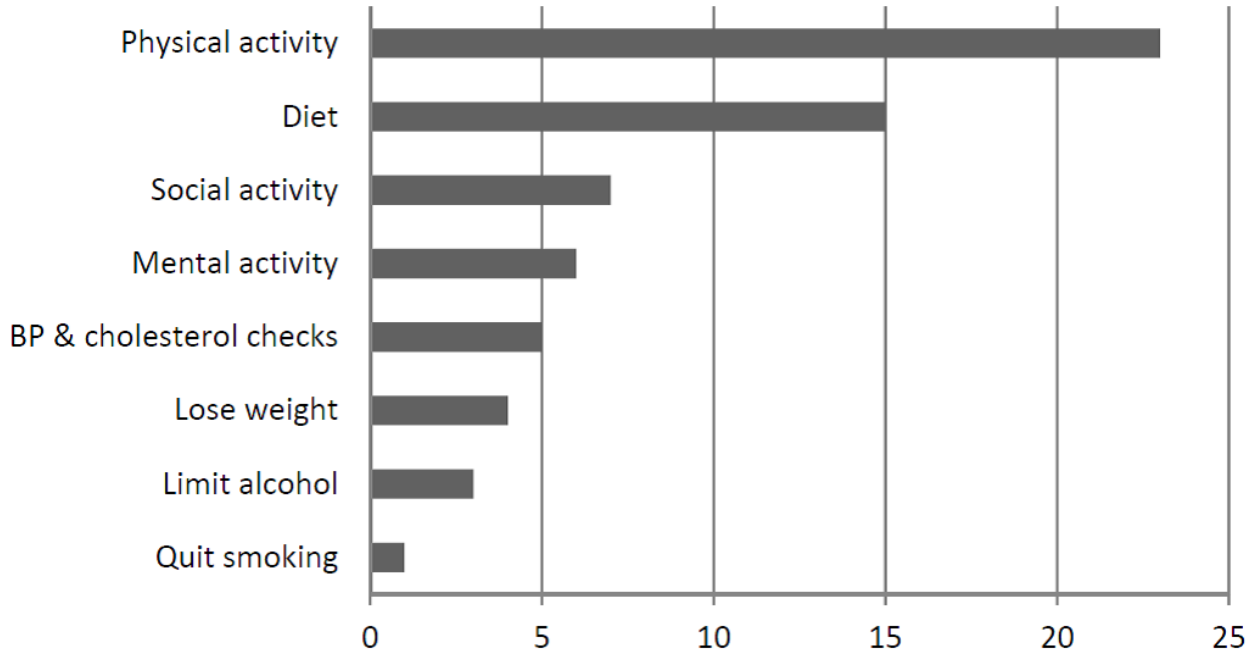


Table 7. Mean (SD) ratings of how useful respondents felt suggested additional resources would be to them (n=65). Ratings: 1=not at all; 2=not very; 3=somewhat; 4=quite; 5=very (helpful).

Potential resource	Mean rating (SD)
An assessment, that you could complete online, to determine your individual risk of developing dementia (eg, a 10% risk).	4.20 (1.01)
An assessment, that you could complete online, to identify your personal risk factors for developing dementia (that is, the things in your life that you could improve).	4.29 (0.80)
One off advice about what you can do to reduce your risk of dementia, based on your assessment, that is tailored to your individual circumstances.	4.19 (0.86)
Personalized dementia risk reduction programs for you to follow over time, based on your assessment and tailored to your individual circumstances.	4.10 (1.07)
Regular reminders and new challenges to help you follow your personalized dementia risk reduction programs.	4.03 (1.08)
The results of your assessment for you to take to your GP to help you discuss dementia risk reduction with them.	4.18 (0.98)
Regular reminders to see your GP to monitor any medical aspects of dementia risk reduction that apply to you.	3.76 (1.28)
General educational sessions about dementia risk reduction that you could attend to learn more, discuss issues and ask questions.	3.80 (1.16)
Activities or workshops to learn practical dementia risk reduction strategies (eg, healthy cooking, memory strategies, exercises).	3.81 (1.22)
Regular general updates, not personalized, such as a newsletter.	3.77 (1.05)
Regular updates on the latest dementia risk reduction research.	4.06 (0.97)
Information about services in your local area that you could utilize to help you do more dementia risk reduction activities.	4.06 (1.03)

Table 8. Selected responses to the open question "What else do you think you need to help you to make changes to improve what you do in relation to the factors listed? Are there any particular resources, facilities, information, services, etc, that you think would help you?"

Risk or protective factor	Suggested resources
Alcohol	Safe level of consumption
	Minimum consumption
Blood pressure	Fact sheet on lowering BP
	What range of BP is healthy
Cholesterol	List of foods with cholesterol ratings
	Checks by nurse at health center
Diet	List of foods with salt, sugar, etc ratings
	Recipes
	Diet plan
Mental activity	Brain exercises
	Information on different types of mental activity
Physical activity	Tips to make it easy to exercise
Social activity	Tips to make it easy to socialize

Discussion

Major Findings

This study aimed to evaluate users' perceptions of a website providing information and resources related to health and lifestyle factors associated with the risk of developing dementia. An online survey revealed that the MYM website was viewed as being helpful and the majority of respondents perceived the website content to be interesting, informative, easy to understand, and useful.

The "MYM" and "About Dementia" sections were rated as the most interesting and helpful, suggesting visitors to the website were most interested in information about reducing dementia risk. This was supported by the finding that the most selected reasons given for visiting the website were concerns about memory or thinking and wanting to know what to do to reduce dementia risk. A recent Australian community survey found that the fear of developing dementia was second only to the fear of having cancer [33]. The fear increased with age, with 75% of people over 60 agreeing that they are afraid of developing dementia [33]. These findings suggest that there is much community interest in understanding what individuals can do to reduce their risk of dementia.

A study investigating the preferences of potential users of websites providing physical activity interventions found that ease of use was considered essential to the design of an appealing website [34]. Respondents found the MYM website easy to navigate and the content easy to understand. Ratings for how easy to understand the content was averaged between "just right" and "somewhat simplistic", suggesting the site achieved the aim of providing complex information in simple, easy to understand user-friendly terms. Respondents also had no difficulty with navigation, suggesting the layout of information was appropriate to most users' needs.

One of the principal aims of the MYM website was to improve knowledge about dementia risk factors and what individuals can do to reduce their risk. Respondents' ratings of their knowledge about the links between given risk or protective factors and dementia risk significantly increased after visiting the website for all factors. Prior knowledge was rated highest for mental activity and physical activity, and lowest for diabetes and cholesterol. This was consistent with previous community survey findings that there was some awareness of the links between mental stimulation and dementia risk reduction, and physical health and dementia risk reduction, but there was very little awareness of the association with cardiovascular risk factors [21]. Encouragingly, knowledge about diabetes and cholesterol improved the most after visiting the website. Respondents' subjective impression of how much they learned from the website was also encouraging, with an average rating approaching learned "a fair bit".

Another principal aim of the MYM website was to promote behavior change by providing users with information and resources to assist them to adopt lifestyle and health strategies that may reduce their dementia risk. In this cross-sectional study, we did not measure actual behavior change, but assessed perceived importance of monitoring behavior and intentions to change behavior. Respondents' ratings of how important to them monitoring what they do in relation to given risk or protective factors significantly increased after visiting the website for all factors except smoking. The smaller increase in importance for smoking was likely due to very few respondents being smokers (the highest average rating for how well respondents were currently doing in relation to risk or protective factors was for smoking).

The majority of respondents rated how much the information provided overall motivated them to do something about reducing their dementia risk as "quite a bit" or "a lot", suggesting the website content was able to encourage users to consider behavior change. This was also supported by the finding that 73/81 (90.2%) respondents rated their intention to make lifestyle changes as "very strong", "somewhat strong", or "considering it'. Of course, intentions do not always translate into actions and it is well recognized that raising awareness and motivation are only part of the process of behavior change. Only 43/81

(53.1%) respondents rated their intention to visit their doctor as “very strong”, “somewhat strong”, or “considering it’. This may suggest that people do not see medical support in this area as important. The older age group making up the majority of respondents may already be having the recommended regular checks of cardiovascular risk factors, and therefore do not see the necessity to visit to the doctor another time.

Among those who felt they needed to change, the highest rating for intention to change was for smoking, followed by physical activity. There are many public messages about the dangers of smoking. Perhaps the association with increased dementia risk could help motivate smokers to try to quit. Physical activity is an issue many people think about given its prominence in public health messages and the media. More people specified increasing physical activity as a change they intended to make than any other factor.

The personal relevance and applicability of Web-based health information has previously been shown to be important to users [35,36]. On average, respondents rated whether the practical advice and resources provided for specific risk or protective factors were relevant and useful to them between “somewhat useful” and “very useful” for most factors, suggesting they did see the information as applicable to them as individuals. Mental activity was rated highest, suggesting users saw the tips for being more mentally active as particularly relevant to them. Smoking was rated lowest, likely due to few respondents being smokers. Respondents also on average rated the information provided in sections of the website to be helpful to them.

Potential additional resources that might help people to adopt the healthy behaviors recommended on the MYM website were suggested, and respondents were asked to rate how helpful these would be to them. The high ratings given suggested that respondents’ motivation to address their health related to dementia risk was high, and that in general people were looking for practical resources to assist them. Personalized assessments of their risk factors, tailored advice to address risk factors, and assessment results to take to their doctor were rated highest. Previous studies have similarly found that health website users would like to see more interactivity and more specific practical information that tells them exactly what they need to do, making it easy for them to adopt healthier behaviors [26].

Survey respondents were predominantly female and well-educated, consistent with findings that these demographic characteristics were associated with more frequent health-related Internet use [25,27,37,38]. Respondents were also predominantly older, with 86/122 (70.5%) aged over 50 and 55/122 (45.1%) aged over 60. This was likely related to community survey findings which suggested that more people over age 50 worry about developing dementia [33], and to the most selected reasons for interest in the MYM website being related to concerns about dementia. Nevertheless, this self-selected sample limits the generalizability of the findings to other sectors of the community, younger people and males in particular. Perhaps future research and development of Web-based health resources could address promotion strategies aimed specifically at men [27,39].

Respondents rated their current healthy behavior related to the risk or protective factors on average as doing “pretty well”, suggesting the people most likely to access the MYM website and respond to the survey felt that they were already leading a healthy life. This was consistent with previous findings and suggests that another important target group for future Web-based health interventions is those with weak health motivation [27,39]. While people who are more committed to a healthy lifestyle are more likely to seek and use Web-based health information, it is important to reach those who could benefit the most from these Internet interventions, that is, those who engage in unhealthy risk behaviors. However, as people will pursue information sources in relation to their own interests and needs, this is not straightforward.

Limitations and Future Studies

Generalizability of the findings from the current study to the general community was limited by the use of a self-selected sample, and a lack of data on visitors to the website who did not complete the survey. Because an opt-in survey was used, it was not possible to calculate a response rate for the survey or to determine any demographic differences between survey respondents and visitors who did not participate in the survey. While the resulting sample size was modest, the study was able to detect significant positive effects of visiting the MYM website.

A further limitation of the current study was that knowledge about risk or protective factors for dementia and the importance ascribed to them were not assessed before participants viewed the website. Their subjective report of prior knowledge and importance were assessed with the survey after they had read the website. The study was also unable to measure whether participants actually made lifestyle changes. Nevertheless, respondents’ felt their knowledge had increased, as had the importance they ascribed to monitoring their health-related behavior.

Further longitudinal studies are required to better assess knowledge prior to exposure to the MYM information, and any lifestyle modifications after exposure. Future research should also examine whether the beneficial effects of providing dementia risk reduction information can be enhanced by also providing interactive and personalized Web-based features. Enhancements to the MYM website are in development which will include the ability for users to assess their dementia risk and be provided with tailored advice and resources. Research is also underway to evaluate whether such an interactive program results in better health outcomes for users than an information website alone. This ongoing research program aims to inform future developments of dementia prevention initiatives for Australia [9].

Conclusions

This study has demonstrated that a dementia risk reduction website successfully increased users’ knowledge and the importance they attributed to monitoring their health behavior. Positive ratings of the website content suggest it was relevant to users and presented in a manner they easily understood. Users felt well-equipped to improve their behavior and found the

practical tips provided useful. They also felt that suggested additional resources would be helpful, such as interactive and personalized resources on the website to further engage people to enable behavior change. These findings will inform future developments of the MYM program and website.

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Conflicts of Interest

The author is an employee of Alzheimer's Australia, the trademark and copyright owner of Mind your Mind and the Mind your Mind website.

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Abbreviations

MYM: Mind your Mind

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Original Paper

Evaluation of Active Transition, a Website-Delivered Physical Activity Intervention for University Students: Pilot Study

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Abstract

Background: While physical activity in individuals tends to decline steadily with age, there are certain periods where this decline occurs more rapidly, such as during early adulthood. Interventions aimed at attenuating the declines in physical activity during this transition period appear warranted.

Objective: The purpose of the study was to test the feasibility and efficacy of a theoretically informed, website-delivered physical activity intervention aimed at students entering university.

Methods: Using a quasi-experimental design, 65 participants (44 females; mean age 18.51, SD 0.91) were assigned to either an intervention (receiving website access plus weekly prompts) or comparison condition (receiving unprompted website access only), completing questionnaires at baseline and follow-up 8 weeks later. The intervention website, “Active Transition”, was specifically designed to target students’ physical activity cognitions and self-regulatory skills.

Results: Intervention usage was low, with only 47% (18/38) of participants assigned to the intervention condition logging into the website 2 or more times. Among the broader student sample, there were significant declines in students’ physical activity behaviors ($F_{1,63}$=18.10, P<.001), attitudes ($F_{1,62}$=55.19, P<.001), and perceived behavioral control ($F_{1,62}$ =17.56, P<.001). In comparisons between intervention users (29/65, individuals logging in 2 or more times) and non-users (36/65, individuals logging in once or not at all), there was a significant interaction effect for intervention usage and time on perceived behavioral control ($F_{1,62}$=5.13, P=.03).

Conclusions: Poor intervention usage suggests that future efforts need to incorporate innovative strategies to increase intervention uptake and better engage the student population. The findings, however, suggest that a website-delivered intervention aimed at this critical life stage may have positive impact on students’ physical activity cognitions. Future studies with more rigorous sampling designs are required.

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KEYWORDS

physical activity; efficacy trial; Internet-based intervention; university students

Introduction

Despite many known health benefits of physical activity, the majority of the Western world does not accrue recommended amounts of moderate-to-vigorous physical activity (MVPA) [1,2]. Given that physical inactivity is a pervasive problem across the general population, concerted efforts are required to develop interventions aimed at specific life stages [3,4]. While most research has focused on increasing participation, little work has been aimed at preventing physical activity declines. Trends across the lifespan show children and youth being the most active segment in the population; however, accelerated erosions in physical activity are evident as this youth population moves toward early adulthood [5,6]. More recently, a number of studies have found the transition from high school to college/university being a period in which young adults are particularly susceptible to significant declines in physical activity [7-9]. Approximately one-third of the young adults that were sufficiently active during high school, become insufficiently active during their first year at university [8]. These declines in physical activity might be largely unexpected as most students enter university with positive attitudes toward physical activity and strong intentions to be active [9,10]. Given that there is potential for exposing university students to sustained health messaging through already established knowledge exchange methods and messengers, and subsidized physical activity facilities, programs, and staffing, the post-secondary environment should be an ideal setting of intervention to attenuate declines in physical activity in contrast to interventions seeking to increase physical activity.

Few attempts, however, have been made to address population-specific perturbations in social (eg, peer influence) and environmental (eg, moving away from home) conditions. To the best of our knowledge, only one intervention study has explicitly targeted students' transition into college and university. Bray and colleagues [11] developed a tailored physical activity guide targeting students entering first year college and university, and the results of the intervention were positive. Compared to students who were given a standard physical activity guide or no guide, those receiving a tailored activity guide were engaging in significantly more MVPA per week during the 6-week intervention period. The caveat, however, was that students who received the tailored activity guide still exhibited significant declines in physical activity upon entry into university. This suggested that further effort is required to develop effective interventions for this population. In particular, although print-based material is low in cost and easy to mass distribute, the Internet is becoming increasingly popular for health behavior change interventions [12-14], and although its effectiveness has varied [15], it is advantageous as information can be delivered in real time and accessed by users at their convenience. Intuitively, the Internet would be an appropriate platform within the context of the university setting. Recent research also provided empirical support, as the Internet is the most frequently used source from which university students gain health-related information [16], and the Internet has been identified as the preferred delivery vehicle for any potential physical activity intervention [10]. The purpose of this investigation was to pilot the feasibility and efficacy of a theoretically informed, website-delivered physical activity intervention called "Active Transition". Specifically, the intervention aimed at attenuating the declines in physical activity behaviors among students as they transition into university.

Methods

Selection and Recruitment of Participants

The current study was a quasi-experimental trial using stratified cluster randomization to recruit participants. A total of 4 floors in residence were asked to take part in this pilot study. There were 2 campus residence buildings that participated, each having 1 floor randomly (by toss of a coin) assigned to the intervention condition, and 1 floor selected to the comparison condition. Early in the fall semester, 198 eligible students living on the selected floors were invited to participate. Written consent was obtained from 146 potential participants. These students were sent a link to the baseline questionnaire, which included measures of demographic characteristics, psychosocial variables of attitudes, subjective norms, perceived behavioral control and intentions, and physical activity behaviors. Baseline data was obtained from 91 (59 female) students, with most students in their first year of study. Following the pilot 6-week intervention (described in detail below), participants that completed the baseline questionnaire were sent a link to a follow-up questionnaire with the same measures of physical activity cognitions and behavior. Further attrition resulted in a final sample of 65 students (44 female; mean age 18.51, SD 0.92) completing both baseline and follow-up questionnaires. The study protocol was approved by the Research Ethics Board at the University of Toronto.

Study Conditions

For pragmatic reasons, and given the pilot nature of the study, a true control group was not included. A minimal-contact condition or comparison condition was used instead, where students were provided access to, but were not prompted to use, the intervention website. Given that the effectiveness of Internet-based interventions are greatly enhanced with the use of additional methods of participant interactions such as email messages [14], participants in the intervention condition were sent weekly emails prompting students to access the intervention website. The emails provided participants with a synopsis highlighting a weekly intervention topic for each of the 6 weeks. For instance, the topic for week 2 of the intervention was focused on the many student-specific benefits of maintaining a physically active lifestyle. To illustrate, students were sent the following email:

> *Hope you're having a great week… Did you know? Being physically active can help you obtain better grades. Physical activity can also give you more energy, allow you to concentrate better, and get you a better night's rest! Find out more about how physical activity can help you with your studies and more.*

An external link accompanied the email message that linked participants to the website with more details about the student-specific benefits of being physically active.

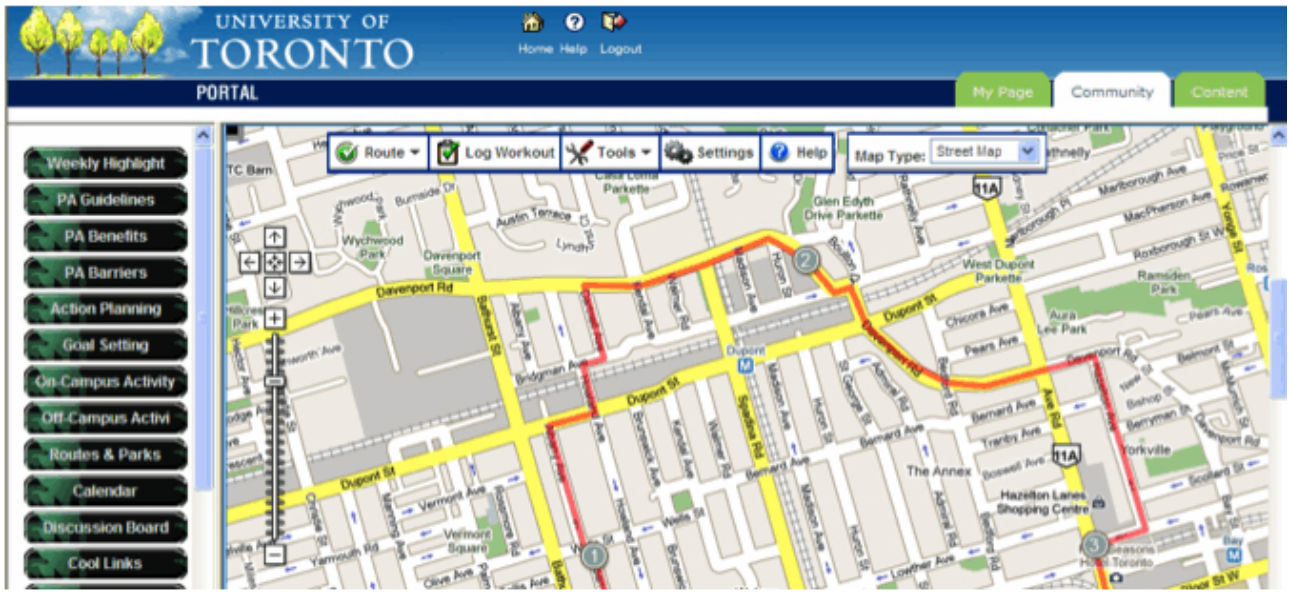
Active Transition

Hosted within a university portal (Blackboard), Active Transition was a password-controlled website developed to be an informational forum specifically targeting psychosocial mediating variables based on Ajzen's [17] theory of planned behavior (TPB), and educating students around self-regulating/self-monitoring techniques. Findings from a recent review reported that Web-based TPB interventions are more effective than other theory-based interventions (eg, social cognitive theory, transtheoretical model) [14], and that control theory techniques (eg, goal setting, action planning) are most effective for changing physical activity behaviors [18]. Designed to be 6 weeks in length, Active Transition was a passive intervention, delivering weekly topics on behavioral, normative, control beliefs in physical activity, as well as goal-setting, action planning, relapse prevention, and behavioral maintenance.

