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Original Papers

Original Paper

Development and Usability of ADappt: Web-Based Tool to Support Clinicians, Patients, and Caregivers in the Diagnosis of Mild Cognitive Impairment and Alzheimer Disease

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Abstract

Background: As a result of advances in diagnostic testing in the field of Alzheimer disease (AD), patients are diagnosed in earlier stages of the disease, for example, in the stage of mild cognitive impairment (MCI). This poses novel challenges for a clinician during the diagnostic workup with regard to diagnostic testing itself, namely, which tests are to be performed, but also on how to engage patients in this decision and how to communicate test results. As a result, tools to support decision making and improve risk communication could be valuable for clinicians and patients.

Objective: The aim of this study was to present the design, development, and testing of a Web-based tool for clinicians in a memory clinic setting and to ascertain whether this tool can (1) facilitate the interpretation of biomarker results in individual patients with MCI regarding their risk of progression to dementia, (2) support clinicians in communicating biomarker test results and risks to MCI patients and their caregivers, and (3) support clinicians in a process of shared decision making regarding the diagnostic workup of AD.

Methods: A multiphase mixed-methods approach was used. Phase 1 consisted of a qualitative needs assessment among professionals, patients, and caregivers; phase 2, consisted of an iterative process of development and the design of the tool (ADappt); and phase 3 consisted of a quantitative and qualitative assessment of usability and acceptability of ADappt. Across these phases, co-creation was realized via a user-centered qualitative approach with clinicians, patients, and caregivers.

Results: In phase 1, clinicians indicated the need for risk calculation tools and visual aids to communicate test results to patients. Patients and caregivers expressed their needs for more specific information on their risk for developing AD and related consequences. In phase 2, we developed the content and graphical design of ADappt encompassing 3 modules: a risk calculation

tool, a risk communication tool including a summary sheet for patients and caregivers, and a conversation starter to support shared decision making regarding the diagnostic workup. In phase 3, ADappt was considered to be clear and user-friendly.

Conclusions: Clinicians in a memory clinic setting can use ADappt, a Web-based tool, developed using multiphase design and co-creation, for support that includes an individually tailored interpretation of biomarker test results, communication of test results and risks to patients and their caregivers, and shared decision making on diagnostic testing.

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KEYWORDS

Alzheimer's disease; biomarkers; decision aids; mild cognitive impairment; precision medicine; risk; shared decision making

Introduction

Dementia is a syndrome diagnosis that is used to describe decline in cognitive functioning that is severe enough to result in a loss of independence in performing everyday activities [1]. A growing proportion of individuals presenting at memory clinics do not (yet) fulfill the criteria for dementia. These individuals are labeled as having mild cognitive impairment (MCI) if cognitive impairment can be objectified [2]. In the course of 3 years, roughly half of the MCI patients develop dementia, whereas the other half remain stable or improve [3]. Therefore, the label of MCI entails a prognosis, rather than a diagnosis.

The prognosis of MCI patients depends on the etiology of the symptoms. The most common underlying cause is Alzheimer disease (AD), a neurodegenerative disease that develops gradually, with dementia as the final stage [4]. AD biomarkers, assessed through, for example, magnetic resonance imaging (MRI) or cerebrospinal fluid (CSF), reflect AD related pathological processes and can therefore provide information on the underlying cause of cognitive impairment [5]. In early stages of the disease, AD biomarkers are particularly valuable, as this information allows a more precise estimate of the patient's risk of developing dementia [6]. However, interpreting and communicating biomarker results is complex, as the understanding of probabilistic information is known to be difficult for clinicians and patients and caregivers [7]. Moreover, test results may be unclear or conflicting and thus may not always offer the certainty that clinicians, patients, and caregivers are looking for [8].

As a result, the clinician has to face a growing number of challenges during the diagnostic workup, for example, which and how many diagnostic (biomarker) tests should be performed, how much and what type of information does the patient actually want, what can we expect from a specific diagnostic test, does a patient prefer to be provided with information on the likely course of their symptoms, and how can this information best be conveyed. Given that patients may weigh potential benefits and harms of AD biomarker testing differently, considering the patients' preferences and needs are essential when making decisions for or against biomarker testing and the disclosure of results. In this situation, where an increasing number of reasonable options emerge to address the patients' situation, clinicians and patients should engage in a process of shared decision making to ensure that the decisions made best fit the individual [9]. However, in a memory clinic setting, involving patients in decision making is often limited to providing information only [9,10], and explicit risk communication about the development of dementia is barely observed in individuals with MCI. This demonstrates that there is room to support clinician-patient communication [9].