The first 2 weeks of the intervention targeted students' motivation (ie, attitudes, perceptions of control), including student-specific benefits of being physically active (eg, improving concentration, helping with social life), and coping strategies to deal with salient barriers that students typically face during their transition into university. In an attempt to bridge the gap between students' intentions and subsequent behaviors [9], topics for week 3 and 4 focused on behavioral modification techniques. The intervention material included information on how to effectively set goals, as well as providing sample schedules of how to action plan (Figure 1). Action planning and goal setting are two strategies that have been found to be effective in translating people's intention into behaviors [19,20]. The topics for the final 2 weeks of the intervention focused on relapse prevention and behavioral maintenance, encouraging students to maintain behaviors despite the normal disruptions that occur while at university. In addition to the highlighted topics, the website included additional resources for students, including a discussion board to facilitate social networking (eg, finding other people with similar interests), links to available leagues and facilities on or nearby campus, mapped out running/biking routes (Figure 2), as well as the opportunity to contact a physical activity expert. Prior to the intervention, Active Transition was pre-tested with students and physical activity experts. A few minor changes were made regarding the text and material; however, there was consensus that the intervention was both acceptable and user-friendly [21].

Figure 1. Screenshot of the intervention topic on action planning.

Figure 2. Screenshot of running map as example of intervention resources.



Measures

Moderate-to-Vigorous Activity

MVPA was measured using the 2003 Behavior Risk Factor Surveillance System (BRFSS; CDC, 2003 [22]). Participants reported the *average number of sessions* as well as the *average duration* of both moderate and vigorous physical activity engaged in per week. Example questions used to collect this information included (1) in a usual week, how many days do you do vigorous activities (such as running, aerobics, hockey, squash) for at least 10 minutes at a time that cause large increases in breathing or heart rate? and (2) On days that you do vigorous activities for at least 10 minutes at a time, how much total time per day do you spend doing these activities? MVPA was computed by adding the products of the average weekly frequency and duration for both moderate and vigorous intensity activities. Consistent with previous research on students' transition into university [8,9], an 8-month recall was used to capture average MVPA prior to the intervention and 6-week recall was used at the follow-up measure to capture average MVPA during the intervention period.

Physical Activity Cognitions

Social cognitive variables comprised of TPB measures that were developed and used in a previous study [9,23]. For the purposes of clarity and consistency, each measure used the common reference of being "physically active" (defined as engaging in MVPA on most days of the week for at least 30 minutes per day). Multi-item measures were summed and averaged; reliability of scales were all within acceptable range (alpha=.76 to .91).

Attitudes

Rated on a 7-point Likert scale, 6 items were used to measure attitudes. Two items captured the instrumental component (ie, being physically active is harmful/beneficial and useless/useful), 3 represented the experiential component (ie, enjoyable/unenjoyable, pleasant/unpleasant, and fun/boring), and a good-bad scale.

Subjective Norms

A single item was used to reflect subjective norms, asking: important people to me think I should be physically active. Participants were required to rate each item on a 7-point Likert scale (1= strongly disagree, 7= strongly agree).

Perceived Behavioral Control

To measure PBC, 6 items were used. Three questions assessed controllability and 3 questions assessed self-efficacy. For example, questions pertaining to controllability included, "how much control do you have to be physically active?" (1=extreme lack of control, 7=extreme control), and questions assessing self-efficacy included, "how confident are you that you can be physically active?" (1=extremely unconfident, 7=extremely confident).

Physical Activity Intentions

Three items were used to measure participants' intentions to be physically active (1=strongly disagree, 7=strongly agree), asking, "I intend, I will try, and it is my desire to be physically active".

Results

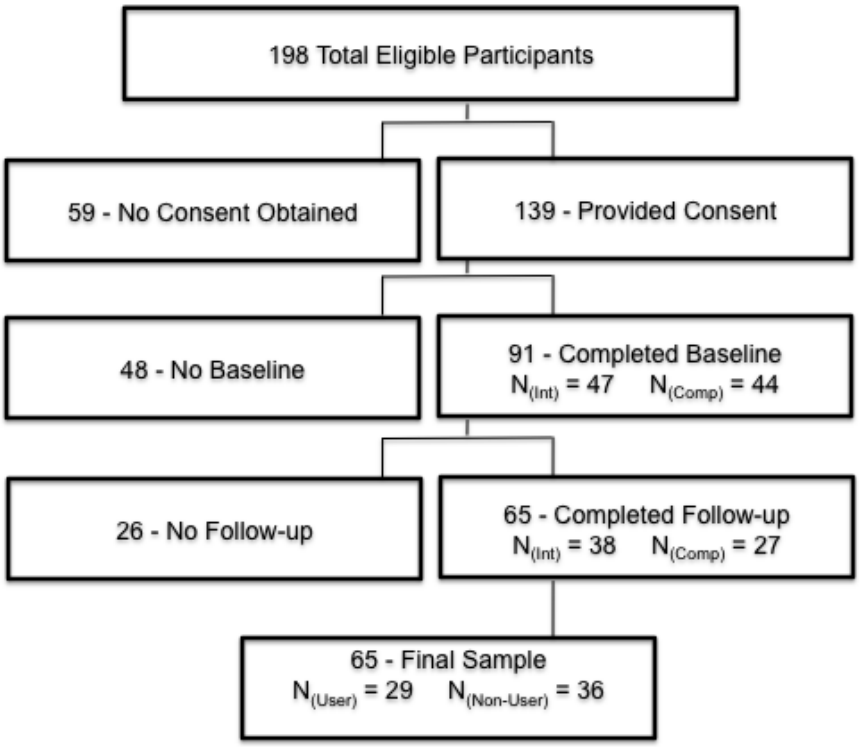
Process Evaluation

To examine the feasibility of the website-delivered intervention, study compliance was first examined. Among a total of 198 eligible participants living in the selected residences, 65 of the students completed both baseline and follow-up questionnaires. Initially, 74% (139/198) of all the eligible students had provided written consent, expressing interest in the physical activity intervention and participating in the study. Baseline data, however, was obtained from only 91 (59 females) of those students, representing a 62% response rate; and of the 91 participants that completed the baseline questionnaire, 65 completed the follow-up questionnaire (44 females), representing a 71% (65/91) retention rate. One-way ANOVAs revealed no significant differences between adherers and

dropouts for baseline physical activity levels ($F_{1,89}$=1.67, P=.17), or on any of the physical activity cognition measures (P's >.05); thus the final sample of 65 participants was available for subsequent analyses. A comprehensive breakdown of participant responses is shown in Figure 3.

To determine the level of engagement that participants had with the intervention, usage data (the number of times participants logged into the intervention website) was also examined. Importantly, it uncovered that 41% of the participants assigned to the comparison condition were actually users of the intervention (11/27, defined as logging into the website 2 or more times), and 53% in the intervention condition were non-users (20/38, defined as logging in once or not at all). More broadly, usage results indicated that compliance to the intervention was low, with only 6% of participants (4/65) entering the website on an average of one time per week (ie, 6 or more occasions), and only 45% of participants (29/65) logging onto the intervention website on more than 2 occasions. Similarly there were only 5 participants that used the discussion board during the intervention period, and only 1 student had contacted the physical activity expert. Given that this was a pilot study that resulted in unexpected usage within both study conditions, subsequent comparisons in physical activity cognitions and behaviors are made between intervention users (29/65) and intervention non-users (36/65).

Figure 3. Detailed breakdown of participant recruitment.



Changes in Physical Activity Cognitions and Behaviors

The descriptive statistics showing mean scores (SD) for the users and non-users at baseline and follow-up are presented in Table 1. Results of an initial one-way ANOVA found no significant differences in baseline MVPA between users and non-users of the intervention $F_{1,63}$=0.13, P=.72). Differences between groups and over time for each of the measured variables were evaluated using the following equation: 2 (time: baseline/follow-up) X 2 (usage: user/non-user), with repeated measures ANOVAs treating the first factor as a within-subjects variable and the second factor as a between subjects variable. Results revealed significant main effects for time, in MVPA ($F_{1,63}$=18.1, P<.001, η_p^2=.22), attitudes ($F_{1,62}$ =55.19, P<.001, η_p^2=.47), and perceived behavioral control ($F_{1,62}$=17.56, P<.001), η_p^2= .22). The main effect of time for intentions ($F_{1,62}$=2.91, P=.08, η_p^2=.06) also approached significance. Main effects for usage conditions were all non-significant (P's>.05).

A significant interaction effect was observed between usage and time on perceived behavioral control ($F_{1,62}$ =5.13, P=.03, η_p^2=.08), indicating that intervention users maintained higher levels of perceived control over time, while steeper declines in these perceptions occurred among non-users from baseline to follow-up. While the interaction effects were non-significant

between usage and time on attitudes ($F_{1,62}$=2.02, P=.16, η_p^2=.03) and usage and time on intentions ($F_{1,62}$=1.97, P=.16, η_p^2=.03), mean scores suggest that intervention users were also able to better maintain positive attitudes and higher physical activity intentions while non-users showed greater negative changes in these perceptions over time. The interaction effect between intervention usage and time on physical activity ($F_{1,63}$=1.54, P=.22, η_p^2=.03) was not significant. Additional analyses, however, uncovered significant differences in the proportion of students exhibiting declines in their MVPA during the intervention period comparing intervention users and non-users (χ^2_1=6.11, P=.01, Cohen's d=.64). The results found fewer intervention users (15/29, 48%) declined in their MVPA scores from baseline to follow-up compared to non-users (8/36, 78%). Findings did not differ when intention-to-treat analyses were conducted, treating dropouts as non-users.

Table 1. Descriptive statistics of physical activity behaviors and cognitions by study condition.

Variables	Full sample N=65 Mean (SD)	Study conditions	
		Intervention users[a] n=29 Mean (SD)	Non-users[b] n=36 Mean (SD)
Baseline			
MVPA	595.00 (424.41)	594.47 (443.49)	595.74 (404.34)
Attitude	5.52 (0.93)	5.52 (0.84)	5.52 (1.01)
Subjective norm	5.25 (1.59)	5.24 (1.38)	5.25 (1.52)
PBC	5.44 (0.96)	5.46 (0.86)	5.43 (1.04)
Intentions	6.01 (0.96)	5.99 (0.86)	6.03 (1.04)
Follow-up			
MVPA	366.96 (341.35)	393.47 (352.18)	329.63 (328.37)
Attitude	4.39 (0.86)	4.63 (0.69)	4.18 (0.94)
Subjective norm	5.38 (1.68)	5.21 (1.38)	5.25 (1.76)
PBC	4.90 (1.10)	5.21 (0.71)	4.63 (1.30)
Intentions	5.79 (1.28)	5.94 (0.77)	5.66 (1.59)
Barriers self-efficacy	5.49 (2.52)	5.61 (2.65)	5.32 (2.38)

[a]Intervention users were participants in the intervention condition that logged in 2 or more times

[b]Non-users were participants in the comparison condition that logged in 1 or less times.

Discussion

Principal Findings and Further Research

Overall, the results of this pilot study were largely mixed. Positive results found 75% (139/198) of the students living in the selected residences had initially expressed interest in the study (ie, being a part of a physical activity intervention), and that implementation of the website-delivered physical activity intervention on campus is feasible and of interest to students. Participant engagement, however, was highly problematic, as response, retention, and compliance rates were all low. In particular, it was alarming that only 45% (14/38) of the participants in the intervention condition were considered users of the intervention, despite a liberal categorization of usage (ie, considered users if logged in 2 or more times over 6 weeks). At minimum, participants should have been accessing the intervention on a weekly basis. The low usage appears consistent with the notion that students may be generally ambivalent about their physical activity levels [10]. However, with intervention usage, there is some evidence that Active Transition may be helpful in attenuating some declines in students' physical activity cognitions and behaviors.

Adherence to intervention protocols is essential for physical activity interventions to be successful [24], and our results clearly demonstrated the need to identify innovative strategies to both engage participants and maintain their interest over the duration of the intervention. The development of Active Transition was constrained by limited financial resources. With adequate funding, future interventions with appropriate resourcing should incorporate other Internet-based tools, such as social media, social networking, and/or enhanced visual prompts (ie, video-messaging), and increase participant interaction (eg, providing students with immediate feedback) [25,26]. In an effort to better engage the student population, Active Transition for example, can be augmented to incorporate elements of social media (ie, Facebook, Twitter), and/or integrate the use of short message service (SMS) and photo/video text messaging. There is empirical evidence to suggest that intervention effects are markedly improved if it is theory-based and integrated with personalized contact [13,14]. Given that technology has profoundly changed the way information is being delivered, and how people connect with one another, it appears imperative that attempts are made to integrate these emerging technologies with intervention efforts

aimed at behavior change. However, it may also be necessary to first better understand what appeals to students, and how they would want technological tools incorporated to help them facilitate greater physical activity participation.

Consistent with the research literature [7-9], there were significant declines in MPVA among the university students between baseline and follow-up, both for intervention users and non-users. Despite a non-significant interaction between average MPVA and usage, a significantly greater proportion of intervention users were able to maintain or even increase their physical activity behaviors. It is noteworthy that users of the intervention reported engaging in 30 minutes of MVPA more each week during the 6-week intervention period, and if maintained over time, this could have some clinical significance. One plausible reason, however, for why the intervention did not have a statistically significant interaction effect on the mean physical activity scores is because Active Transition specifically targeted MVPA declines through psychosocial mediators (ie, TPB variables). MacKinnon [27] suggested that if the intervention is specifically developed to target social cognition variables, it is very likely that there would be a delayed effect on the behavioral outcome. In other words, the length of the intervention may have been too short to see meaningful differences in behavior. It is necessary to ensure that future implementation of the intervention targets these proposed mediators with a higher fidelity [28].

Findings from this pilot also uncovered substantial decreases in students' attitudes, perception of control, and physical activity intentions over the course of the first semester. Given that most participants were first-year students, decreases in physical activity cognitions may be a direct reflection of the adaptations required for students entering a new environment, consisting of more barriers to physical activity compared to at high school [10,29], entering a volatile period requiring constant changes and corresponding adjustments. There was evidence to suggest that intervention users were better able to maintain their perceptions of control. Maintaining strong perceived control and intentions towards activity is critical, as they are considered to be the most proximal determinants of behavior [16]. Larger efficacy trials are needed to determine the extent to which perceptions of control are maintained over the course of a calendar year at university. Future work is also required to replicate these findings, and to determine whether the attenuations in students' physical activity cognitions can lead to significant attenuations in the declines in physical activity typically seen during students' transition into university.

Study Limitations

There are several important limitations to acknowledge. First, a self-report measure was used to assess physical activity, and such measures are susceptible to recall errors and social desirability bias. Second, the study was limited by a small sample size. Given that the purpose of the study was to pilot the feasibility and efficacy of a newly developed intervention, power calculations were not conducted a priori. However, a post-hoc power calculation was conducted, confirming that we were indeed underpowered ($1\text{-}ß_{err\ prob}=0.69$). To be sufficiently powered, the sample size would require 43 participants in each group. Third, the study design excluded a true control group, resulting in unanticipated usage for some participants initially assigned to the comparison condition. Lastly, it should be acknowledged that the study design had a relatively short follow-up period. Without a subsequent follow-up, it is unknown whether the declines in physical activity cognitions are sustained throughout the academic year.

Conclusions

Notwithstanding the notable limitations, this was the first theory-based website-delivered physical activity intervention aimed at students entering university. Although the institutional portal provided a platform for Active Transition that was potentially advantageous in terms of student access (eg, approximately 70,000 students have access to it at this institution), and its high potential for adoption and diffusion by other colleges or universities, there were major issues with low usage of the intervention. Future work must better target student engagement. Modifications to future interventions should utilize and incorporate other technological and interactive tools that motivate students to continually engage with the intervention. Physical activity decline continues to be problematic during students' transition into early adulthood, and research must continue to develop innovative strategies for encouraging students to maintain a physically active lifestyle that can be sustained through university and beyond.

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Conflicts of Interest

None declared.

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Abbreviations

BRFSS: Behavior Risk Factor Surveillance System
MVPA: moderate-to-vigorous physical activity
SMS: short message service
TPB: theory of planned behavior

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Original Paper

Mobile Emergency, an Emergency Support System for Hospitals in Mobile Devices: Pilot Study

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Abstract

Background: Hospitals are vulnerable to natural disasters, man-made disasters, and mass causalities events. Within a short time, hospitals must provide care to large numbers of casualties in any damaged infrastructure, despite great personnel risk, inadequate communications, and limited resources. Communications are one of the most common challenges and drawbacks during in-hospital emergencies. Emergency difficulties in communicating with personnel and other agencies are mentioned in literature. At the moment of emergency inception and in the earliest emergency phases, the data regarding the true nature of the incidents are often inaccurate. The real needs and conditions are not yet clear, hospital personnel are neither efficiently coordinated nor informed on the real available resources. Information and communication technology solutions in health care turned out to have a great positive impact both on daily working practice and situations.

Objective: The objective of this paper was to find a solution that addresses the aspects of communicating among medical personnel, formalizing the modalities and protocols and the information to guide the medical personnel during emergency conditions with a support of a Central Station (command center) to cope with emergency management and best practice network to produce and distribute intelligent content made available in the mobile devices of the medical personnel. The aim was to reduce the time needed to react and to cope with emergency organization, while facilitating communications.

Methods: The solution has been realized by formalizing the scenarios, extracting, and identifying the requirements by using formal methods based on unified modeling language (UML). The system and was developed using mobile programming under iOS Apple and PHP: Hypertext Preprocessor My Structured Query Language (PHP MySQL). Formal questionnaires and time sheets were used for testing and validation, and a control group was used in order to estimate the reduction of time needed to cope with emergency cases. First, we have tested the usability and the functionalities of the solution proposed, then a real trial was performed to assess the reduction in communication time and the efficiency of the solution with respect to a case without Mobile Emergency tools.

Results: The solution was based on the development of a mobile emergency application and corresponding server device to cope with emergencies and facilitate all the related activities and communications, such as marking the position, contacting people, and recovering the exits information. The solution has been successfully tested within the Careggi Hospital, the largest medical infrastructure in Florence and Tuscany area in Italy, thus demonstrating the validity of the identified modalities, procedures, and the reduction in the time needed to cope with the emergency conditions. The trial was not registered as the test was conducted in realistic but simulated emergency conditions.

Conclusions: By analyzing the requirements for developing a mobile app, and specifically the functionalities, codes, and design of the Mobile Emergency app, we have revealed the real advantages of using mobile emergency solutions compared to other more traditional solutions to effectively handle emergency situations in hospital settings.

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KEYWORDS

emergency; hospital emergency; emergency communication management; mobile emergency

Introduction

Disaster response to in-hospital mass-casualty incidents represents one of the greatest challenges in emergency management. Hospitals must provide care to large numbers of casualties in damaged infrastructures, with personal risks, limited resources, inadequate communications, and lack of information [1]. Often, data regarding the true nature of the incident are inaccurate, needs are not clear, hospital personnel is not efficiently coordinated nor informed on the real available resources. In this chaotic environment, new technologies in communications and advanced "smart devices" have the potential to vastly improve the emergency medical response to incident disasters. There are numerous examples of the benefits of timely access to information in emergencies and disasters. The role of information technology is becoming increasingly important for information-sharing during emergencies and disasters, including sensible information and video [2]. Most reports of information technology applications to emergencies or disasters concern applications that are hospital-based or occur during non-response phases of events [3-5]. In most cases, the information is propagated via voice [6], while it is also accepted that relevant information has to be communicated via chat or messaging. Also, logistics were noted to be of concern, in particular regarding the movement of personnel and patients within and outside the hospital. The availability of a mobile device granting support in locating hospital personnel and emergency exits can be of great help. There is consensus that information and communication technologies can play a vital role in coordinating crisis response between pre-hospital services and the hospital emergency departments.

In particular, new-generation mobiles devices with wireless Internet, television-camera, and geo-positioning may have the greatest impact on improving communications, information management and distribution, the overall disaster response, and the emergency medical care [3]. Medical personnel need to access updated information and knowledge in emergency conditions when staff is demanded to cover different roles. This information allows medical and paramedical personnel to adopt local standard intervention protocols and prescribe appropriate pharmaceutical dosages based on specific patient conditions during continuously changing situations. In hospitals, continuously updated information on protocols and prescription dosages is propagated in short time or real-time through specific terminals and mobile devices especially in emergency/critical-conditions.

Therefore, mobile devices are mandatory tools for information access and to help in decision making. On such grounds, the solution has to guarantee the access to any right and updated information in the needed time [7-10]. Physicians found the usage of personal device assistants (PDAs), which are comparable to smartphones, very useful during night duty and in emergency conditions [11]. Medical personnel tested intelligent, triage-based PDA systems that can gather all the emergency medical services with positive results [12].

The purpose of this study was to test an emergency system solution, called Mobile Emergency, which was designed to improve the readiness of hospital personnel during emergencies and allowing more efficient treatment procedures to be performed to the victims of disasters. The mobile application can help the hospital personnel to communicate with the in-hospital emergency headquarter, also known as the Central Station, to obtain better information on the situation, resulting in the best possible care for patients.