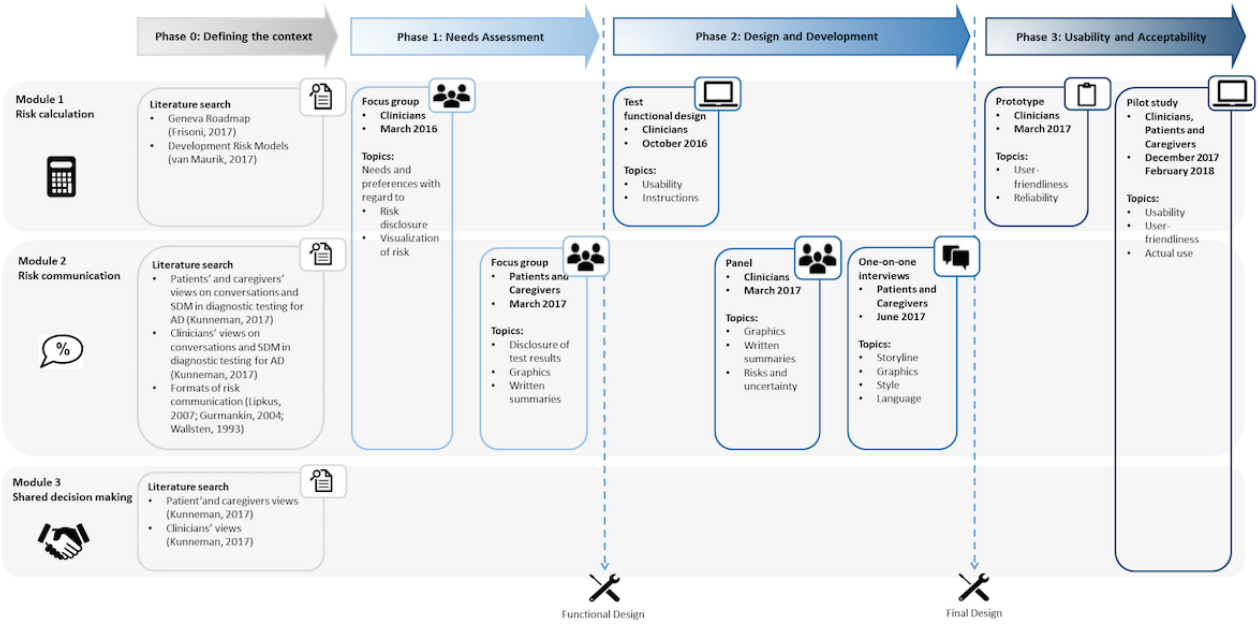
In the context of the Alzheimer Biomarkers in Daily Practice (ABIDE) project, we aimed to develop a Web-based tool for clinicians in a memory clinic setting that (1) provides personalized risk estimates of progression to dementia to aid the clinician in interpreting test results, (2) supports clinicians in communicating biomarker test results and risks to MCI patients and their caregivers, and (3) supports clinicians to engage patients in decision making regarding the diagnostic workup of AD. Following a user-centered design, this paper describes the process of development, usability, and acceptability of the Web-based diagnostic support tool named ADappt.

Methods

Study Design

This study was conducted as part of the ABIDE project, which has been funded in the context of the Dutch Deltaplan Dementia [11]. ABIDE has been designed to improve and facilitate the use and interpretation of AD biomarkers in clinical practice, taking into account patients' preferences toward diagnostic testing and communication of test results. Here, we describe the development and testing of the usability and acceptability of ADappt, a Web-based tool to support clinicians in the diagnostic process of AD in patients with MCI. The tool consists of 3 modules: (1) risk calculation: this module provides personalized risk estimates of progression to dementia to aid the clinician in interpreting test results (MRI and CSF); (2) risk communication: this module provides a summary of the biomarker results, including a graphic representation of the risk to facilitate communication of test results; (3) shared decision making: this module entails a conversation starter to support clinicians to engage patients in shared decision making regarding diagnostic testing.

Figure 1. Study overview. AD: Alzheimer disease; SDM: shared decision making.



The overall study adopted a user-centered mixed-method approach with emphasis on co-creation and was conducted in the 3 phases described in Figure 1. The board of the medical ethics review committee of the Vrije Universiteit (VU) medical center reviewed and approved this study. For each module, input and feedback of end users (professionals, patients, and caregivers) was obtained. Modules were developed in independent yet overlapping trajectories such that module 1 was developed first, closely followed by module 2. Module 3 was developed last, based on a set of earlier studies conducted in the context of the ABIDE project [9-10,12].

Thematic content analysis was used to analyze the qualitative data collected during focus groups, panels, and one-on-one interviews [13]. In total, 2 coders (IvM and LV), with a background in psychology, used an inductive approach to independently formulate lists of themes that appeared from summarized data. The themes were discussed to reach consensus.