The main idea behind Mobile Emergency was to provide a support for managing communications among medical personnel during maxi emergencies that may occur into large medical centers. Large medical centers are made of several buildings located in a large area. The medical center is a sort of village where thousands of medical personnel units work with thousands of patients and visitors on any given day. In these large and complex scenarios, several emergency events may occur per week, and at times per day. They may range from simple water problems (flooding or shortages), lack of power, problems on oxygen, to serious fire outbursts. Moreover, in some cases the emergency may arrive externally from disasters (eg, an earthquake, a big crash in the railway/highway, a terrorist attack, a gas explosion in the city, etc), thus forcing a localized reorganization within the hospital to cope with an increasing stream of people and patients. These events may cause an unusually high number of new patients entering the hospital emergency area and affecting other specialized units (eg, burn units), thus snarling up the reception desk structure and analysis centers. Among the possible internal emergencies, fire is one of the most awkward situations as it may require general evacuation of hospital patients and staff, taking patients away from their care. Our aim was to create an application for mobile devices to improve the readiness of hospital personnel during emergencies, facilitate communication, assure positioning, provide information and knowledge, and help rescue teams in taking action, thus allowing more efficient rescue operations for the victims.

In hospitals and during emergency medical situations, there are many additional constraints. In general, communication connections (ie, WiFi; universal mobile telecommunications system, UMTS; general packet radio service, GPRS) can be discontinuous when patients are moved along passageways, in the countryside, in tunnels, on the street, or on the ambulance.

In this scenario, off-line services on mobile devices may not be powerful enough, as information and knowledge is no longer accessible in real-time. The ideal mobile device should to be able to foresee the user's intentions and wishes, and be capable of providing suggestions within the context of the situation and user profile. The information has to be recovered and processed intelligently to provide suitable suggestions to medical personnel in real-time. In the context of this paper [10], this is the so-called Mobile Medicine scenario.

This paper describes the main scenarios and requirements for the mobile emergency solutions. The architecture of the mobile emergency solutions and details of the proposed mobile app Mobile Emergency are also described. The coding of the quick response (QR) code for location modeling is presented, together with some snapshots of the mobile application. The Mobile Emergency tools used during operative conditions and data on the validation experiments are depicted in the Results section, together with critical and positive comments and opinions collected during the validation phases of the trials.

Methods

Phase 1: Requirements Analysis

In order to extract and identify the requirements for developing this mobile app, the general scenarios regarding the emergency conditions have been formalized and depicted by using standard unified modeling language (UML) models. They have been revised with the experts about maxi emergency completing them with all needed details and explaining the critical aspects about the communication. Analyzing the scenarios allowed us to identify a number of requirements, which we classified into 2 groups: (1) requirements collected according to the point of view of the medical personnel, and (2) general level requirements which included the point of view of the Central Station monitoring the disaster and supporting, coordinating the personnel, and the needed intervention actions. The Central Station is typically in the central service room (in the hospital administration building) to manage emergency in the hospital.

Finally the requirements were extracted and formalized. The identification of the requirements was performed by reviewing the scenarios, reviewing the literature, and interviewing emergency experts and various medical personnel within the hospital area, asking them to answer questions regarding what is needed, what should be avoided, and how the issues are evolving in the best and worst cases.

Phase 2: Design and Development

The Mobile Emergency app can be installed on an iPad, iPhone, or iPod to provide the medical personnel with the needed support during the emergency. The Mobile Emergency app is distributed on Apple Store free of charge. The Mobile Emergency app provides a user-friendly interface and medical personnel do not need to spend too much time and effort on learning how it works. It was designed according to the ISO 13407:1999 standard, which deals with user centered development aspects. Our user centered development process started with the definition of the scenarios and requirements, and their validation with referent users. The next phase was the effective coding for development of a first prototype that has been tested and validated by previous and other users. The process itself is typically iterative, grounded on macro and micro life cycles. Macro lifecycle are those in which major features have to be analyzed, developed, and tested. They are planned to have a duration of 1-2 months. Micro cycles cope with the single elementary aspects of a feature development and have typically a duration of 1-2 weeks, including detailed analysis, development, and validation. The application was written using Objective-C and SQLite was used for data storage. The server component was written in PHP/HTML using an SQL server for data storage.

Phase 3: Test and Validation

The proposed solution has been exploited during validation trials. The test and validation has been performed by following 2 phases. First, we tested the usability of the functionalities of the solution proposed, and second, a real trial was performed in order to assess the reduction in communication time and the efficiency of the solution with respect to case without Mobile Emergency tools. The assessment of the usability of the functionalities of the solution proposed was performed after 10 minutes with the mobile phone in the hands of the participants, describing what can be done and how. Such tests have been performed in the small area of the Careggi University Hospital, which is a large community hospital located in Florence, Italy. The hospital has approximately 100 different buildings, connected with streets and underground tunnels. Each building may have thousands of rooms, elevators, stairs, corridors, telephone numbers, cafeterias, restrooms, and local receptions.

In order to verify the validity of the solution, 30 medical personnel with previous experience in dealing with emergency events using conventional ways were included in the tests. A control group with 24 medical personnel were also involved with the same critical emergency conditions, but without the usage of the Mobile Emergency solution. This control group used mainly phone calls and maps hung on the walls of the hospital when possible. Both groups were not familiar with the paths to the facility's exits from the critical area or how to reach the collecting areas. In addition to the participants, there was an observer and an evaluator. The emergencies consisted of fire, smoke, in single and multiple rooms, with the corridor also shrouded in smoke. The participants of the experimental group were asked to follow the instructions provided by the Mobile Emergency app. A variable number of patients were involved as well, with some visitors that did not abide by the decisions of the medical personnel. One of the tasks that participants had to perform was to move two patients from emergency situations. The personnel were asked to form groups in order to move two patients. One patient was in a room where the ceiling was about to give way, while the other patient was trapped in a fire in part of the building. The described trials have been replicated twice with different people (both patients and participants). The same identical conditions and commitments were asked to the control groups.

In order to assess the validity and effectiveness of the mobile solution for emergency situations within the hospital, the following indicators were taken into account: the estimation of

the reaction time with and without using the Mobile Emergency solution, evaluation of clarity about the leadership in the participants groups (in both cases, validation and control), the speed to reach the exit, the usability of the mobile app in presence of fire and smoke (different levels), the effect of different degrees of illumination on use, presence and absence of network connection, and different size of the QR code.

Results

Identified Requirements

The medical personnel (doctors and nurses) are typically the first people to inform the Central Station about an emergency condition. According to most emergency protocols, the alarm may be sent by a phone call, an SMS, or other mechanisms. In most cases, additional information is needed to identify and assess the emergency conditions and the people at risk. An image and/or a video depicting the emergency event immediately at its occurrence could be useful (for better understanding and for reviewing later the conditions).

During an emergency, the medical personnel and the hospital have to be reorganized to provide patients with assistance. Many personnel are required to evacuate patients, for example, 4-6 medical personnel are needed to evacuate a patient confined to a bed. The traditional emergency guidelines and protocols do not offer support for team creation to cope with such problems. Furthermore, additional gathering areas for each emergency triage level have to be set up. These activities may be performed by recalling in a medical personnel temporarily from other areas of the hospital, thus permitting direct communication among personnel.

If the recalled medical personnel have to keep abreast of the specific situation with updates on the procedures and tools to be applied during that emergency, the hospital organization has to provide them with the missing information. For example, with tutorials, checklists, dosages tools, decision support systems [10]. To make this information more accessible, checklists on the activity to be performed for different emergency situations should be available on mobile phones. Moreover, such devices have to be continuously updated since many involved aspects may change.

The personnel involved in the emergency may be not fully aware about the precise location of each department, and building. Therefore, they have to be supported in finding the rooms and departments where their presence is requested, for example to help other personnel to cope with patients confined to bed or for other critical situations.

If the position of each medical personnel within the hospital is made accessible, the Central Station may better coordinate the reaction to the emergency event. Central administration could provide a device or tag for each medical personnel to allow such tracking. Although constant position tracking of medical personnel may be a privacy violation, their position may be inquired anyway by Central Station when called for support at the emergency scene. There are many technical solutions to identify positions, including WiFi, radio-frequency identification (RFID), global positioning system (GPS), QR code, and maps (typically outdoor maps, as Google Maps, TomTom). WiFi might not be the best solution for all cases, as it is not very precise and dependent on power. RFID readers are not available on low cost mobile devices (they could be used to read the passive RFID tags reporting location information). GPS solutions have low reliability in underground tunnels and within buildings. QR codes are very simple and cheap; they can be placed inside several stable elements such as plates, indication printouts, and maps. This means they can be integrated very easily with current widespread solutions, which are based on maps and plates. In emergency situations, the medical personnel and staff at the Central Station need to react in certain ways, outlined in Textboxes 1 and 2.

Textbox 1. Considerations of medical personnel in emergency situations.

- Provide information regarding the emergency inception to the Central Station. It can be performed by using a simple form (to collect the minimal formal information, such as the situation and its gravity) or in a more effective manner by providing a picture or a video describing the detected emergency conditions.
- Recover the position within the hospital and obtain the easiest, feasible, and updated path to exit from the area interested by the emergency. The best exit path may change over time according to the changing emergency conditions (eg, if a certain set of stairs to an emergency route is blocked), thus the medical personnel has to keep abreast of the situation and updates are needed according to the patients' conditions and disabilities.
- Communicate the identified position to the Central Station to receive help and make easier for the Central Station to gather medical personnel for the evacuation.
- Get in contact with neighboring medical personnel to receive help in moving a patient or support to operate on a patient. The system should be able to identify the nearby colleagues and provide the means of contacting them.
- Recover information about the emergency collecting areas for patients who may share triage tags or other colored standard labeling. The paths to reach the collecting areas are also very relevant; in most cases, it is not enough to have one of the exits, but to have the correct one that may bring you to the specific collecting area where your patients have to be led to.
- Recover information about the emergency severity, status updates, and whether people in the area are in danger, to arrange for an evacuation. In most cases, the best solution to cope with the emergency is to wait for its close without abandoning the room where the emergency managing personnel recommended. When it becomes difficult to communicate the best possible solution for a specific emergency, the fastest and easiest way to communicate would be via direct mobile messaging using push notification.
- Recover the position of the emergency coordinator and the related team to cope with specific intervention fields, such as the transfer of a patient, the management of a collecting area, etc.
- Recover and/or get access to procedures to be followed such as: ACLS, BLS, and/or checklists, decision support, dosages to be applied, etc [10]. This information is typically available in the central room of the medical department and may not be accessible from the location of the medical personnel at the time, for example in a patient room, as they cannot abandon their position in emergency conditions.

Textbox 2. Additional requirements of the emergency management via central station.

- Receive the emergency calls from mobile phones and other devices with the minimal but correct information. Such calls have to be collected on the basis of the local emergency manual or guidelines. Emergency conditions are coded according to their severity, measured in terms of the number of patient and/or people involved, their autonomy in moving, etc.
- Aggregate the emergency calls coming from the same area and regarding the same emergency. This allows for a better evaluation of the severity of the emergency.
- Keep track of the emergency status and its evolution, from its inception to its solution, and thus keeping the involved personnel informed on such changes. A trace record should be kept for the emergency event, from its inception, its confirmed status, and up to the final solution. The record should also contain information about the personnel involved, the performed actions, the involved rooms and departments, the temporal evolution, the involved patients, and other relevant details.
- Identify medical personnel needing support in the emergency, support them in creating collaborative teams/groups and defining their coordinator, and/or reaching the collecting areas via escape doors.
- Control the conditions of the medical personnel being potentially involved. In some cases, the Central Station of the hospital does not know precisely who is in the area under emergency. Personnel who are supposed to be in one area may not actually be in that area at the exact time of the emergency. To this end, a verification could be very useful to see if there are some missing people or unclear situations.
- Identify medical personnel who could be involved in solving the emergency, since they are near the emergency location or are supposed to be in that area. In this case, the system should be able to alert them in order to communicate their condition and position to the Central Station.
- Identify medical personnel who could be recalled to support other colleagues in managing problems and patients in the collecting areas. In this case, the system should be able to alert them while providing all the needed information, such as where to go and the contact point to be in touch with when they arrive. The selection of personnel to be recalled can be performed on a general basis or according to their position and/or competence profile.
- Inform the personnel if patient evacuation is needed or if new incoming patients are arriving in the collecting areas.
- Inform other hospitals and other institutions about the occurrence of the emergency, for example the fire department, the police, the Engineer Corps, and the military authorities.
- Accept alarms that are coming only from qualified personnel. Therefore, the qualification cannot be limited to mobile devices, since it may be in the hands of unqualified people. On such grounds, authenticated access to emergency services is needed. Non-authenticated emergency calls and alarms can be accepted as well, but should be treated in a different manner.

System Design and Development

According to the above requirements, a Central Station and a Mobile Emergency app have been designed and developed. The design of both solutions used standard UML. Therefore, the main architecture of Mobile Emergency solution is composed of 3 main elements, depicted in Figure 1. The Mobile Medicine Best Practice Network and Service [10] is a service portal used to produce collaborative content for supporting the medical personnel during the emergency, in day-by-day conditions and for permanent medical education. The Best Practice Network is supported by a player application called Mobile Medicine, which has been taken as a starting point to develop Mobile Emergency solutions and mobile application [10]. The content itself may perform reasoning on semantics, thus providing different behaviors on the basis of content descriptors, user preferences, and contextual information [13]. The early version of Mobile Medicine was developed for PDA in Windows Mobile 6.5 and for iPhone by using MPEG-21 [14,15]. The present extended version of the Mobile Medicine application is called Content Organizer, available for iPad, iPhone, Windows Phone 7, and Android. Content Organizer served as the basis for further Mobile Emergency app development for these platforms.

The Central Station provides services to the Mobile Emergency apps, collecting emergency alarms, supporting the personnel during the emergency, providing support to identify the best escape doors, providing support to build collaboration among personnel, and sending messages to mobile devices by using the Apple Push Notification Service.

The main elements of Mobile Emergency app are marked in bold in Figure 1 (right). The permanent memory in the mobile phone is used to store the information regarding the maps (that are updated continuously), to store the procedure to be played by the Mobile Medicine tools, and to store the history of all the actions. These can be used to reconstruct possible problems and events whenever a legal analysis of the facts is requested. In respect of privacy policies, the user is informed about these aspects. The configuration of the system also includes the emergency protocol and classification according to the hospital emergency manual. This information is enforced into the system during the set up and configuration by using XML files.

The Emergency Manager allows the user to formalize and send the emergency alarms, with a media file attached (typically a video or some images, collected by using the Media Acquisition and Delivering module). The Emergency Manager verifies and follows the emergency manual adopted by the structure. For example, in the case of the Careggi Hospital, the emergency manual provides the emergency, inform the Central Station, the fire department, and transportation service, coordinate the first aid, coordinate the patients' escape, verify if the alarm has been propagated, and inform the director. Moreover, the Emergency Manager monitors the status of the actual emergencies that have been signaled to and from the Central Server, and recovers all the communications and actions carried out on the device for possible reconstruction of the events and the performed actions. The Emergency Manager periodically gets fresh information about the emergency status, maps for exits and collecting areas, and may receive direct calls from the Central Server in push (by using the push service of Apple). The pushed information may include suggestions and assignments to move towards a collecting area, to join a team, to become the leader of a team, or to move to a different area and room.

Collaboration Discovering and Connection module allows the user to discover if there are some other colleagues in the nearby area according to the user's position. If so, such colleagues are listed and their related positions stored and visualized in the present map. This allows the reception of direct calls from colleagues in the same emergency area. In certain conditions, it may be possible to have such communication carried out in spite of any lack of connection with the Central Station.

The Exits and Paths Manager help the users to get their position via nearby QR codes (see Figure 2). QR code images are directly generated by the Central Server to be placed at any strategic points within the hospital. Once the user has taken his/her position, the device informs the Central Station and downloads the updated possible exit solution. In case of connection loss, the mobile device uses the maps stored into the local database to provide suggestions for directions. It finds the correct direction to get to the exit according to the emergency conditions and the locations of exits or collecting areas established by the Central Server. It also receives automatic map updates and other information.

The Exits and Paths Manager performs some reasoning about the map information/descriptor, taking into account the position and the movements of the users. It estimates the current position by using the accelerometers of the mobile device to perform adjustments with respect to the position set using a QR code or via GPS (for example when the user is outside). QR codes are coded with 30% redundancy where the QR string is defined as: <serverURL>ID<Position ID><checkdigit> (see Figure 2 left and middle). On the Mobile Emergency app, when the user has acquired the QR code, the device creates a connection to the Central Station by using the HTTP protocol, which provides the information of the corresponding position. If the user is authenticated, the system updates his/her position by inserting the new location of the user in the Central Station database. The access to QR code URL by means of the Mobile Emergency app implies the access to additional information used by navigation system, including: building code, department code, currently updated image URL, room code, spatial coordinates of the QR code position on the map, spatial coordinates of the nearest exits, and spatial coordinates of the nearest collecting areas. The Mobile Emergency app exploits this additional information and, together with the maps downloaded from the server, is able to navigate the user to the nearest exit, a collecting area, or a specific position.

On the other hand, the coding of a QR code as an URL allows the Central Server to react to different QR readers in a different manner. Thus, if the QR reader is not read by the Mobile Emergency Application, a simple map with the current position, exits, and collecting areas is provided (see Figure 2, right). This allows all users to exploit the information associated with QR code placed in the hospital by simple applications, even if with limited capabilities when there is no navigation, no emergency status, or no networking.

Mobile Medicine engine and mobile applications can download, store, retrieve, and put in execution Mobile Medicine intelligent content [10]. This content is meant for the information and the training education of the medical personnel. It can be recovered and downloaded by using a different model of QR codes.

The content item area is indexed according to the descriptors and taxonomical classification of medicine, and it provides support for querying and organizing content according to the user data and requests. The adoption of HL7 (Health Level Seven International) compliant protocols for communicating with general hospital information system should be performed inside the mobile medicine intelligent content [10]. These aspects are not central for the Mobile Emergency app and solution. Moreover, on the same mobile device, it is possible to have other medical applications addressing the access to the HL7 information as well. For these reasons, the other aspects of HL7 have not been addressed.

Figure 1. Architecture of the Mobile Emergency app: Central Station (left) and Mobile Emergency Application (right).

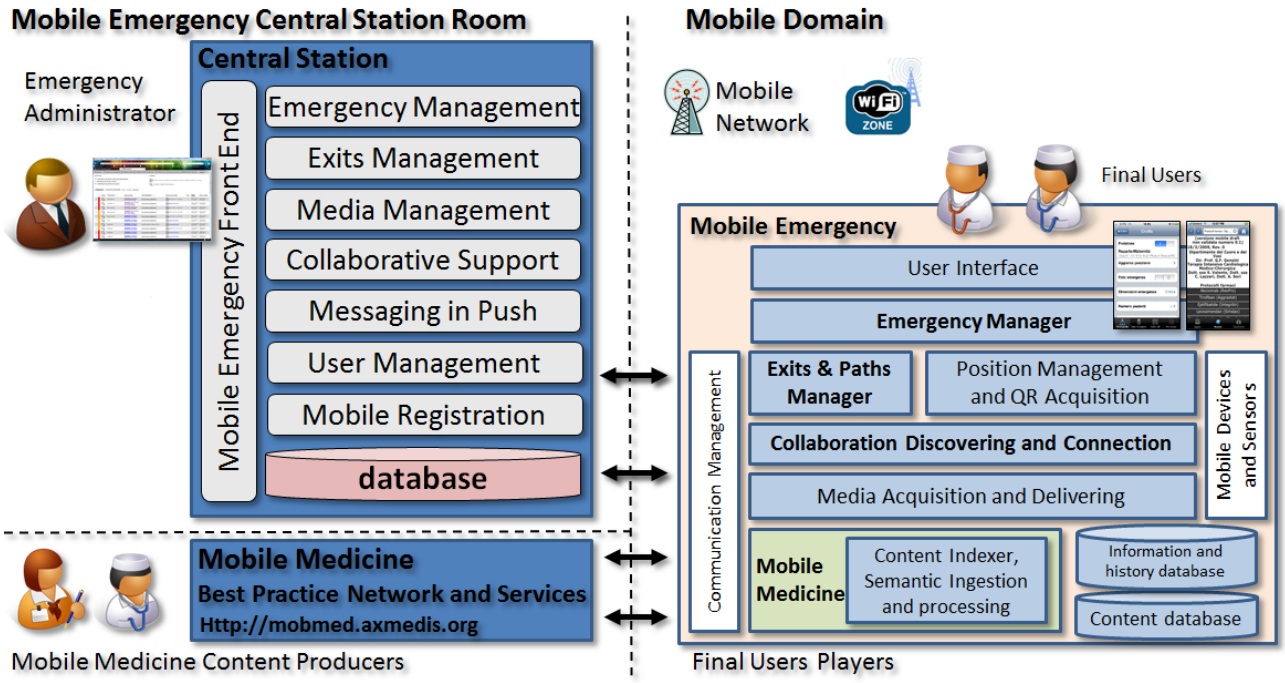

Figure 2. Example of QR coding regarding position.

QR code aspect	Description and meaning of the QR code for location, an example	Map provided to standard QR readers
	"00039": position identifier of QR **"n"**: control code based on SHA-1 algorithm. String BarCode: http://mobmed.axmedis.org/me/ID00039n	

System Test and Validation

A typical usage of the mobile application is depicted in Figures 3 and 4 through a series of scenarios. For more information about application use, consult the user guide.

The Scenarios A starts with an earthquake causing serious damage to the pathologic anatomy building. A medical operator uses the Mobile Emergency application and selects "Launch emergency" (3.1), the type of emergency (3.2), and the position, number, and the state of the people involved (3.3 and 3.4). Finally, the emergency is sent (3.4) and a confirmation is requested (3.5).

The personnel at the Central Station receives the emergency call and decides to send a rescue team (Scenario B). To this end, in Figure 4 (4.1 to 4.6), a push message is sent to rescue personnel to cope with the emergency (4.1) asking each of them to accept the message from Mobile Emergency app to check the status. Once the notification is accepted, the application displays the details of the emergency intervention (4.2). From that page, the user can select a map to get directions to the location where the emergency has occurred from outside or inside the building (4.3).

Once the right building has been spotted, the personnel can compare their position at the time with respect to the position

of the emergency by using a QR code placed near doors and other relevant points (eg, maps on walls, 4.4 and 4.5). Once the position of the medical personnel is recognized, they can track their position on the building map in relation to the emergency location (4.6). The scenario can go on by reaching the point and addressing the emergency, performing the triage, and going to the exit (see Scenarios C) or moving the patients to the collecting area (see Scenario D). Scenario C describes the simpler point of view of personnel able to leave the emergency location without waiting for the rescue team. This scenario is depicted by considering the sequence (4.4) and (4.5) to take their own position and continue with (4.7) to (4.9) to reach Exit 2 assisted by the application's internal navigator. Scenario D consists of moving from the emergency location to a collecting area. In those cases, the position can be taken by GPS or by using (4.4)-(4.5), while different maps can be selected by using (4.10) for reaching indoor (4.11) and outdoor (4.12) collecting areas.

Scenario E (in Figure 4) depicts the advantage of the local wireless exploitation in connecting the operators who can locate one another by using the discovery mode (4.12). With this functionality, operators can communicate both with a chat in broadcasting mode (4.13) and directly with a private chat with a single user (4.14).

Mobile Medicine, Medical Procedures, and Content

In the Mobile Medicine scenario, the useful content types may range from *single files* (ie, audio, video, images, documents, slides, and animations) to *cross media files* (ie, files containing interactive supportive tools such as calculators of health measures to help the user make correct decisions). Examples are treatment algorithm triage, Assessment of Consciousness, SNG (Nasogastric tube), and Apache Score [10]. For example, the estimation about the probability of pulmonary emboli, the estimation of a dosage on the basis of patient weight, and the assessment of neurological conditions on the basis of standard quantitative models.

Test and Validation: Numerical Data

The average time to perform the emergency call (Scenario A) was reduced by 18% (from an average of 57.33 seconds with SD 6.8 seconds, to 48.67 seconds and SD 2.3 seconds), with a higher value of the emergency call quality in terms of data (ie, precision of the emergency location and no missing information, see Table 1). According to Scenario B, once the directions from the Central Station had been received, the rescue team without help from the mobile app started to search for route to the emergency scene more quickly, whereas those with the mobile app spent more time on studying the map first before starting to move. After reaching the emergency location, triage was performed and the patients were moved to the same collecting area (Scenario D). Although medical personnel without the mobile app started to move faster, they took longer to reach the emergency area. Therefore, the total time for all movements (from the start time to the time they reached the emergency scene, but without the time spent on triage which was almost constant for all) showed that the groups with the Mobile Emergency app were much faster (mean time 9 minutes 57 seconds and SD 57 seconds) than those without (mean time 16 minutes 20 seconds and SD 7 minutes 5 seconds). This implies an averaged reduction in the time needed to move into the collecting area of more than 35%.

Figure 3. Scenario A: the Emergency Call delivering.

Figure 4. Scenario B: from 4.1-4.2, the emergency team reaches the emergency location. Scenario C: direct exit from (4.4-4.5) to move out (4.7-4.9). Scenario D: from emergency location (4.4-4.5) to collecting areas indoor (4.11) and outdoor (4.12). Scenario E shows some snapshots of direct discovering and chat among personnel in the emergency area (4.13-4.15).

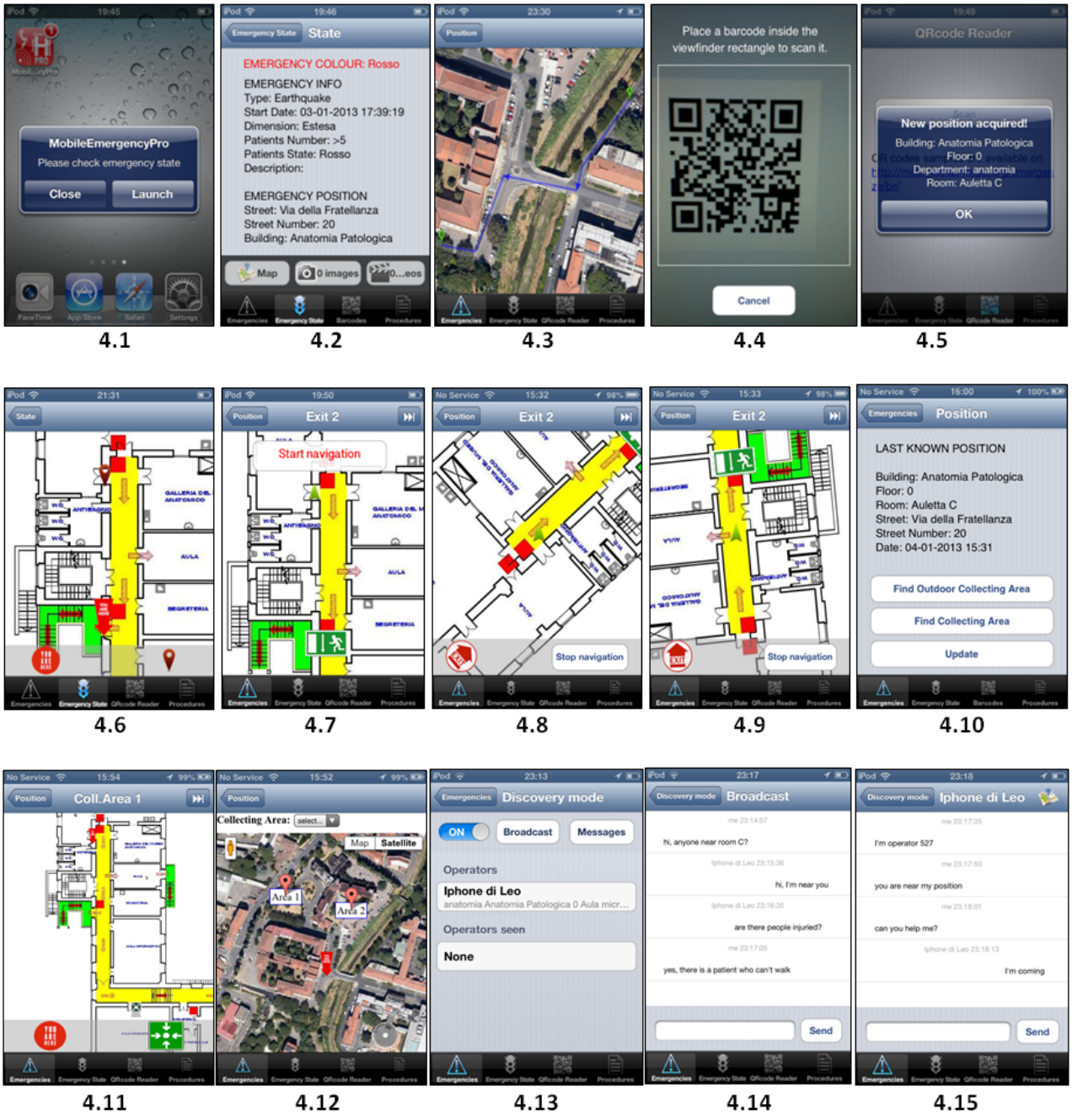

Table 1. Measured data from the experiments.

	With Mobile Emergency app		Without Mobile Emergency app	
	Average value	SD	Average value	SD
Time to perform the emergency call, sec	48.67	2.30	57.33	6.80
Quality of the emergency call in terms of received information, score[a]	4.98	0.05	3.66	0.22
Time to start going towards emergency location, min:sec	1:58	0:07	1:02	0:15
Time spent to reach the Emergency area by the rescue team, min:sec	4:19	0:34	12:58	6:33
Cumulated Time to perform all the movements from the beginning to the emergency location and from there to reach the collecting areas (excluding time to triage), min:sec	9:57	0:57	16:20	7:05

[a]The score was based on a Likert scale: 5=very good; 4=good; 3=barely acceptable; 2=poor; 1=very poor.

Discussion

The results of the test and validation phase about usability of functionalities allowed us to identify problems, solutions, and determine the validity of the solution. Thus some improvements have been applied to reach the version presented in this paper. Some considerations are reported in this section.

The positioning of the QR codes was very important. They should be placed by doors at different heights to accommodate for different walking positions, such as crawling during smoky conditions. The dimensions of the QR codes should be 2 to 4 times the size shown in Figure 2, so that the QR code can be captured from 80cm away in presence of a significant level of smoke. Initially, the QR codes consisted of 7% redundancy, increased to 30% recently. They are more robust due to lack of visibility and corruption [16].

When cellular signal levels are low, it is impossible to make voice phone calls for emergency communication, but the Mobile Emergency app was able to send the emergency alarm and receive instructions. The possibility of having a guided form (Figure 3) to communicate the emergency was really appreciated, since there was the security of providing the right data and in short time. The noise of the alarm also disrupts normal voice communications, therefore the chat communication, direct production of the emergency form, and reception of information about the emergency on the phone was more efficient than direct voice calls. When the situation is complicated by lack of visibility, respiratory difficulty due to smoke, or tearful eyes, the usage of a mobile device and reading the maps on the walls becomes difficult. In those critical conditions, using the Mobile Emergency app is the best choice. The app can be very useful for coordinating the activities of medical personnel in emergency situations, but a strong coordination with the Central Station is needed as well. In these situations, the communication and the information recovered via the Mobile Emergency app can be more robust, more precise, and more reliable than any voice mechanisms.

The adoption of mobile emergency solution proved to be very effective in spotting the position and communicating the occurrence of an emergency to the Central Station, thus reducing the time needed to reach the collecting areas. In smoky conditions, the time to reach safety areas was faster for medical personnel using the app compared to those who did not have the app. Another very important positive factor was the opportunity of being informed about the emergency status in any place in the hospital, thus reducing panic from people who are not involved with the situation. This effectively avoids many irrelevant calls to the central server and congestion of the system.

This paper addressed the aspects of communication with the medical personnel formalizing the modalities and the information to guide such personnel during emergency conditions with the support given by a Central Station, providing: information, emergency status, exits, link to responsible colleagues, directions to the collecting areas, guidelines, and dosages. The Mobile Emergency app is a proven solution, demonstrated in Careggi Hospital, the largest medical infrastructure in Florence and Tuscany area in Italy. Our app can help the hospital personnel to communicate with the in-hospital emergency headquarter (in the same emergency room) which can then provide the emergency medical personnel with better information to assure the best available care. We have identified the requirements, scenarios, and a mobile app that can efficiently cope with emergencies within hospitals. The Mobile Emergency app allowed medical personnel to be able to locate their position within large facilities, the site of emergency, location of exits, to get updated information about the emergency, and to push direct calls to the Central Station to appropriately handle the emergency situation.

The proposed solution is presently under trial by the Maxi Emergency team of the Careggi Hospital. The trial implies the usage of the solution during the exercitations for the master in emergency to pass successively for regular usage when this phase has been successfully completed.

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Conflicts of Interest

None declared.

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Abbreviations

UML: unified modeling language
PHP MySQL: PHP: Hypertext Preprocessor My Structured Query Language
PDA: personal device assistant

UMTS: universal mobile telecommunications system
GPRS: general packet radio service
QR: quick response

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Viewpoint

Designing eHealth that Matters via a Multidisciplinary Requirements Development Approach

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Abstract

Background: Requirements development is a crucial part of eHealth design. It entails all the activities devoted to requirements identification, the communication of requirements to other developers, and their evaluation. Currently, a requirements development approach geared towards the specifics of the eHealth domain is lacking. This is likely to result in a mismatch between the developed technology and end user characteristics, physical surroundings, and the organizational context of use. It also makes it hard to judge the quality of eHealth design, since it makes it difficult to gear evaluations of eHealth to the main goals it is supposed to serve.

Objective: In order to facilitate the creation of eHealth that matters, we present a practical, multidisciplinary requirements development approach which is embedded in a holistic design approach for eHealth (the Center for eHealth Research roadmap) that incorporates both human-centered design and business modeling.

Methods: Our requirements development approach consists of five phases. In the first, preparatory, phase the project team is composed and the overall goal(s) of the eHealth intervention are decided upon. Second, primary end users and other stakeholders are identified by means of audience segmentation techniques and our stakeholder identification method. Third, the designated context of use is mapped and end users are profiled by means of requirements elicitation methods (eg, interviews, focus groups, or observations). Fourth, stakeholder values and eHealth intervention requirements are distilled from data transcripts, which leads to phase five, in which requirements are communicated to other developers using a requirements notation template we developed specifically for the context of eHealth technologies.

Results: The end result of our requirements development approach for eHealth interventions is a design document which includes functional and non-functional requirements, a list of stakeholder values, and end user profiles in the form of personas (fictitious end users, representative of a primary end user group).

Conclusions: The requirements development approach presented in this article enables eHealth developers to apply a systematic and multi-disciplinary approach towards the creation of requirements. The cooperation between health, engineering, and social sciences creates a situation in which a mismatch between design, end users, and the organizational context can be avoided. Furthermore, we suggest to evaluate eHealth on a feature-specific level in order to learn exactly why such a technology does or does not live up to its expectations.

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KEYWORDS

health care information systems; health informatics; requirements analysis; software design techniques; user-centered design

Introduction

Requirements are the foundation of technology design. They describe what a technology should do, what data it should store or retrieve, what content it should display, and what kind of user experience it should provide. The development of requirements includes all the activities devoted to their identification, the communication of requirements to other developers, and their evaluation [1]. Involving end users and stakeholders in the creation of requirements has been shown to be a fruitful approach. It improves usability [2], prevents the inclusion of superfluous features [3], and can prevent the spending of money on bad design [2].

Within the literature on electronic health (eHealth) design, reports on the development of requirements are scarce. Coble et al [4] have reported on their experiences during the development of an information system for clinicians that displays their patients' test results. Caligtan et al [5] discussed their creation of requirements for bedside information technology for patients. Thew et al [6] finally, have documented their experiences while creating requirements for geographic visualization tools for the epidemiology domain. Often, the creation of requirements is left to engineers who apply a technology-driven approach. However, The potential of eHealth technology can only be fully exploited when it is developed by a multi-disciplinary team who apply a human-centered approach that takes the specifics of the context (both organizational and that of the individual user) in which the technology is to be used into account [7,8]. This mismatch between context and technology has been recognized by the World Health Organization as the main reason for why up to three quarters of new medical devices fail [9]. This issue can be resolved by properly developing requirements, driven by the designated context of use. In the past, several context-driven approaches, such as human-centered design, have been suggested. However, these approaches mostly consist of a few starting points (eg, human-centered design propagates user-involvement from as early as possible). And when they do come accompanied by step-by-step instructions such as SCRUM they are not geared towards the specifics of the eHealth domain. This domain is fundamentally different from other domains such as eCommerce. Therefore, a focus on its specifics is important. In the eHealth domain, the target group for a technology is in most cases known before development starts (eg, patients with Rheumatoid Arthritis, or nurses on an oncology ward). In commerce, a distinctive user group often forms naturally after the introduction of a technology. eHealth developers can and should profile their designated users in detail and should gear design towards this profile, as the end user population can be quite heterogeneous [10]. Next, the relationship between end user and technology provider is a special one. Where a for-profit organization sells a technology directly to a consumer with a limited set of after-sales facilities, an eHealth technology is often offered to insured patients or health professionals as part of a greater service; namely treatment or prevention of a disease or condition. The organization offering this service is then a medical one (eg, a hospital) that bought the technology from the manufacturer. These services are often offered free of charge. This complicates business models that need to satisfy the interests of medical organizations, insurers and external profit, and non-for-profit parties [11]. And as these technologies are part of the treatment or prevention plan, requirements entail more than a list of functionalities only, but also specify how the technology should be embedded in the care context and what the content should convey [12]. Finally, the requirements development approach needs to take into account the boundaries eHealth settings have regarding research options. Care providers may lack time and motivation to participate as their first priority lies with patient care and continuity of care, and workload is generally high. This calls for a well-planned and structured requirements development approach because it is often difficult or impossible to apply endless iterations. In order to deal with these challenges, a dedicated requirements development approach that involves multidisciplinarity is a great asset [7,13].

The current lack of a requirements development approach for eHealth poses several problems. First and foremost, a mismatch between the eHealth technology and the context of use is likely to occur, which can lead to faulty use of the technology, dissatisfaction, low adoption rates, and/or loss of money. Second, it is hard to judge the quality of design activities. It remains unclear which procedures have been followed to collect data to profile the intended end user and to map the designated context of use, and how this data has been translated into eHealth intervention design consequently. Finally, requirements are seldom documented in such a way that they can serve as the basis for evaluations: they are not accompanied by measures for success. This can make it difficult to assess what features or aspects of an eHealth intervention make it effective or not.

In order to deal with domain-specific issues, dedicated requirements development approaches have been introduced in other domains, such as the eGovernment context. Here, the provider of the technology and the user (a citizen, or organization) often hold a contradictory view of the task to be completed and the substeps involved; governments need to design for the mainstream as well as for exceptional situations; users apply, sometimes illegal, workarounds that are necessary for completing a procedure, but which a government cannot design for; etcetera [14]. As a result, several publications have discussed how to deal with these issues in requirements development [15-17]. The eHealth domain has not yet reached this level of maturity.

This article presents an approach for requirements development for eHealth which incorporates activities from disciplines such as engineering, human-centered design and business, with the goal of creating a human-centered design as well as a business model and implementation plan. Rather than providing an overview of all the possible instruments that one *can* apply here, we provide a hands-on guideline on how to conduct one set of attuned activities. In the next section, we will introduce, the Center for eHealth Research (CeHRes) roadmap, the holistic design approach in which we have embedded our requirements development approach. Then, we discuss its constituent phases. We end this article with a discussion of the (dis)advantages of the approach.

Methods

Center for eHealth Research Roadmap

The CeHRes roadmap [13,18] is a development approach for eHealth interventions. In order to create value-adding and sustainable eHealth technologies, it incorporates both a human-centered design and a business modeling focus. Human-centered design implies that, prospective, users are consulted throughout the design process, their use of prototypical versions of the system is researched empirically, and iterative design (going through several cycles of design and evaluations) is used [19]. Business modeling focuses on creating an optimum fit between technology, organizational procedures, and organizational resources [11]. Furthermore, the CeHRes roadmap places a strong emphasis on creating persuasive technologies, for example to motivate citizens to conduct healthy behavior. The inclusion of persuasive features in eHealth has been shown to have positive trade-offs such as increased adherence [20]. The roadmap consists of five phases (see Figure 1):

1. *Contextual inquiry*. Here, information on the context of use, the designated end users and the professionals that need to implement the eHealth intervention is collected.
2. *Value specification*. Data from the contextual inquiry is translated into stakeholder values and requirements for the technology.
3. *Design*. Prototypes of the eHealth technology are created on the basis of requirements and tested.
4. *Operationalisation*. The final version of the eHealth intervention is launched and additional resources (eg, user support) are mobilized.
5. *Summative evaluation*. Finally, the uptake and effect of the eHealth technology is evaluated.

Throughout the development process, formative evaluations should be conducted in order to test design assumptions and prototypes. If necessary, developers should revisit a phase in the design process in order to update their insights. This also applies to the requirements development process.

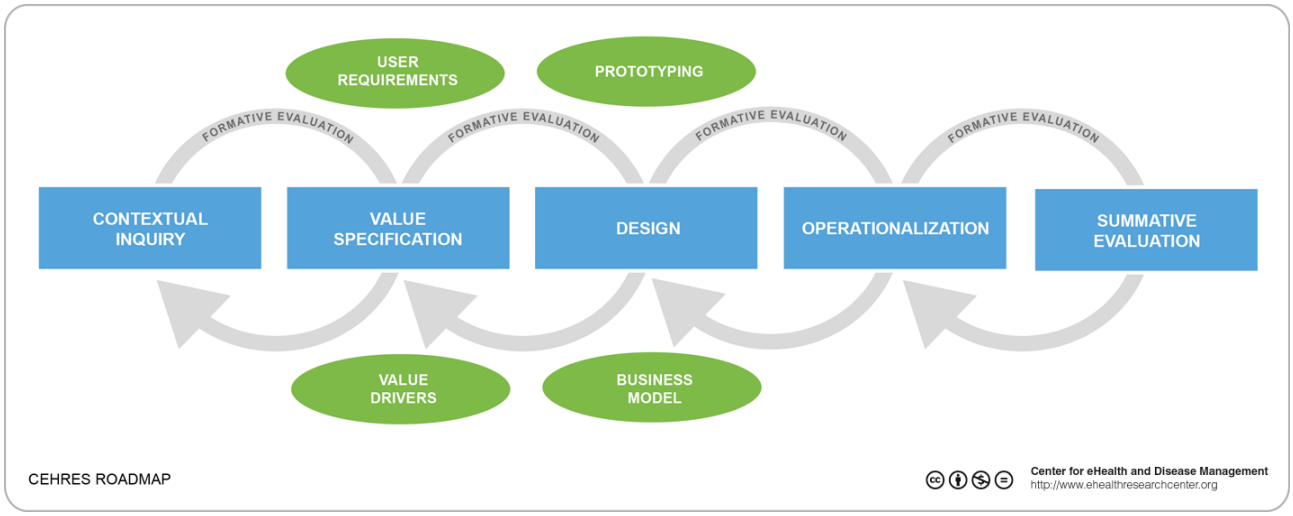
Many factors that determine whether or not an eHealth technology is useful or usable go beyond the interface and interaction design [21], and can only be uncovered when activities aimed at eliciting requirements specifically address the designated context of use [7,22]. Therefore, we present an approach that is founded in the CeHRes roadmap and puts emphasis on the modeling of this context. It is beyond the scope of this article to discuss every possible method for developing requirements. Instead, we will present one possible approach that caters for the demands the health care setting places on creating technology, as we discussed before. It provides the reader with a selection of appropriate and attuned methods out of the huge toolkit and in the end will result in a set of requirements that can lead to value-adding and viable eHealth technology.