Module 1: Risk Calculation

Phase 0: Defining the Context

In 2016, the Geneva Task Force on the roadmap of Alzheimer biomarkers published a strategic roadmap to foster the clinical validation of AD biomarkers [14]. This roadmap adopted a 5-phase approach from cancer research and dedicated 1 phase to the diagnostic and prognostic performance of biomarkers in MCI patients. Both for MRI and CSF biomarkers, evidence still appeared incomplete [15,16]. In particular, limited evidence was available on the combination of biomarkers and how they perform to predict prognosis in individual MCI patients. In a previous study, we therefore constructed individualized prediction models that provide personalized risk estimates for MCI patients, on the basis of MRI, CSF, or the combination of these 2 biomarkers based on data from the Amsterdam Dementia Cohort [6,17,18]. Probabilities (with CIs) of progression to AD dementia for 1 and 3 years of follow-up can be calculated using these models (for a detailed description see van Maurik et al [6]). These models serve as input for the risk calculation module of ADappt.

Phase 1: Needs Assessment

Focus Group Clinicians

We organized a 2-hour focus group (n=8, 7 neurologists and 1 geriatrician) led by experienced focus group leaders (RP and MK). During this focus group, we discussed the interpretation of biomarker test results and communication of results in terms of risks to patients based on 2 clinical cases that were shortly introduced. Used examples of risk visualizations were based on a commonly used format in cardiovascular risk management [19] and breast cancer therapy risks (Adjuvant! Online) [20].

Phase 2: Design and Development

Test Functional Design

A prototype of the risk calculation module (module 1) was developed from the results of phase 1. Functionality of the initial design was tested by end users in 2 rounds. In both rounds, end users were asked, via a questionnaire, if they considered the module to be logical, clear, and useful. In the first round, a neurologist, a geriatrician, and 2 researchers provided input on a preliminary design and layout (risk calculation functionality was not yet available). From their input the prototype was further developed. Next, 9 professionals (5 neurologists, 2 geriatricians, and 2 health care professionals) provided input on the prototype with a fully functioning risk calculation.

Phase 3: Usability and Acceptability

Questionnaire Feedback Prototype

During the annual Dutch Dementia Conference (Dementia Update) in 2017, the risk calculation module was presented and interested attendees were given the opportunity to try out the prototype. A total of 24 attendees (4 geriatricians, 10 neurologists, 5 with another profession [internist or nursing

home physician specialist], and 5 did not indicate their profession) provided written feedback by filling out a brief questionnaire.

Module 2: Risk Communication

Phase 0: Defining the Context

In a previous survey study [10], clinicians indicated that they find it difficult to convey MCI as a diagnosis because of the uncertainty of the diagnosis of MCI and the lack of treatment. Nonetheless, the majority of clinicians indicated to always disclose the risk of developing dementia [10]. This however does not sufficiently fulfill the information need of patients and caregivers, as patients expressed a wish for more information on the prognosis of the disease [12].

In risk communication, numeric formats are generally preferred, relative to other formats, to increase patients' understanding [7,21,22]. For example, verbal communication of risk (unlikely, possible, and rare) is vulnerable to a high degree of variability in interpretation and therefore not considered a best practice [7]. Among numeric formats, natural frequencies (20 out of 100 people similar to you) are favored over other formats (probabilities, odds, or classical probabilities), as a reference class is included that reduces misinterpretation [7,23]. A numeric format should ideally be complemented with a visual representation of risk and include a specific time frame in which an event may occur [24].

Phase 1: Needs Assessment

Focus Group Clinicians

Input from clinicians with regard to risk communication was obtained in the same focus group as described in phase 1 for module 1 (see the section above for details).

Focus Group Patients and Caregivers

A total of 4 1-hour focus groups were organized for MCI patients and were led by an experienced focus group leader (RP). A total of n=13 patients participated (3 to 4 participants per session, mean age 66 years (SD 8); 31% (4/13) female) and 63% (8/13) were accompanied by a caregiver (all partners, n=4 (50%) female). The topics that were discussed included how patients and caregivers looked back on receiving the diagnosis and test results and whether they had any recommendations for the disclosure of test results. In a second part, participants brainstormed hands-on in a paper, pencil, and scissors session on useful (graphical) summaries of test results.

Phase 2: Design and Development

Panel Clinicians

During the annual Dutch Dementia Symposium (Dementia Update) in 2017, clinicians were invited to attend a short panel discussion on their preferences about tools to support communication of test results, in terms of graphics, written summaries, and explanations of risks and uncertainty. A total of 5 clinicians attended this panel discussion and provided feedback.