The five phases in the requirements development approach within the CeHRes roadmap, their main activities, and the products that are the result of each phase are displayed in Table 1.

Table 1. Phases and main activities in the requirements development approach.

CeHRes roadmap phase	Requirements development phase	Main activities	Products
Contextual inquiry	Preparation	Composing the project team	
		Deciding upon the overall goal(s)	
Contextual inquiry	end user and stakeholder identification	Audience segmentation	List of primary end users and stakeholders
		Stakeholder Elicitation	
Contextual inquiry	Requirements elicitation	Conducting interviews, focus groups, observations	Transcripts
Value specification	Requirements analysis	Determining values, attributes and requirements	Values, attributes and requirements
			Personas
Design	Communicating requirements	Completing requirement notation templates	Design document
		Creating the design document	

Figure 1. CeHRes roadmap.



Preparation

First, the project team needs to be assembled. As we discussed before, a multidisciplinary design team is a must for coping with the specific demands the eHealth context places on design. The team needs to consist of at least 2 experts in the field of eHealth design and business modeling, 1 relevant medical expert, and, preferably, 1 representative from the programmers. They are responsible for project management and together they have to decide on the overall goal(s) of the eHealth technology. This is also the moment in time where constraints have to be identified (like legal or accessibility guidelines which need to be followed) and an eventual technology push (eg, opting for a mobile eHealth technology as mobile apps will dominate the market soon) has to be decided upon.

End User and Stakeholder Identification

In eHealth, the end user population can often easily be determined at the start of the development process. However, which end user group is then most important within this population remains unknown. The design team should identify these groups. This way, they know whose characteristics and wishes they should uncover and take into account. Plus, the wide range of stakeholders must be uncovered so that their needs can be accounted for in order to let the implementation of the technology proceed smoothly and to create a sustainable business model.

End users are people who will use the technology directly, like citizens using a mobile app to lose weight or nurses using a teledermatology system [23]. Stakeholders are all the persons or organizations that have a task or role in relation with, or are affected by, the eHealth intervention [24], like organizational purchasers, marketing staff, or a user support department. A person can be both an end user as well as a stakeholder.

Audience Segmentation

Profiling the end user in a *professional setting* is often a relatively simple task. The idea for such an eHealth technology is developed with a clear-cut, relatively homogeneous end user population in mind, such as nurses on an oncology ward. In the case of *public eHealth technology*, the profiling of the end user is more difficult. These technologies are designed for patients groups (eg, people with a sleep disorder), or sometimes even for the whole population of a country (eg, a website on when to visit your family doctor) and these are heterogeneous populations. Their motivations for (not) using these technologies or complying with the advice they provide are diverse, and they are people with different cultural backgrounds, skills, and disabilities [15]. In order to deal with the heterogeneity of the end user population of a public eHealth technology, one should identify, profile and design for distinctive audience segments.

Audience segmentation is concerned with identifying homogeneous sub-populations (segments) within a population, and their profiling. In this phase, identifying audience segments is the main goal, profiling is done later on. In order to identify audience segments, one must first uncover the determinants of knowledge, attitudes, and behavior for a given context; preferably from existing research. Then, one must identify audience segments based on distinctive patterns of these determinants [25]. Ideally, the identification of audience segments is based upon the analysis of large sets of quantitative data [26] and uses a combination of demographical, health, and psychographical variables [27]. For a more thorough discussion of audience segmentation we refer to Slater [25].

Stakeholder Identification

Stakeholder identification aims at creating a list of stakeholders that need to be involved in the design of the eHealth intervention. In the literature, several lists of variables such as [24,28] and frameworks, as cited in [29,30], can be found that serve as input for thinking about who to include as stakeholder. However, a clear-cut and relatively simple procedure is missing. The approach we suggest to identify stakeholders consists of four steps:

1. A first inventory of relevant stakeholders is created based on the relevant protocol(s) or clinical pathway(s) for a given context. One should scrutinize the documents to identify actions and the person(s) or organization(s), responsible for each action. If these documents are not available, one can hold a brainstorm session with the client.

2. This inventory is then checked with the client and/or an expert in the field. Are the identified stakeholders correct? Which stakeholders are missing?
3. If the list of identified stakeholders is too long, a selection is made, based on an estimation of each stakeholder's power, legitimacy, and urgency. A combination of these factors make up their salience [24].
4. These stakeholders are invited for a stakeholder session (see section on requirements elicitation). During this session, the role(s) each stakeholder plays in the prevention or treatment of a condition or disease is mapped (see [31] for questions that can guide this discussion). On the basis of this map, the stakeholders discuss which stakeholders are missing, thereby creating the final overview. If new, important stakeholders are identified, they need to be interviewed about their role in the prevention or treatment.

As protocols or clinical pathways are not always very clear on the role each stakeholder plays in a given context, it is important to validate the list that results of step 2 and 3 with the stakeholders themselves, as we suggest in step 4.

Requirements Elicitation

Now that one has identified the end users or end user segments for an eHealth technology, it is time to profile them and to map their context of use. The identified stakeholders need to be consulted in order to map the current prevention or care path for a given condition or disease, and the opportunities and barriers for the eHealth technology and its implementation. By focusing on these matters one can determine what the eHealth technology needs to do and how it should be implemented. Requirements elicitation methods provide the tools to elicit the necessary input.

One kind of knowledge that is important to uncover during the requirements elicitation phase, is so-called 'tacit knowledge'. This kind of knowledge is "neither expressed nor declared openly but rather implied or simply understood and is often associated with intuition" [32]. Mostly, this consists of steps taken in routine tasks; like comforting a distressed patient. These tasks do not consist of predefined steps which are easy to explain to somebody. Rather, it is something one 'just does'. This makes it a difficult procedure to map. However, it is an important activity, as it is crucial that the features and interface and interaction design of an eHealth technology are in line with the end users' tacit knowledge. Several methods can be applied to elicit tacit knowledge; like observing potential end users, or asking them to tell stories about typical tasks or occurrences on the job (for a complete overview see [33]). Regardless of the method one uses, it is important to determine before data collection how to go about eliciting tacit knowledge since it will not be handed to the project team on a plate.

There is a wide variety of requirements elicitation methods, each with their own strengths, and limitations (for overviews, see [34,35]). We will shortly address the three most popular methods:

- *Interviews* may be used to uncover end users' or stakeholders' behavior or opinions, their motivations or rationale for these, and their wishes regarding the to-be-developed eHealth technology. They are also well-suited for collecting data upon which personas can be based (see [36]). Personas are fictitious users whose characteristics resemble the average for an end user (segment) and who is presented in a biography with a photo [37]. Personas are well suited in this context, as they are easy to understand for the wide variety of stakeholders involved in eHealth design. They can then be used to spark the discussion among stakeholders during a focus group or can serve as input for content requirements. Interviews should be used to profile end users and stakeholders, and to elicit requirements that will specify functions, content, and the user experience. For more information on how to conduct a requirements elicitation interview, refer to [38].
- *Focus groups* can be used for establishing the context, roles and primary tasks that are or could be supported by technology with stakeholders, and what business model should support this. Via personas, scenarios and task demonstrations, stakeholders can gain insight into, and reach consensus on the context, the division of roles, the scope of the eHealth technology, the flow of funds, requirements, and requirement priority. Focus groups can also serve to explore the context and need of a new activity or work practice that involves eHealth, to learn how this could be designed and introduced into current work patterns or daily activities [39]. Again, personas and scenarios may be used to elicit ideas on the new activity. In short, focus groups are very well suited to elicit input for implementation strategies and business models. For instructions on how to conduct focus groups, refer to [40].
- *Observations* can be especially useful for understanding actual end user behavior and their social, physical and spatial surroundings [41]. As a result, they also provide the option to see what tacit knowledge drives end users. Observations can be used to elicit requirements that specify the functions and modality of the eHealth technology. For more information on observations, see [42].

Requirements Analysis

Once requirements elicitation sessions are completed, their output needs to be translated into requirements. This step often remains unmentioned in requirements engineering reports, and methodological explanations of this step are scarce. We hereby present a method for translating raw data into requirements, based on [43]. In this method, for each part of a transcript that is worthy of translation into a requirement, three derivatives are determined: values, attributes and requirements.

- *Value* is an ideal or interest a (future) end user or stakeholder aspires to or has.
- *Attribute* is a summary of the need or wish that is spoken out by the (future) end user or stakeholder.
- *Requirement* is a technical translation of an attribute.

Each derivative can be used to communicate about the eHealth technology with a specific group of people (technologists understand requirements, marketing departments use attributes, and policy makers prefer values). Furthermore, attributes and values can be used to group requirements, which makes it easier to set priorities later on.

The basis for the translation process are the transcripts created from the requirements elicitation sessions (eg, the typed-out interviews). One issue that first needs to be resolved is to determine what counts as something that should be translated into a requirement. It is impossible to formulate fixed rules for solving this dilemma. And tempting as it may be, focusing on prevalence does not guarantee success. When an issue is often brought forth, it does not mean it needs to be translated into a requirement (eg, it may be an issue that should be resolved by creating new legislation). If an issue is brought forth only once, it is possible that it provides a great contribution to the eHealth technology. Rather, we follow Braun and Clarke [44] and suggest that an issue should be translated into a requirement when it captures something important in relation to the overall goal(s) of the eHealth technology.

To aid the translation process, the analyst can complete a translation table. The translation table shown in Table 2 is filled with data from the development project of bedside technology to aid hospital nurses in making prudent and correct use of antibiotics. The following steps should be taken to ensure a reliable translation of data into requirements.

1. The analyst familiarizes him or herself with the data.
2. Quotes that capture something important in relation to the overall goal(s) of the eHealth technology are identified and listed in the “user expression” column.
3. For each quote, the attribute or attributes are determined. An attribute should be formulated as a very short summary of the end user or stakeholder expression.
4. Quotes are grouped on an attribute level. Quotes that can be transformed into the same attribute are merged in one row.
5. The analyst checks all quotes and the attributes that flow from them, and determines whether the attributes are correct and distinctive. If necessary, attributes are adjusted.
6. Per attribute, one or more requirements are formulated. They specify the end user or stakeholder expression into terms a system designer can work with. Requirements should be formulated as precisely as possible, and usually are sentences like ‘The system must…’
7. An independent analyst checks the attributes and requirements formulated. He or she notes disagreements or suggestions. Then, the initial and second analyst discuss these findings.
8. Attributes and requirements are adjusted based on the discussion between the first and second analyst.
9. The first and second analyst determine the values together. Most often, there are only a few values that are linked to many attributes. Values should be formulated in a few words.

Once the translation table has been completed, the requirement templates can be filled out (see Section for Completing requirement notation templates). At the same time, personas can be constructed on the basis of the raw data (for a stepwise procedure, see [45]). These personas can then be used to formulate content requirements, or as input for stakeholder sessions.

Table 2. Data analysis table for antibiotic stewardship app.

User expression	Value	Attribute(s)	Requirement(s)
Nurse 1: “But wouldn’t it be nice if you have the medications in the electronic prescriptions system, and that you can click on the medication and just click on through.”	Easy access	One-stop-portal for information	The system incorporates data from databases for patient and protocol/procedural information
Pharmacist: “that you can instantly…”			The system provides access to all (types of) information via one interface
Nurse2 : “directly…”			
Nurse3: “yes, that it is available directly”			
Pharmacist: “Yes, for prescribing [a medicine] I can imagine that he [the physician] needs the information from an indication-point of view. And for you I can imagine that you would want to have the information focused on the application; how to do it all.”			
Nurse 3: “What should I pay attention to.”			

Communicating Requirements

Completing Requirement Notation Templates

At this point, the project team will have a list of requirements, derived from elicitation activities. These should be expanded with requirements, derived from relevant literature (like persuasive design tactics when persuasive technology is developed), legal constraints, and demands on accessibility. Each requirement needs to be documented in such a way that it enables programmers to understand what needs to be made and why. Requirements documentation should also serve as the starting point for evaluations (both aimed at generating redesign input, and aimed at assessing the effect or return-on-investment). We created a requirements documentation template, based upon the Volere template [46], as it supports the aforementioned goals. The template is depicted in Figure 2 and completed for one requirement from the same development project on bedside technology for hospital nurses.

Figure 2. Completed requirements notation template.

Requirement #: 3	**Requirement type:** functional
Value: easy access	**Attribute:** one stop portal for information
Description: The system provides access to all (types of) information via one interface.	
Rationale: Nurses spend a lot of time gathering information from different (types of) sources while performing their antibiotic-related tasks. When all information can be accessed from one interface, one starting point, searching for information is facilitated.	
Source: Focus group 1 & 2, fragment 1,2,3,10,13	
Fit criteria **1. Acceptance testing:** not applicable **2. Usability testing:** The application allows participants to find the desired information within one minute. Note: time frame to be adjusted upon inspection of the high-fidelity prototype. **3. Summative evaluation:** Participants feel they have to spend less time on searching information via the app. Searching for information via the app results in an increase in success and a decrease in time, in comparison with searching for information in the traditional way.	
Priority: High	**Conflicts:** possible conflict with mobility and real time access and synchronization requirements because access to these databases at all places via the interface may be impossible due to limitations in wireless connections and security options.
History: Created on March 9 2012, adjusted on May 8 2012	

Requirement Number

Each requirement is assigned a unique ID.

Requirement Type

There are different kinds of requirements that need to be shared with different kinds of people that are involved in the creation of the eHealth technology. We discern these types:

- *Functional and modality requirements* specifying technical features and on what kind of technology (eg, tablet, smartphone or desktop PC) and operating systems the technology should work. Mostly meant for programmers.
- *Service requirements* specifying how services surrounding the technology, like marketing or user support, need to be organized. Mostly meant for managers, responsible for these services.
- *Organizational requirements* specifying how the technology should be integrated in the organizational structure and working routines. Mostly meant for managers of the organizations in which the technology is to be used.
- *Content requirements* specifying the content that needs to be communicated via the technology and, if applicable, language level, persuasive approach, and special accessibility demands. Mostly meant for content managers.
- *Usability & User experience requirements* specifying the interface and interaction design of the technology and how user experience factors, such as trust or fun, should be integrated into the technology. Mostly meant for human factors specialists.

Value, Attribute, and Description

Here, the value, attribute, and description (the requirement itself) are noted down.

Rationale

Each requirement is accompanied by a short statement justifying the need for this requirement, preferably linked to a source. The rationale must convince a programmer that the requirement is worthy of inclusion.

Source

The source(s) of each requirement (eg, the interview number or persona) is noted down for reference purposes.

Fit Criteria

Requirements are a translation of end users' and stakeholders' needs and wishes into design, and should therefore be checked. Fit criteria are measures of success for this translation and are the basis of evaluations. Often, functional requirements cannot be evaluated with users as they are simply implemented or not (like a requirement specifying that type of data x is collected from database y). In this case, formulating a fit criterion is useless. In the other cases, whether or not a fit criterion is formulated or not depends on its priority (when there is no possibility to evaluate all requirements, only those with a high priority, or controversial requirements should be evaluated), and whether or not the prototypical version of the system that will be used supports evaluating the fit criterion (eg, testing for usability with a simple prototype will yield very limited results). Roughly, we discern 3 kinds of evaluations.

Acceptance Testing

By demonstrating a very simple prototype (eg, paper and pencil sketches) that demonstrate the main functionality and look & feel of a technology, and its associated working routine, user and stakeholder acceptance of crucial or controversial features can be determined early on [47]. Based on this evaluation, the inclusion of these features should be settled. A fit criterion should tell when the feature or working routine, specified in the requirement, is considered to be accepted.

Usability Testing

By making end users or experts interact with a clickable prototype that approximates the final version of the technology in terms of functionality and interface & interaction design, usability issues can be found [48]. Typical usability evaluation methods, such as heuristic evaluation, cognitive walkthroughs or thinking-aloud, can support the elicitation of these issues [49]. This evaluation drives the modification of the interface & interaction design of the technology. A fit criterion should tell when a requirement is translated in a usable manner.

Testing for Effect

With the version of the eHealth technology that is launched, its effect and return-on-investment can be assessed. Often, it is difficult or impossible to determine the effect of an eHealth technology on its overall goal. For example, proving that a reduce in general practitioner consultations for tick bites is due to a mobile app that instructs people how to prevent or deal with tick bites, is impossible to do. Many factors outside the mobile app will play a role and it is extremely difficult to map all of these factors, and to establish causal links to the number of general practitioner visits. Therefore, following the concept of attribution theory [50], evaluations of eHealth technology should focus on outcomes on a lower level, that can be linked directly to a specific feature, and indirectly to the overall goal(s) of the eHealth technology. The fit criterion field in the requirements template forces the project team to use the requirement for the formulation of feature-specific effect measures. Several methods, like data log analysis and user surveys (for a full overview, see [51]) can be useful here.

We do not think that all requirements should be evaluated, or should be evaluated at all 3 instances. We advocate the evaluation of requirements with a high priority, or controversial requirements (like those to do with privacy). When a fit criterion is not met, the (prototypical) system should be redesigned and re-evaluated.

Priority

Often, not all requirements that are elicited and formulated can be realized in the design. Limited resources, like time and money, force the project team to make a selection. In the literature, many approaches are described that guide the prioritization process (for an overview, see [52]). However, these methods often demand from the project team that they consult their stakeholders and end users repeatedly, and often use complicated metrics. For the design of large-scale eHealth systems (like a national electronic patient file) one should apply these methods in order to deal with the large number of different stakeholders and limited budgets. However, for the scope of many eHealth projects, these approaches are too time-consuming and complex. Therefore, we recommend to set stakeholder and requirement priority by a discussion among the project team members. They should distinguish stakeholders and requirements with a high, medium and low priority. When ranking stakeholders, their power, legitimacy, urgency and salience should be taken into account [24]. When determining the priority of a requirement, the following should be considered: the priority of the associated stakeholders, its importance, the penalty for not implementing the requirement, cost, lead time, risk, and volatility [52].

Conflicts

If applicable, conflicts with other requirements should be listed here. The project team should find a solution to a conflict, and must translate this into a new requirement, or one requirement should take precedence over the other, based on priority.

History

In this section, it should be documented how the requirement is translated into design, or the reasons why it was omitted. Furthermore, changes to the design because of evaluations should be listed, as well as scores of effectiveness measures. This way, a complete overview of a requirement's origin, translation into design, and effect can be created.

Results

Creating the Design Document

Once all requirements are documented in templates, the design document can be created. It is important that such a document is made for several reasons, like making it possible to estimate the costs of creating the technology, preventing programmers from making their own requirements, and preventing a brain drain if a project team member leaves the project [53]. This document must allow the people that need to program or implement the eHealth technology to do so. Therefore, it has to include an overview of the eHealth technology goals, requirements and a low-fidelity, or paper, prototype. It must also include sections that specify the technological design of the technology, such as entity-relationship diagrams or dataflow diagrams. Besides creating a design document, we recommend to also present the directives in person to programmers and involved managers. Finally, the information gathered from the different stakeholders, must serve as input for an implementation plan and business model.

Discussion

Principal Findings

In this article we have presented a multidisciplinary requirements development approach for eHealth design. Its main aim is to support the creation of context-driven eHealth technology that matters by applying a human-centered, context-driven design approach that includes the creation of an implementation plan and business model. The approach supports the identification and profiling of end user groups and stakeholders, forces the project team to identify requirements in an empirical manner, and advocates the formulation of feature-specific effect measures for the eHealth technology. The latter allows researchers and policy makers to learn exactly why an eHealth technology does or does not live up to its expectations.

In the literature and practice, several other approaches to requirements development are often discussed and applied: agile design (eg, SCRUM), participatory design, and more technical approaches (eg, RUP). Agile design shows quite some overlap with our approach, as it makes use of iterative design cycles in which the prospective end user is a focal point for design. The downside of agile design approaches is that they do not take the organization into account and hence, do not support the development of an implementation plan and business model [54]. Our approach does provide a basis for the generation of these. In participatory design, the end user and other stakeholders play an active role in the design team [55]. This way, their view and context are brought into the design. This approach is somewhat similar to human-centered design and we think it is certainly possible to incorporate activities from participatory design into our approach. For example, a design workshop in which end users and the development team create a first prototype together would be a very suitable method for the requirements elicitation phase to generate design ideas, and to elicit the aspects of the end users' context that need to be taken into account. However, the literature on participatory design often fails to provide hands-on guidelines on how to apply a method. Our approach guides the project team in detail. Finally, the technical approaches, such as RUP, are very limited in their capabilities to incorporate the needs, wishes and organizational context of the end user into design [56]. Our approach is the first to take into account the specifics of eHealth technology and to overcome the limitations of the popular requirements development approaches. Furthermore, this approach allows a great degree of freedom for choosing the most suitable method for activities like identifying end user sub-groups and requirements elicitation. We feel this is important as each development process is unique (in terms of time, budget or the amount of research on which the development builds forth) and the methods one uses should be geared towards the development context.

Limitations

The approach to requirements engineering we have presented has some downsides. First, because it is very thorough it takes quite some time and effort to go through all the steps. This critique has been voiced towards many requirements engineering approaches, and several faster and less thorough, or agile, approaches have been proposed as a counter reaction. Agile approaches advocate the development of technology with a small team of experts and customers, and the rapid development of prototypical versions of the eHealth technology which are evaluated and redesigned [57]. However, as we discussed above, agile development does not take into account the implementation plan and business model. Furthermore, agile design may not always be possible in health care settings, where research activities can demand too much time, or can put too much emotional constraints on health care workers or patients, whose first and greatest priority lies with getting well or providing good care and not in participating in eHealth development activities. Consulting them repeatedly about the technology in a short time-span may prove to be impossible. Being well-prepared and having a thorough plan like the approach we describe here, adds to development efficiency: it allows designers to get the maximum out of each stakeholder or end user consultation. Maybe for this reason, the application of agile approaches is not widely adopted yet. We encourage project teams that do opt for an agile design approach, to still utilize a structured manner of data analysis and requirements notation, as we have set out in this article. A second downside of our approach is that it requires the use of specialists in requirements elicitation and notation. Conducting a useful requirements elicitation interview, or constructing good requirements with proper fit criteria is not an easy task and requires a lot of experience. Therefore, we advocate the inclusion of an experienced requirements developer in the project team.

The danger of consulting end users and stakeholders, and making their voices and interests the primary focus of the to-be-developed eHealth intervention, is that it limits creativity [58]. It is therefore important to find a balance between end user and stakeholder input, and creative ideas from the design team. The latter should not necessarily be made subordinate to end user and stakeholder input, but should be given a fair chance in acceptance and usability tests. Participatory design sessions with end users or other stakeholders can release this creativity

[59]. Resulting creative solutions can then be noted down as a requirement or several requirements in the requirements notation template. However, creativity in eHealth design is a topic that has not been paid enough attention to in the design literature to date. Future research should delve into it and determine its place and value in eHealth design processes. Furthermore, methods for identifying and involving organizational stakeholders into the design of eHealth are often very comprehensive and time-consuming. The development of lightweight methods for these goals would be a welcome addition to the requirements developer's toolkit.

Conclusions

We hope that this article will inspire eHealth technology designers to apply a more systematic approach for their requirements engineering activities. This is most likely to have beneficial consequences for the eHealth technology (in terms of costs, usefulness, adoption, etc), as well as for the community as a whole. We also encourage researchers to report case studies of their requirements development experiences (either guided or not guided by our approach). This way, we will be able to estimate the worth of different requirements development approaches for the eHealth domain and the benefits and downsides of the design methods used.

Conflicts of Interest

None declared.

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Abbreviations

CeHRes: Center for eHealth Research

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Original Paper

The Natural History of Spina Bifida in Children Pilot Project: Research Protocol

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Abstract

Background: Population-based empirical information to inform health care professionals working with children with spina bifida currently is lacking. Spina bifida is a highly complex condition that not only affects mobility but many additional aspects of life. We have developed a pilot project that focuses on a broad range of domains: surgeries, development and learning, nutrition and physical growth, mobility and functioning, general health, and family demographics. Specifically, we will: (1) explore the feasibility of identifying and recruiting participants using different recruitment sources, (2) test a multidisciplinary module to collect the data, (3) determine the utility of different methods of retrieving the data, and (4) summarize descriptive information on living with spina bifida.

Objective: The overall objective of the project was to provide information for a future multistate prospective study on the natural history of spina bifida.

Methods: Families with a child 3 to 6 years of age with a diagnosis of spina bifida were eligible for enrollment. Eligible families were identified through a US population-based tracking system for birth defects and from a local spina bifida clinic.

Results: This is an ongoing project with first results expected in 2013.

Conclusions: This project, and the planned multistate follow-up project, will provide information both to health care professionals experienced in providing care to patients with spina bifida, and to those who have yet to work with this population. The long-term purpose of this project is to increase the knowledge about growing up with spina bifida and to guide health care practices by prospectively studying a cohort of children born with this condition.

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KEYWORDS

spina bifida, musculoskeletal disorder, health, children, follow-up

Introduction

Spina Bifida Overall

Spina bifida (SB) is a neural tube defect (NTD) that occurs early after conception when the neural tube that forms the brain and the spine does not close properly. SB generally is considered one of the most complex birth defects compatible with life [1]. In recent decades, survival rates have increased dramatically, primarily due to improved care and the use of antibiotics [2]. A recent study suggested that the overall prevalence of SB among children and adolescents in 10 regions of the United States was 3.1 per 10,000 in 2002 [3]. Although rates of SB differ substantially across countries [4], probably no country is excluded from having children born with this potentially disabling condition. The necessary follow-up surgery and care can present considerable physical, emotional, and financial burdens. In spite of substantial differences between and within countries in terms of care available and provided to individuals with SB, it is important to study how SB impacts the child and his/her family long-term.

The most severe form of SB, myelomeningocele, is the most common of the NTDs, and the most complex birth defect compatible with long-term survival [5]. There are a substantial number of people whose everyday lives are directly or indirectly affected by SB, prompting a real need for prospective comprehensive data to provide evidence regarding health promotion, prevention of secondary conditions, access to appropriate preventive health care, and caregiver support. We know of no US—and few international—population-based studies or programs focusing on the natural history of SB. This is important because people with SB often experience condition-specific difficulties (eg, incontinence, mobility limitations, and cognitive challenges) and secondary conditions (eg, pressure sores, urinary tract infections, and depression) that detrimentally affect several aspects of their lives. Little information is known about how and when to intervene to prevent or reduce the number of modifiable problems from occurring during childhood, and there is still much to be learned about the natural course of SB throughout the lifespan. Because SB is a relatively rare condition and people with SB traditionally have not lived to adulthood, many—if not most—available treatments are based on expert opinions in lieu of evidence-based research [6]. To remedy this lack of data, the current pilot project was developed by the National Spina Bifida Program at the Centers for Disease Control and Prevention (CDC) in collaboration with partners at NORC (formerly the National Opinion Research Center) at the University of Chicago, and the Neuropsychology Department at Children's Healthcare of Atlanta. The current project will provide useful information on research design and methodology that will inform the planning and implementation of a prospective US multistate SB project. The larger prospective study will enroll a large cohort of children with SB to provide population-based data on some of the most pressing concerns for this population.

Part of the complexity associated with SB is that a number of body systems tend to be severely affected. In this project, we focus on the following medical specialties: orthopedics (eg, mobility), urology (eg, incontinence, urinary tract infections, and renal failure), and neurosurgery (eg, hydrocephalus and Arnold-Chiari II malformation). Psychosocial issues and specific learning problems also are reported frequently and addressed in the project. A brief review is provided in the following sections.

Medical Concerns, Mobility, and Functioning

SB is challenging—it affects neurological functions, urological and kidney functions, and mobility for virtually everyone with the condition. Secondary conditions such as pressure sores [7] and pain [8] are other areas of concern. Children with SB often undergo multiple surgeries and need to adhere to long-term medical and behavioral treatments. Hydrocephalus co-occurs with SB 80-95% of the time [9-12] and most of these children exhibit Arnold-Chiari II malformation [11]. These brain abnormalities typically require neurosurgical interventions in the form of shunt insertions, shunt revisions, decompression, or any combination thereof. The presence of hydrocephalus and Arnold-Chiari II malformation has been associated with worse performance on certain cognitive tasks [11]. Shunt revisions also have been associated with negative outcomes. Results from a British community-based follow-up study of adults with SB showed an inverse relationship between the number of shunt revisions and long-term achievement as defined by level of independence, using a car, and employment [13].

Other medical consequences include neuropathic bladder, malfunctioning kidneys, urinary tract infections, and urinary and fecal incontinence. Although overall urological goals are similar if not identical (in that they focus on maintaining normal renal function, gaining urinary continence, and maximizing independence [14]), the methods used to achieve these goals differ among health care providers. Renal failure still is reported as a leading cause of mortality and morbidity among people with SB [15-16], even though renal failure among this group is almost completely preventable [17]. Incontinence occurs frequently, can interfere with achieving independence, and is a source of embarrassment for the individual [18]. Estimates of how often incontinence occurs, and to what extent it affects life, differ depending on the definition of incontinence, as well as sampling methods. Among young adults in Europe with SB, approximately 60% reported being incontinent, regardless of the type of bladder management used, and approximately 70% reported that being incontinent presented a problem [18]. Clean intermittent catheterization (CIC), medication, and surgeries are typical methods of treating incontinence. Many urologists recommend that CIC start at an early age [14,17], but research is needed on the timing and method of implementation of a CIC plan, as are prospective data on how a successful CIC regimen can be achieved. A French study assessing the frequency and types of associated malformations of NTDs showed that about 25% of infants with SB had at least one other major malformation, including orofacial clefts and cardiac defects [19]. These malformations require medical interventions and could further complicate the lives of people with SB.

Mobility is affected negatively among most people with SB and is related to the level of lesion (LOL). Different definitions of LOL exist, but generally a higher LOL results in more severe

mobility restrictions. The presence of scoliosis, kyphosis, club foot, hip and knee contractures, or other orthopedic conditions habitually warrant surgery and can affect mobility, and subsequently independence, negatively.

Development and Learning

There is great heterogeneity in terms of cognitive function among people with SB [20]. In addition to the SB diagnosis, performance on cognitive assessments is contingent on factors such as having a higher LOL, hydrocephalus or shunting, or both, and Arnold-Chiari II malformation [11,21-23]. Researchers from an Australian population-based study linked several databases from Western Australia and reported that 18.8% of people born with SB (1980-1999) had received a diagnosis of intellectual disability (IQ <70) during childhood. In comparison, only 1% of individuals born during the same period but without a diagnosis of a birth defect had a diagnosis of intellectual disability [24].

Regardless of overall cognitive function, people with SB are at increased risk of specific problems that adversely affect their ability to learn, often resulting in academic difficulties. Substandard scores on certain types of memory tests [9,25] and a number of tasks related to executive functions [12,26] are reported consistently. In addition, attention-deficit/hyperactivity disorder, and in particular the predominantly inattentive type, has been reported more frequently among this population compared with their peers without SB [10]. Learning problems, independent of overall cognitive ability, often make up an additional burden for people living with SB. Studies generally have suggested that nonverbal learning problems (eg, deficits in motor, visual-spatial, and mathematical abilities) in particular constitute an area of concern. Although the increased risk of learning problems among people with SB has been established, there is a need for prospective research that assesses early predictors of learning problems and development, as well as research on strategies that can facilitate functioning for people with these types of problems.

Physical Growth, Nutrition, and General Health

While parts of the world struggle with lack of a steady food supply and malnutrition, obesity has received much attention in the United States and parts of Europe. Lack of exercise and unhealthy eating habits have long been associated with preventable morbidity and preterm mortality. Few researchers have focused on weight issues among people with SB. However, it is known that, in general, individuals with disabilities in the United States are at higher risk than people without disabilities of not reaching recommended levels of exercise [27] and are at an increased risk for obesity and poor health. Many reasons for not exercising are similar for people with and those without disabilities, although people with disabilities can face additional hurdles to exercising that are unique to them. Barriers in the environment have been listed as an important correlate of lack of exercise for people with disabilities [28]. In a Japanese study that addressed weight among children with SB, no significant differences in percentage of body fat were found between a group of children with SB and a control group without SB before 5 years of age. An increase in body fat was noted among the group with SB after 6 years of age [29]. Additionally, a positive relationship between the presence of hydrocephalus and a higher percentage of body fat was noted [29].

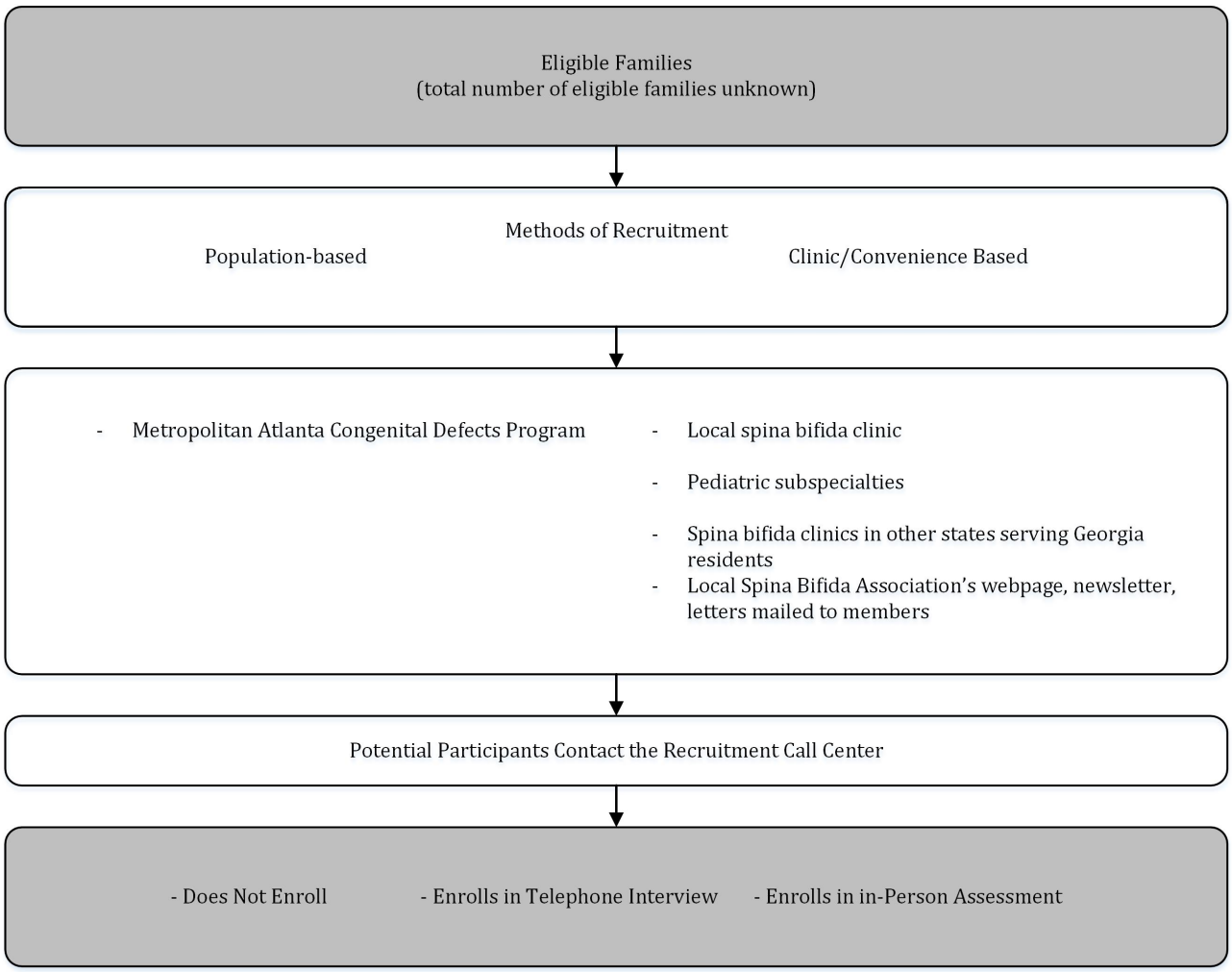
The overall aim of the study was to assess the research design and methodology to inform a future multistate prospective study on the natural history of SB. In addition, the project has four main objectives: (1) to explore and compare the feasibility of identifying and recruiting participants using different recruitment sources, (2) to test a multidisciplinary model to collect data, (3) to determine the utility of different methods of retrieving data (ie, telephone surveys, in-person assessments, and record abstraction), and (4) to summarize preliminary descriptive information on the natural history of SB. As part of the third objective, we will investigate whether participants prefer in-person assessments or a telephone survey.

Methods

Participants

Families with a 3-, 4-, 5-, or 6-year-old child with a diagnosis of SB (International Statistical Classification of Diseases and Related Health Problems, Ninth Revision, Clinical Modification (ICD-9-CM) codes 741.0 and 741.9 without 740.0 and 740.1 or the codes 741.00-741.99 without 740.00-740.10 from the modified British Paediatric Association coding system) currently residing in the State of Georgia in the United States will be eligible to participate. Confirmation of diagnoses will be possible in those cases where we can extract the ICD code from the medical records. Children with a diagnosis of SB occulta will be excluded, as the natural history of SB occulta is presumed to be quite different from that of SB aperta. CDC already tracks children born with certain congenital conditions, including SB, in selected areas in a limited number of states in the United States. In Georgia, this population-based surveillance system is called the Metropolitan Atlanta Congenital Defects Program (MACDP). Using MACDP for recruitment purposes provides certain strengths for the project, such as an established sample frame of eligible children, a physician-confirmed diagnosis of SB, and limited contact information that is updated periodically. A drawback of recruiting solely from the MACDP is that it is limited to five metropolitan Atlanta counties. The experience of growing up with SB might be quite different for children with SB and their families who are not living in a metropolitan area. For example, the type of care available and the experience and knowledge of the professionals working with these children and their families might differ. Recruitment strategies for these families will be different as well. Therefore, a convenience sample will be included and we will use different methods to recruit families who are not part of MACDP (Figure 1). The convenience sample also will provide information on how to create a sampling frame in the absence of a surveillance program.

Figure 1. Recruitment Scheme.



Data Collection

Family involvement will be solicited in the SB clinic in Atlanta in person and by mail, or through a letter from the MACDP. A recruitment center headed by NORC will be notified of those who are interested and those families will be contacted. After an interested family is contacted by the recruitment center, the project recruiter will ask the parent to orally confirm that the child has a diagnosis of SB (myelomeningocele) and is in the 3–6 years of age range. An explanation of the project will follow, during which parents will be encouraged to ask any project-related questions they might have. If they are interested in participating, contact information will be obtained. Next, the parents will choose which project component they wish to complete (telephone survey or in-person assessments). Only the telephone component is available for monolingual Spanish-speaking individuals. Randomizing participants into project components would be desirable. However, because we are interested in assessing which component parents prefer, and because long driving distances might deter those living far from the assessment site from participating if they were to be randomized to the in-person component, we decided not to randomize. If a parent chooses the in-person component, an appointment will be scheduled and a reminder letter and directions to the assessment site will be mailed to the parent. If a parent chooses the telephone survey component, the project recruiter will proceed either by conducting the survey or by scheduling an appointment to complete the survey at a later time. Parents who choose not to participate will be asked for the main reason for that decision (open-ended) and thanked for having taken the time to learn more about the project. A separate recruitment log will be used to record the reasons stated for deciding not to participate. These data will be an important part of the project, as anecdotal information has shown it is difficult to recruit participants for research related to SB. These data can provide direction on how to design future longitudinal projects to maximize participation.

Procedure

Telephone Survey Component

After oral consent is obtained, the interviewer will read all questions verbatim in the order indicated in the questionnaire. Each participant's responses will be marked directly on the paper-and-pencil interview copy of the survey. At the conclusion of the telephone survey, the interviewer will store the completed paper-and-pencil interview form in a secure, locked cabinet and project staff will enter the survey data into an electronic data file that will be stored on a secure network. Identifying information that is collected during the course of the telephone survey (eg, names, addresses, and telephone numbers) will be separated physically and permanently from the survey data and

entered into a separate database. The telephone survey is estimated to last approximately 90 minutes. Participants will receive $25 for participating.

In-Person Component

Data will be collected from both the child and the parent. After the informed consent process is completed, a licensed clinical child neuropsychologist will assess the child. The parent will complete the parent portion of the assessment in a separate room with assistance from the project coordinator (Table 1). Assessments and questionnaires that require scoring will be scored immediately after the participant has completed the entire project component (Table 2). The in-person component is estimated to last no more than 3 hours per family. To reduce the time commitment of the in-person component, the child and parent will be assessed or interviewed, as applicable, simultaneously when possible. Each family will receive a $50 honorarium and get reimbursed for transportation costs.

The project survey, created specifically for this project, contains items related to medical concerns, development and learning, nutrition and physical growth, mobility and functioning, general health, and family demographics. The survey used in the in-person component contains the same items as the survey used in the telephone survey component. Parents participating in the in-person component will be asked to fill out the McMaster Family Assessment Device which measures family functioning, the Behavior Rating Inventory of Executive Function- Preschool version (BRIEF-P) to measure executive functioning, and the Pediatric Evaluation of Disability Inventory (PEDI) which measures functional abilities. Parents will also be asked to fill out the Adaptive Behavior Assessment System (ABAS), which measures daily living skills, and the Children's Health Care Patient History Questionnaire, developed by the neuropsychologists at the Children's Healthcare of Atlanta clinic. The neuropsychological battery will consist of 5 separate assessments: the Differential Abilities Scale II (DAS-II) will be used to measure cognitive abilities, the Peabody Picture Vocabulary Test 4th edition (PPVT-4) will be used to measure receptive vocabulary, the NEPSY-II will be used to measure cognitive abilities, the Wide Range Assessment of Visual Motor Abilities (WRAVMA) will be used to measure visual-motor integration, and finally, the Bracken Basic Concept Scale (BBCS-R) will be used to measure basic concept acquisition, receptive language, and school readiness. More details on the different study instruments can be found in Tables 1 and 2.

Medical Records and Early Intervention Data Collection

If the parent completes the telephone survey, he or she will be mailed hardcopy forms to authorize release of the child's medical and early intervention records. The parent will be asked to read, sign, and return the forms in a self-addressed, stamped envelope provided by the project. If the parent completes the in-person component, written authorization to release the child's medical and early intervention records will be sought at the beginning of the in-person session. Copies will be made of the medical records or the early intervention records, or both, at the respective clinics and sites and taken to the coordinating office. Relevant data will be extracted from the records and transferred onto 2 separate forms that have been created specifically for the project. Reliability is often a concern in most types of records abstractions. In this pilot, we are primarily interested in investigating if the data we are interested in can be found in the records.

Data Analysis

Descriptive statistics will be computed on the quantitative data. Specifically, means, standard deviations, and confidence intervals will be computed for continuous variables, and frequencies and percentages will be computed for dichotomous and categorical data. If the sample size is sufficient, we will compare the participants based on LOL, sex, and race and ethnicity using multivariate statistics. The child assessment results will provide information on how this sample of young children with SB scored compared with the normative scores. We also will reevaluate whether the standardized measurements and tests were appropriate for this specific group of individuals, or whether other measurements might be more appropriate in the future. The qualitative data will be reviewed carefully, summarized, and used to inform future recruitment of individuals with SB or other potentially disabling conditions, with an emphasis on improving recruitment strategies for surveillance systems. Following project completion, recruitment data will be reviewed and summarized. We also will calculate how many participants chose the in-person component versus the telephone survey component. Participant feedback on both components will be reviewed carefully and summarized to guide and inform potential changes that might be necessary to improve future projects. Missing data patterns will be reviewed to assess if there were particular items or sections that families were more likely to skip. These types of data are essential, as the long-term goal is to follow children with SB longitudinally.

Ethical Considerations

The project already has undergone ethical review and been approved by three separate institutional review boards (US government, university, and hospital). The project has also undergone Office Management and Budget review and been approved. Oral consent will be obtained from those participating in the telephone survey and written consent will be obtained from those participating in the in-person component. Verbal assent will be obtained from children 6 years of age before they participate in the in-person component.

Limitations

As in many studies that do not rely solely on clinic-based samples, we have no accurate way to determine how many families are eligible to participate, thus making it difficult to make an assumption of sample size. We will use different approaches to inform and recruit participants. Although the current project is cross-sectional, preventing determination of causality, we are in the process of planning a multistate prospective study that will be better suited to address causality, as appropriate. The in-person component will not be available in Spanish, which will limit the options for monolingual Spanish-speaking participants.

Table 1. Parent administered instruments to be used.

Instrument	Number of items	Topics/domains	Cronbach alpha coefficients	Reliability coefficients
Project survey[a,b]	201	(1) medical concerns, (2) development & learning, (3) nutrition & physical growth, (4) mobility & functioning, (5) general health, & (6) family demographics	not applicable	not applicable
McMaster Family Assessment Device [30][b]	60	Family functioning (1) problem-solving, (2) communication, (3) roles, (4) affective responsiveness, (5) behavior control, & (6) general functioning	.57-.86 [31]	one-week test-retest .67-.76 [31]
BRIEF-P [32][b]	63	Executive functioning Subscales (1) emotional control, (2) shift, (3) inhibit, (4) working memory, & (5) plan/organize Indices (1) inhibitory self-control, (2) flexibility, & (3) emergent metacognition	.80-.95 [32]	4.5-week test-retest-.78-.90 [32]
PEDI [33][b]	217	Functional abilities Subdomains (1) self-care, (2) mobility, & (3) social function Parts (1) functional skills, (2) caregiver assistance, & (3) modifications	.95-.99 [33]	not applicable
ABAS-II [34][b]	241	Daily living skills 10 skill areas Domains (1) social, (2) practical, & (3) conceptual	.98-.99 [34]	.90 [34]
Children's Health care Patient History Questionnaire[b]		6 sections (1) identifying information, (2) pregnancy & newborn history, (3) developmental history, (4) medical history, (5) educational background, & (6) social history	not applicable	not applicable
Medical & early intervention records data abstraction forms[a,b]		For medical and early intervention abstraction from records Medical (1) neurosurgery, (2) urology, (3) orthopedics, & (4) hospitalization	not applicable	not applicable

[a]Used in the telephone component

[b]Used in the in-person component

Table 2. The child assessments to be administered (in-person component only).

Assessment	Topics/domains subtests included	Cronbach alpha coefficients	Reliability coefficients
DAS-2 [35]	Cognitive abilities, 7 core subtests from early years battery (1) verbal comprehension, (2) picture similarities, (3) naming vocabulary, (4) recall of objects, (5) pattern construction, (6) matrices, & (7) copying	not applicable	not applicable
PPVT-4 [36]	Receptive vocabulary 20 content areas and parts of speech across all levels of difficulty	.94 [36]	one-week test-retest-.93 [36]
NEPSY-II [37]	Cognitive abilities (1) comprehension of instructions, (2) word generation, & (3) sentence repetition	.90-.91[37]	.72-.89 [37]
WRAVMA [38]	Visual-motor integration WRAVMA matching visual-spatial subtest WRAVMA pegboard fine-motor subtest	exceeding .90 [38]	.81-.91 [38]
BBCS-R [39]	Basic concept acquisition & receptive language, school readiness composite (1) colors, (2) letters, (3) numbers/counting, (4) sizes, (5) comparisons, & (6) shapes	not applicable	.86 [39]

Discussion

The lack of information about the natural history of SB needs to be rectified by collecting multistate longitudinal data at all life stages. Having this information will facilitate the development of appropriate health care recommendations and general guidelines for people with SB at different life stages, affecting outcomes in self-management, relationships, and learning and employment. It is imperative that knowledge be gained regarding the identification of developmental delays before the optimal time of developmental achievement has passed. Determining the interventions needed to address these delays will help people living with SB to be more likely to realize their full potential. Such an undertaking requires pilot testing of the proposed methods prior to implementation on a larger scale. The current project, although cross-sectional, is a first step towards recruiting and following a larger sample of children born with SB. By using different data retrieval methods, we will learn which yield the most valid and reliable data. We also will learn what data collection method is most acceptable to participating families, optimizing participation rates and reducing attrition for future projects.

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Conflicts of Interest

None declared.

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Abbreviations

ABAS-II: Adaptive Behavior Assessment System
BBCS-R: Bracken Basic Concept Scale
BRIEF-P: Behavior Rating Inventory Preschool Version
CDC: Centers for Disease Control and Prevention
CIC: clean intermittent catheterization
DAS-2: differential abilities scale 2
ICD: International Statistical Classification of Diseases and Related Health Problems
LOL: level of lesion
MACDP: Metropolitan Atlanta Congenital Defects Program
NEPSY-II: developmental neuropsychological assessment
NTD: neural tube defect
PEDI: Pediatric Evaluation of Disability Inventory
PPVT-4: Peabody Picture Vocabulary Test
SB: spina bifida
WRAVMA: Wide Range Assessment of Visual Motor Abilities

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Protocol

Terminology, Taxonomy, and Facilitation of Motor Learning in Clinical Practice: Protocol of a Delphi Study

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Abstract

Background: Facilitating motor learning in patients during clinical practice is complex, especially in people with cognitive impairments. General principles of motor learning are available for therapists to use in their practice. However, the translation of evidence from the different fields of motor learning for use in clinical practice is problematic due to lack of uniformity in definition and taxonomy of terms related to motor learning.

Objective: The objective of this paper was to describe the design of a Delphi technique to reach consensus on definitions, descriptions, and taxonomy used within motor learning and to explore experts' opinions and experiences on the application of motor learning in practice.

Methods: A heterogeneous sample of at least 30 international experts on motor learning will be recruited. Their opinions regarding several central topics on motor learning using a Delphi technique will be collected in 3 sequential rounds. The questionnaires in the 3 rounds will be developed based on the literature and answers of experts from earlier rounds. Consensus will be reached when at least 70% of the experts agree on a certain topic. Free text comments and answers from open questions on opinions and experiences will be described and clustered into themes.

Results: This study is currently ongoing. It is financially supported by Stichting Alliantie Innovatie (Innovation Alliance Foundation), RAAK-international (Registration number: 2011-3-33int).

Conclusions: The results of this study will enable us to summarize and categorize expert knowledge and experiences in a format that should be more accessible for therapists to use in support of their clinical practice. Unresolved aspects will direct future research.

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KEYWORDS

motor learning; Delphi technique; clinical practice; consensus; definitions

Introduction

Background

Motor learning has been a central topic in the sport domain, and has more recently received increased attention in the context of rehabilitation [1], especially in people with neurological disorders [2,3]. In both populations, research into fundamental (eg, underlying mechanisms) [4] as well as clinical (eg, application to individuals) aspects [5,6] of motor learning is increasing. Although the target populations within sport and rehabilitation do not seem to be comparable, the processes, principles, and underlying assumptions of their learning process share considerable features. However, a clear structure for the translation of knowledge and evidence, not only from sports to rehabilitation, but also from laboratory research to the clinical situation, is currently absent.

Speaking the Same Language

Within the behavioral motor learning literature, usually in the context of skill acquisition in sports, several models and concepts exist where different terms, classifications, and/or taxonomies are used (eg, [7-13]). Often, the degree to which conscious knowledge is involved in the learning process is used as a starting point. Forms of learning that result in the accumulation of non-conscious, procedural knowledge are described as implicit, whereas forms of learning that result in the accumulation of conscious, declarative knowledge are generally described as explicit [14,15]. In recent years, there has been a significant increase in the number of studies evaluating the application of implicit and explicit forms of learning. Target populations are not only healthy people and athletes but also patients with neurological disorders [16-26].

Unfortunately, there is a lack of clarity with regard to definitions across studies and consequently the forms of learning are applied differently within study paradigms.

If we want to link research from different fields, we need to enable comparison of evidence and expertise. In order to further translate results into practice, it is important that researchers, therapists, and others professionals involved in facilitating the motor learning process speak the same language and use uniform terminology. Therefore, the main aim of the described study protocol is to achieve consensus on the definitions, descriptions, and taxonomy of terms related to motor learning, using the distinction in implicit and explicit forms of motor learning as a conceptual basis.

Application of Motor Learning

Physiotherapists and occupational therapists are specialized in providing therapy that is tailored to facilitate motor skill learning of patients with a wide range of pathologies. A substantial proportion of the patients therapists treat are older people with pathologies of the central nervous system, related to conditions such as stroke, Parkinson's disease or dementia [27]. As well as motor problems, these patients often experience problems on a cognitive level, making motor learning more difficult [28].

Some general principles of motor learning related to neural plasticity (eg, intensive and task specific training, "use it or lose it") are available for therapists to use in their practice [29,30]. These principles generally direct clinical practice in terms of what to do and how often; however, the application of these theoretical principles during daily practice often remains unclear (eg, When and how to vary between tasks? Which instructions should be given and when?).

Traditionally, therapists often use rational arguments and many verbal instructions to engage patients in motor learning [31] possibly promoting more explicit forms of motor learning. In patients with cognitive impairments, this approach is often not feasible. It remains unclear though to what extent cognitive impairments should influence the choice between more implicit and more explicit forms of learning [32].

Achieving consensus on applying motor learning is probably not realistic and maybe even not desirable, as clinical practice is complex and choices made within the motor learning process are often multi-factorial. Following a "one-size-fits-all" approach to motor learning is not possible in such a dynamic process. However, especially for less experienced therapists, it is important to have a starting point, a framework, which can help guide their practice while leaving enough space for patient tailored decision-making. The second aim of the study is therefore to explore how motor learning can be facilitated in practice and how choices for motor learning strategies can be made, particularly in people with cognitive impairments. The experiences of the experts might provide indications of how theory can be translated into practice and provide a framework to support therapists' choices for designing treatment.

The objective of this paper was to describe the design of a Delphi technique: (1) to achieve consensus on the definitions, descriptions, and taxonomy of terms related to motor learning, and (2) to explore how motor learning can be facilitated in practice and how choices within motor learning can be made, using the distinction in implicit and explicit forms of motor learning as a conceptual basis.

Method

Delphi Technique

The Delphi technique consists of a series of sequential questionnaires or "rounds" aiming to obtain the most reliable consensus of opinions from a group of experts [33]. The Delphi technique was chosen because it is useful for situations where individual opinions and knowledge are selected, compared, and combined in order to address a lack of agreement or an incomplete state of knowledge [33,34]. In this study, at least 30 experts will be invited to provide their opinion of different motor learning-related constructs. Two parallel processes will be initiated in the preparation of the actual Delphi rounds: (1) identification and invitation of experts, and (2) design of the structure and content of the questionnaires in the Delphi rounds.

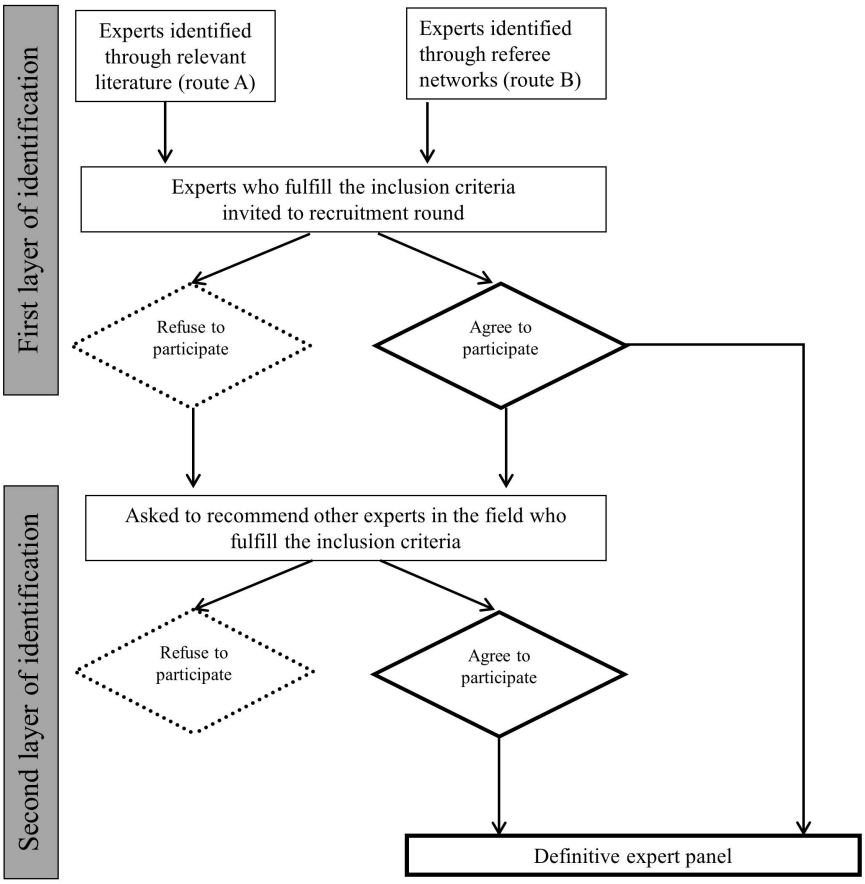
Referee Group

An international referee group, consisting of all authors of this paper, will identify and invite the experts. We will also prepare the content of the Delphi rounds and will supervise and monitor the process. We are a group of 7 researchers and 2 therapists with expertise in the field of motor learning and/or conducting the Delphi technique. Our backgrounds include epidemiology, physiotherapy, occupational therapy, movement sciences, and (sport) psychology. As members of the referee group, we will not participate in the survey.

Identification and Invitation of Experts

Heterogeneity within the expert panel is an important quality criterion [33]. We will therefore seek to include experts from different fields of motor learning. These experts should be researchers, lecturers, experienced therapists, or coaches working in the field of motor learning. Figure 1 provides an overview of how the experts will be identified and the expert panel will be composed. Experts in the field of research will be identified through a literature search (Figure 1, route A). The referee group will identify lecturers, experienced therapists, and coaches using their networks as these experts are more difficult to identify through literature (Figure 1, route B). Both routes together will be termed the *first layer of identification*. The aim of the extensive selection procedure is to create a heterogenic, international expert panel. However, it is not possible to predict to what extent we will succeed, as the expert group will be a purposive sample and not stratified on all characteristics that might be of influence.

Figure 1. Identification and composition of the expert panel.



Experts Identified From Literature (Route A)

Researchers in the field of motor learning will be identified by an extensive literature search. This search will be conducted through PubMed/Medline and PsycINFO. Several search terms will be combined, depending on the search options of the digital database. The most important search terms will be motor learning, implicit, explicit, and skill acquisition. A researcher will be defined as an expert if he/she is the first, second, or last author of at least one empirical publication in the area of motor learning. Publications can be in the field of motor learning or skill acquisition in healthy populations, sports, and rehabilitation. Experts who have only published in the field of fundamental neuroscience related to motor learning will not be invited to participate, as the focus of the Delphi study is on facilitating motor learning in clinical practice. Fundamental research will be defined as studies using only outcome measures evaluating “body function and structures”, according to the International Classification of Functioning, Disability, and Health [35].

Experts Identified From the Referee Members' Network (Route B)

Parallel to the identification through the literature search, experts with practical expertise, such as therapists, lecturers, and coaches, will be recruited from the networks of the referee group. Though somewhat arbitrary, we defined an expert as a therapists, coach, or lecturer with at least 3 years of working experience in applying motor learning in practice and involvement in education or research.

Recruitment Round

All eligible experts will be invited to participate in a recruitment round. Experts will receive an email comprising of a brief introduction of the aim and content of the survey, the amount of time to complete the questionnaires, and a personal link to open the online survey program. The aim of this recruitment round will be twofold. The first aim is to inform experts about the survey and to obtain consent for participation. Participating experts will be asked to provide detailed information on their age, background, years of experience, field of interest, working country, and current position to help to define the composition of the panel (see Multimedia Appendix 1). The second aim is to identify additional experts who were not identified through the literature and the network of the referee group members. All invited experts will be asked to recommend other experts (Figure 1, the so-called *second layer of identification*) irrespective of whether they have agreed to participate or not (ie, snow-ball sampling). They will be explicitly asked to identify expert lecturers, coaches, or therapists who fulfill the inclusion criteria, as those experts are more difficult to identify through publications. This process hopes to limit the extent to which the sample of experts is biased by the network of the referee group.

Panel Size and Composition

There are no clear guidelines for an appropriate panel size for studies using the Delphi technique and there is only limited evidence on the effect of the panel size on the validity and reliability of any consensus that is reached [34]. Therefore, in accordance with another study [36], we consider a panel size of at least 30 experts to be appropriate—approximately 10 researchers from motor learning in rehabilitation, 10 researchers from the field of motor learning in healthy individuals and sports, and 10 experts with experience in applying motor learning in practice. Although it is not possible to predict the number of experts who will be identified, agree to participate, and complete the survey, we used data from earlier studies for guidance. Based on data of a recent, Web-based Delphi study [37], it is expected that 60% of the invited experts will agree to participate, that 70% of the participants will return the first questionnaire, and 50% of the participants will complete the entire survey. Therefore, we will initially invite at least 100 experts to participate (on a voluntary basis), however no upper limit will be imposed on the number of invited experts. Experts who do not respond to the invitation will be reminded twice to do so. If experts agree to participate, they will be considered part of the definitive expert panel. Experts who agree to participate but do not respond to one of the questionnaires will be sent two reminders. As long as experts do not explicitly withdraw from participation (via mail or using a link within the survey), they will be considered part of the panel and will receive an invitation for each round. An exception will be those experts who do not respond to round one and round two. They will not be invited to the third round and will be excluded from the panel.

Design and Content of the Survey

All rounds will be designed and distributed using an online survey program (SurveyMonkey, LLC, California, USA). Figure 2 provides an overview of the process and content of the 3 rounds. In the following section, the content of the 3 rounds and the expected results is described. The description of the first round is more detailed than the second and third rounds, as the content of these rounds will mainly be based on the findings from the earlier ones. In general, the second and third round will each consist of 2 parts. In the first part, answers from the former round will be further verified and the second part will focus on new aspects.

The First Round

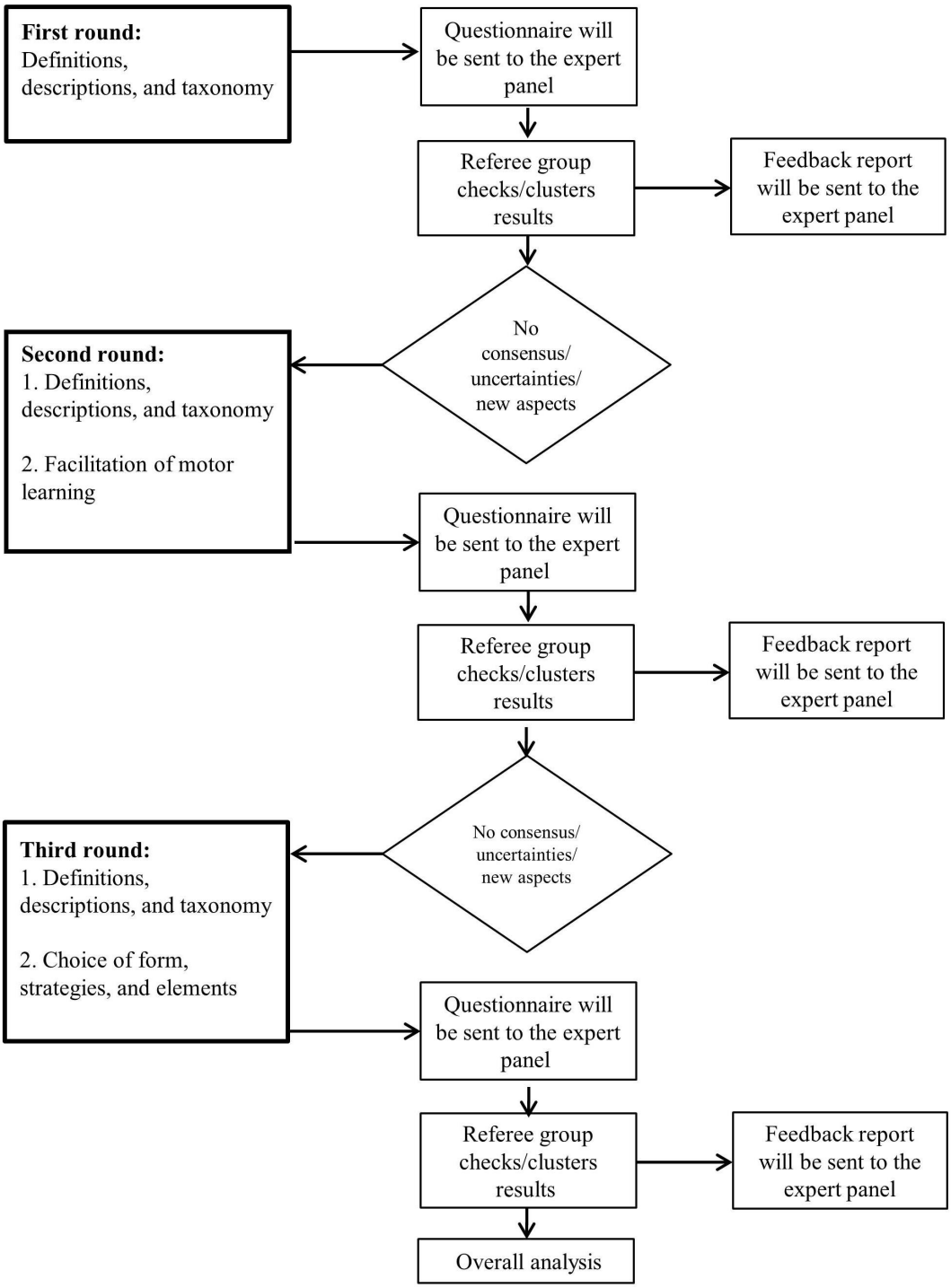
The first round will focus on the definitions, descriptions, and taxonomy of implicit and explicit forms of motor learning and a variety of motor learning strategies.

First, aspects of different definitions and descriptions for implicit and explicit motor learning that are provided in the literature will be presented. Experts will be asked to choose which of these aspects should be included in the definitions. Next, a list of strategies (eg, analogy learning, discovery learning) that are often described in the literature will be presented together with a description of each strategy. Per strategy, experts will first be asked whether they know the strategy and whether they have used the strategy in research or in practice. Experts, who stated to know the strategy, will then be asked whether they agree with the description provided. If they do not agree, they will be asked to provide arguments in an open comment box. Third, experts will be asked whether they can classify the strategy as promoting a more implicit or explicit form of motor learning.

Preliminary Data Analysis After First Round

To prepare the second round, the referee group will perform a preliminary analysis of data. Definitions of implicit and explicit motor learning will be created based on consensus from the separate definitional aspects provided in the survey. Consensus will be defined when 70% or more of the experts agree on a certain aspect. If no consensus is achieved, then percentages of agreement will be presented, however, no definitions will be formulated. Only strategies that more than 70% of the experts state to know will be taken into account in the second round (termed best-known strategies). Descriptions of those strategies will be adapted and if necessary, reformulated based on the open text comments.

Figure 2. Overview of the procedure and content of the Delphi rounds (squares=process steps; rhomboids=decision steps).



The Second Round

The aim of the second round will be twofold. First, a summary of the answers of the first round will be provided. The formulated definitions will be presented to the experts and they will be asked whether they agree with these definitions. The adapted description of the strategies will also be presented again.

The second part of the survey will focus on experts' opinions and experiences on how motor learning can be facilitated in a single therapy session. Experts will be asked to state how

instructions, feedback, and organization of the environment (so-called "elements" of motor learning) can be used to facilitate implicit and explicit learning.

Experts will be presented with a list including elements that could be used to facilitate motor learning. They will be asked whether these elements would facilitate a more implicit or a more explicit form of learning. To make answers comparable, we will mainly use multiple choice questions, however, experts will have the opportunity to comment on every question (either by using the option "other" or "open comment box"). Furthermore, we will assess how these elements relate to the motor learning strategies identified by the experts as the best-known strategies from round one.

The Third Round

If necessary, aspects for which no consensus in definitions, descriptions, and taxonomy was reached in rounds one and two will be presented again. Further, the second aim of the third round will be the identification of factors influencing and directing choices made within the motor learning process. The impact of cognitive impairments for these choices will be addressed specifically.

Data Analysis

The referee group will be unaware of the identity of expert panel members with the exception of two members of the referee group who are responsible for correspondence (MK, SB). The analysis of the responses of the experts will be processed anonymously.

The questionnaires for the 3 rounds will consist of closed/multiple choice questions and some open questions. Closed/multiple choice questions will be used if there is some knowledge available with regard to the answers (eg, from the literature or earlier survey rounds). Each closed/multiple choice question will have the option "other" or "comment" to ensure that experts can also add answers that are not listed. If little or not enough knowledge is available to pre-structure the answer options, open questions will be used. Further, open questions will be used to inventory experiences of the expert panel.

The referee group will not decide for specific aspects where no consensus is reached. They will however, choose between two different options to proceed: (1) the aspect will be presented again to the expert panel in cases where consensus is likely to be achieved in the next survey round, or (2) the variety in answers will be reported in case of very diverse answers.

The answer to all explorative questions (facilitation of motor learning in round 2, and choice of form, strategies, and elements in round 3) will be analyzed using majorities and trends (eg, ≥ 50%). Consensus is not expected for these questions as answers will be more influenced by the specific practical experience the expert has, and the target group he/she works with. Free text comments and answers from open questions will be described and if possible, clustered into themes. Quotes will be used to illustrate the main results.

Feedback Reports

After every round, a summary of the results will be sent to each member of the expert panel. The results will be clustered, but not analyzed or interpreted in detail.

Results

This study is currently ongoing. It is financially supported by Stichting Alliantie Innovatie (Innovation Alliance Foundation), RAAK-international (Registration number: 2011-3-33int).

Discussion

This paper describes the design of a study using the Delphi technique in the broad area of motor learning. To our knowledge, it is the first time that the Delphi technique has been used for this topic area. The objective of this paper was to describe the design of the Delphi technique to reach consensus on definitions, descriptions, and taxonomy used within motor learning and to explore experts' opinions and experiences on the application of motor learning in practice. However, as in any other study designs, the Delphi technique is subject to some points of consideration.

The most important advantage of using the Delphi technique is that it enables the synthesis of existing knowledge from experts with different backgrounds, including unpublished and practical expertise. In addition to gaining more insight into the definitions and taxonomy used within motor learning, the results of this study might also shed light on unresolved questions and controversial aspects within the field. A disadvantage of the Delphi technique is that the questions and answers are generally based on a theoretical, hypothetical basis. In addition, the referee group needs to have some conceptual structure in designing the survey. In this study, the distinction in implicit and explicit forms of motor learning is used, which will probably influence the line of reasoning and answers of the participants to some extent.

A well-composited expert panel is the linchpin of this study. As the scope of the Delphi topic is broad, it is important that the expert panel truly represents the available expertise on the subject. Experts from different fields of motor learning and with different backgrounds must participate in the Delphi study. As invited experts will be asked to recommend other experts, we will try to invite as broad a sample of experts as possible to prevent selection bias, however, only after the results are available can a judgment of the representativeness of the expert panel be made.

No new evidence will be generated by this study. The Delphi technique will merely be used to summarize existing knowledge and experiences regarding motor learning from experts with different backgrounds. It is therefore important that the results of this study will be considered as a starting point for future applied research. The aim of this research should be to confirm results and further explore unresolved aspects found in this study. At the same time, the available knowledge and experiences from the experts in this study can be accessed by therapists (and other users) who might find the information useful to directly support their clinical reasoning and practice.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Example from the online survey.

[PNG File, 44KB - resprot_v2i1e18_app1.png]

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Original Paper

Improving Primary Health Care in Chronic Musculoskeletal Conditions through Digital Media: The PEOPLE Meeting

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Abstract

Background: Musculoskeletal (MSK) conditions are the most common cause of severe chronic pain and disability worldwide. Despite the impact of these conditions, disparity exists in accessing high quality basic care. As a result, effective treatments do not always reach people who need services. The situation is further hampered by the current models of care that target resources to a limited area of health services (eg, joint replacement surgery), rather than the entire continuum of MSK health, which includes services provided by primary care physicians and health professionals. The use of digital media offers promising solutions to improve access to services. However, our knowledge in this field is limited. To advance the use of digital media in improving MSK care, we held a research planning meeting entitled "PEOPLE: *P*artnership to *E*nable *O*ptimal *P*rimary Health Care by *Le*veraging Digital Media in Musculoskeletal Health". This paper reports the discussion during the meeting.

Objective: The objective of this study was to: (1) identify research priorities relevant to using digital media in primary health care for enhancing MSK health, and (2) develop research collaboration among researchers, clinicians, and patient/consumer communities.

Methods: The PEOPLE meeting included 26 participants from health research, computer science/digital media, clinical communities, and patient/consumer groups. Based on consultations with each participant prior to the meeting, we chose to focus on 3 topics: (1) gaps and issues in primary health care for MSK health, (2) current application of digital media in health care, and (3) challenges to using digital media to improve MSK health in underserviced populations.

Results: The 2-day discussion led to emergence of 1 overarching question and 4 research priorities. A main research priority was to understand the characteristics of those who are not able to access preventive measures and treatment for early MSK diseases. Participants indicated that this information is necessary for tailoring digital media interventions. Other priorities included: (1) studying barriers and ethical issues associated with the use of digital media to optimize MSK health and self-management, (2) improving the design of digital media tools for providing "just-in-time" health information to patients and health professionals, and (3) advancing knowledge on the effectiveness of new and existing digital media interventions.

Conclusions: We anticipate that the results of this meeting will be a catalyst for future research projects and new cross-sector research partnerships. Our next step will be to seek feedback on the research priorities from our collaborators and other potential partners in primary health care.

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KEYWORDS

primary health care; Internet; digital media; health service delivery

Introduction

Musculoskeletal (MSK) conditions are the most common cause of severe chronic pain and disability worldwide [1-4]. Approximately 33% of adults in the United States reported having chronic joint symptoms and arthritis [5]. In Canada, arthritis alone affects 4.4 million people (age ≥ 15 years) and is projected to affect 7 million in 20 years [2]. Effective treatments are available. For example, strong evidence indicates that lifestyle interventions such as exercise [6-8], weight management [9-11], and education [12,13] can reduce pain, improve quality of life [6,14,15], and have potential to reduce the progression of joint damage in those with osteoarthritis [16]. Also, there is ample evidence supporting the early and consistent use of disease modifying medications for treating inflammatory arthritis [17-19]. However, despite the evidence, most people in Canada do not receive the basic care in a timely manner to maintain MSK health [20-22] or cannot access treatment at all [23-25]. The situation is further hampered by our current models of care that invest in a limited aspect of services provided by specialists (eg, triaging for early diagnosis of inflammatory arthritis or provision of joint replacement surgery), rather than the entire continuum of MSK health [26], which includes treatments and health promotion strategies provided by a variety of primary care health professionals [27].

The use of digital media offers promising solutions to improve access to services. Digital media, which are electronic media that operate on digital codes, offer a broad range of applications, such as social networking tools, online games, animation, interactive websites, and mobile applications. They provide tremendous flexibility for delivering health-related information at a time and place that is chosen by the individual. In the past, digital media referred to "new media" for specific applications. Today, digital media is everywhere. In contrast, our knowledge on their use in health promotion, treatment, and self-management is still in its infancy. To advance the use of digital media in improving MSK care, we held a research planning meeting on October 13-14, 2011 in Vancouver, Canada, entitled "PEOPLE: *P*artnership to *E*nable *O*ptimal *P*rimary Health Care by *Le*veraging Digital Media in Musculoskeletal Health". The purpose of this paper was to report the research priorities generated from this meeting.

Pre-meeting Consultation

The PEOPLE meeting was supported by the Canadian Institutes of Health Research (CIHR)-funded Model of Care in Arthritis Team (CIHR Funding Reference Number: EMT-92253) [28]. Twenty-six invitees, representing health and computer science disciplines, clinical communities, and patients/consumers groups participated at this meeting. All participants were considered equal contributors in discussions and the development of research priorities. Before the meeting, a series of individual consultations were held by the co-chairs (Linda Li and Aileen Davis) to learn about participants' expectations of the meeting, and their opinions regarding the use of digital media in primary health care. Comments from each participant were reviewed to develop new probing questions for subsequent consultations.

Overall, participants agreed that the meeting should focus on three areas: (1) gaps and issues in primary care for maintaining/improving MSK health, (2) successes and pitfalls of current applications of digital media in health care, and (3) challenges to using digital media for improving primary health care in underserviced populations.

PEOPLE Meeting

The PEOPLE meeting consisted of 3 sessions; each included short, thought-provoking presentations and facilitated discussions (Multimedia Appendix 1). The meeting ended with a group brainstorming on research priorities. At the start, participants agreed to adopt Health Canada's definitions of "primary care" and "primary health care". Primary care was defined as the point of first contact with the health care system. It includes "the diagnosis, treatment, and management of health problems with services delivered predominantly by physicians, but increasingly by other professionals with direct patient access" [29].

Health Canada defined primary health care as "an approach to providing health care that involves health professionals working together and delivering care within the context of the broader determinants of health of individuals and communities". As such, primary health care encompasses a range of services, "including illness prevention, health promotion, diagnosis, and management of health concerns. It encourages the use of the health professional(s) from the most appropriate health discipline(s) to maximize the potential of health resources" [30].

Session 1: Gaps and Issues in Primary Health Care for Musculoskeletal Health

The session began with a presentation on the current practice, challenges, and opportunities in MSK care (by Dr. Thea Vliet Vlieland). This talk highlighted recent research that used Web-based interventions to improve arthritis care in The Netherlands. This was followed by Ms. Simone Hughes, who shared her past experience as a person with arthritis living in a rural community, and Ms. Robin Roots, who presented her research on rural and remote rehabilitation practice. The final presentation discussed the use of digital media from a physician's perspective (by Dr. Preston Wiley). Participants were asked to reflect on 2 questions after each presentation: 1) What are the issues in primary health care that can/should be addressed by research? 2) How may digital media be applied to improve primary health care?

An issue raised during the discussion was the difficulties experienced by individuals, their families, and health professionals in accessing high quality information about the services required or available to manage MSK health. It was

suggested that in areas where there were physician shortages, nurse practitioners and advanced practice rehabilitation professionals might help to provide care and assist patients to access services. Participants also pointed out that although well-designed digital media tools could help to bridge the information gap, underserviced populations might be the least likely to know about, and have access to, computers and/or mobile devices for information. To quote one participant, "If you build it, they may not come." Therefore, a survey on how people who are currently underserviced access information would be useful.

The group also discussed challenges posed by existing computerized tools for accessing health information (ie, design issues). Participants with a computer science/design background noted that most tools in the health sector were not user friendly, and some were developed without target audiences in mind. They believed that the future digital media tools should be designed to provide customized information, taking into account users' needs and literacy levels. The group also raised concerns about accessing information using digital media portals, particularly with the growing "broadband divide" between those living in the city and those living in areas with unreliable broadband Internet access. This issue needs to be taken into consideration when designing tools to support primary health care and patient self-management in rural and remote areas.

Session 2: Current Application of Digital Media in Health Care

This session began with an overview on research that uses virtual reality, robotics, and social networking programs to manage chronic pain and anxiety disorders (by Drs. Diane Gromala and Chris Shaw). Participants also heard about the research on communication technology and health (Dr. Sherida Ryan). Dr. Ryan raised an important issue of the poor "cyber literacy" of the general population, which included not knowing how to determine the credibility of a website or how to protect one's personal information and identity on the Internet. Finally, Dr. Scott Lear shared his research on telehealth in chronic disease self-management in Northern British Columbia. Dr. Scott stressed the importance of attending to the technical issues and creating a navigation pathway for the online intervention at the start of a project.

After each presentation, participants were asked to reflect on the following question: How might digital media address issues identified in primary health care? Participants gave a few examples to illustrate how digital media could be used, including: (1) health surveillance (eg, provide monitoring and feedback to patients' health status and lifestyle behaviors, such as participation in physical activity), (2) patient-health professional communication (eg, emails, Skype), (3) record keeping and health professional communication (eg, electronic medical record), (4) access knowledge (eg, patient education websites), and (5) continuing professional development (eg, e-communities of practice). In general, participants felt that further effort would be required to assist the public in judging the credibility of online health information. During the discussion about health surveillance, the concern of "self-management overload" and "monitor burden" was voiced by several patients/consumers. There was a tension between the need for monitoring and the focus on symptoms/illness. The latter might reinforce the sickness role and could have a detrimental effect on the individual.

It was suggested that future research could explore how to use digital media tools to provide "staged information" to enhance MSK health (ie, just enough information relevant to the specific stage of the disease, rather than "too much too early"). Also suggested was the need to study the effectiveness of digital media tools for providing personalized monitoring and feedback for patients with MSK disease.

Session 3: Roles and Challenges of Using Digital Media for Improving Primary Health Care in Underserviced Populations

This session began with presentations from 3 different viewpoints on using digital media in the health sector. First, a health educator/a person living with arthritis shared her experience as a member of a primary health care team for homeless people and her view on using online and mobile tools for providing care (Ms. Louise Crane). Next, a computer scientist, Ms. Meehae Song, presented an overview of new digital media technologies for the health sector, especially for marginalized populations (eg, people living in poverty, sex workers). Examples included virtual reality training for chronic pain management, telemedicine, eHealth monitoring bracelets, mobile devices, and smartphone add-ons. Designers of these tools paid attention to optimizing user friendliness while minimizing costs. Finally, a medical sociologist discussed the ethical issues associated with access to technology for self-management (Dr. Anne Townsend). Central to Dr. Townsend's talk was the tension between educating people to self-manage and supporting self-management. The former was based on a health professionals' assumption that individuals lack the knowledge and skills to self-manage, and hence, need to be taught; while the latter took a patient's perspective of needing access to resources and support to manage one's health. Dr. Townsend discussed the potential ethical dilemma these different views might have on the design and implementation of digital media tools in primary health care.

Participants were asked to reflect on the following questions after the presentations: (1) What are the additional issues that need to be addressed to improve primary health care in the underserviced population? (2) What are the potential applications of digital media to improve primary health care in underserviced populations? (3) What ethical issues, which underline the use of digital media for primary health care in underserviced populations, need to be factored into future research?

A variety of topics were discussed in this session. The group began by cautioning against a narrow definition of underserviced population (eg, only focusing on those living in rural/remote areas). People who are underserviced tended to have similar characteristics. Although some demographic characteristics were well known (eg, geography, income, and education), others

such as sex/gender role, race, and access to social capital and network had not been fully explored. A better understanding of these characteristics would help further advance research in digital media and primary health care. It was agreed upon that community-based research principles should be followed when working with underserviced populations. Further, future research should take into account the lived experienced of the target populations.

Participants also discussed the current model of self-management, which was a "deficit model" [31]. This model implied that people became ill because they did something wrong, and so interventions should focus on helping them to "do the right thing". The assumption was that health professionals should help people "evolve" from a passive recipient of care to an active participant (ie, educating people how to self-manage). Yet in reality, people with chronic disease find ways to manage their conditions every day [32], and so interventions should be developed to support self-management instead. Participants felt that this was where digital media might play a role. Finally, to fully leverage the potential of new technologies, the group emphasized collaborations between the health and digital media sectors in future research.

Discussion

During the brainstorming for research priorities, an overarching question emerged: *In the pursuit to optimize MSK health, do digital media offer viable solutions to reach those who are hard to reach?* The PEOPLE meeting participants recognized that a basic challenge to providing primary health care for MSK health was the lack of access to "just-in-time" knowledge. This refers to concise knowledge that is available when and where it is needed by an individual making a treatment, clinical or policy decision, or for maintaining good health. Several research priorities were identified, including:

1. Understanding the characteristics of individuals who are underserviced.
2. Studying barriers and ethical issues associated with the use of digital media tools by underserviced populations to optimize MSK health and support self-management.
3. Identifying design issues for developing new tools/modifying existing technologies to provide "just-in-time" information for users, with attention paid to addressing health literacy and cyber literacy.
4. Increasing knowledge on the effectiveness of new and existing digital media interventions, as well as different implementation strategies.

In conclusion, the PEOPLE meeting has identified research priorities for improving primary health care in chronic MSK conditions through digital media, with the input of a variety of stakeholders. Given that the late adopters have accounted for most of the new Internet users since the late 2000s [33], digital media is not only the future, but is already present. The collaboration between health and digital media sectors is crucial to modernize primary health care for the 21st century. We anticipate that the findings from this meeting will be a catalyst for future projects and new cross-sector research partnerships, and welcome feedback on this report.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

PEOPLE meeting background.

[PPTX File, 566KB - resprot_v2i1e13_app1.pptx]

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Abbreviations

CIHR: Canadian Institutes of Health Research
MSK: musculoskeletal
PEOPLE: Partnership to Enable Optimal Primary Health Care by Leveraging Digital Media in Musculoskeletal Health

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