Individual Interviews With Patients and Caregivers

To evaluate the first prototypes of the risk communication module, we conducted 5 interviews, each with 1 MCI patient (mean age 65 years [SD 9], n=2 (40%) female) and his or her caregiver (all partners, n=3 (60%) female). Interviews took 15 to 30 min and were conducted by the software developer to ensure that the feedback of patients was optimally used to improve this module (co-creation). Patients were presented with an example of the module, in which the diagnostic test results of a fictive case of a man or woman of 60 years were displayed, and patients were asked for their input on the storyline, graphics, style, and the possibility to print these results.

Module 3: Shared Decision-Making Module

Phase 0/1: Defining the Context/Needs Assessment

In shared decision making, clinicians and patients work together to decide which care plan best fits with individual preferences and needs when there is more than 1 reasonable option [25,26]. In the diagnostic routine for AD, there is typically more than 1 reasonable option to choose, making this a situation where shared decision making is the preferred approach. However, in a previous study, we found that shared decision making in the memory clinic is often limited to information giving [10], and shared decision making involves the following 4 steps: (1) create choice awareness, (2) provide information, (3) explore preferences, and (4) decide together [27,28].

Phase 2: Design and Development

For each step in shared decision making, we constructed example phrases in co-creation with communication experts (LV and ES). These phrases might function as a conversation starter for clinicians to engage patients in shared decision making. To inform a patient on the possible pros and cons, we also developed a list with the example language on (dis)advantages for the following commonly used diagnostic tests: neuropsychological investigation, imaging (MRI or computer tomography [CT]), lumbar puncture, amyloid Positron Emission Tomography (PET), consultation with other specialist (neurologist, geriatrician, and psychiatrist), clinical geneticist, and awaiting policy. This list was based on the literature and expert opinions (FB and WF).

All Modules: Pilot Study in 4 Local Memory Clinics

To test the ADappt tool comprising all 3 modules, we organized a multicenter usability pilot study. Both clinicians and patients were asked for feedback in 4 local memory clinics (Reinier de Graaf Ziekenhuis, Elisabeth Tweesteden Ziekenhuis, Jeroen Bosch Ziekenhuis, and Spaarne Gasthuis) and 1 academic memory clinic (Amsterdam University Medical Center (UMC)). Participating clinicians (4 neurologists, 1 geriatrician, and 2 not specified) were asked to use the tool for a minimum of 2 weeks and a maximum of 7 weeks. One of the authors (MvB) was present in the memory clinics to assist clinicians in the first week of the pilot. Clinicians were asked to complete the System Usability Scale (SUS) after using the tool [29]. The maximum score on the SUS is 5, and a higher score indicates better usability. Technical details of the tool are summarized in Textbox 1.

Textbox 1. Technical development of the tool.

The tool was constructed as a responsive Web app, meaning that the tool is available on every device (desktop, tablet, and mobile phone) and is developed in the React framework (hypertext markup language [HTML]/cascading style sheets [CSS]/JavaScript). Hosting is managed by Acato and delivered by Oxillion. Data entered into the tool are not saved in a database to minimize privacy related issues. The tool is compatible with Internet Explorer (10 and 11), Edge (13 and 14), Firefox (50 and 51), Chrome (56 and 57), iPhone operating system (iOS) Safari (9.3 and 10), and Android browser (4.4 and 4.4.4). The tool is located at [30,31]. The risk calculator is not yet available for medical use, but a login for academic use can be provided by the authors or via the contact form on the website [30]. The tool is Conformité Européenne certified (self-certification) in the lowest risk class (B).

Results

Module 1: Risk Calculation Module

Here, we describe the results of the co-creation steps leading to the final layout of the risk calculation module shown in Figure 2.

Phase 1: Needs Assessment

Focus Group Clinicians

On reviewing the discussion on the preferences with regard to risk calculation, 3 main findings emerged (the findings and adaptations are presented in Table 1). First, clinicians preferred the reporting of percentages over a risk table or bar chart, as in the latter, the information was perceived not to be clear at one glance. Second, regarding reliability and validity; clinicians whished information about CIs and information on how the models were constructed and how they perform. Therefore, we included a link to the publication, explaining how the models were constructed. Finally, clinicians emphasized user-friendliness of the module, for example, every professional should be able to use the module.

Figure 2. Final design of the risk calculation module (module 1).Left: start page with disclaimer. Middle: risk calculation module based on demographic information only (probability of AD dementia without biomarkers). As an example, we entered data of a fictional female MCI patient, age 67 years and mini mental state examination (MMSE) score of 28, resulting in a 1 year probability of progression of 13% and 3 year probability of 47%. Right: adding biomarkers for the same patient; Hippocampal atrophy (visually rated with Medial temporal lobe (MTA) atrophy scale), global cortical atrophy (GCA), Abeta, and and total tau. In this case, the normal biomarkers (the tool calculates with continuous data) resulted in a strong decrease of progression probabilities. To appreciate the change in probabilities, the tool repeats the initial risk based on demographic data at the lower part of the module.

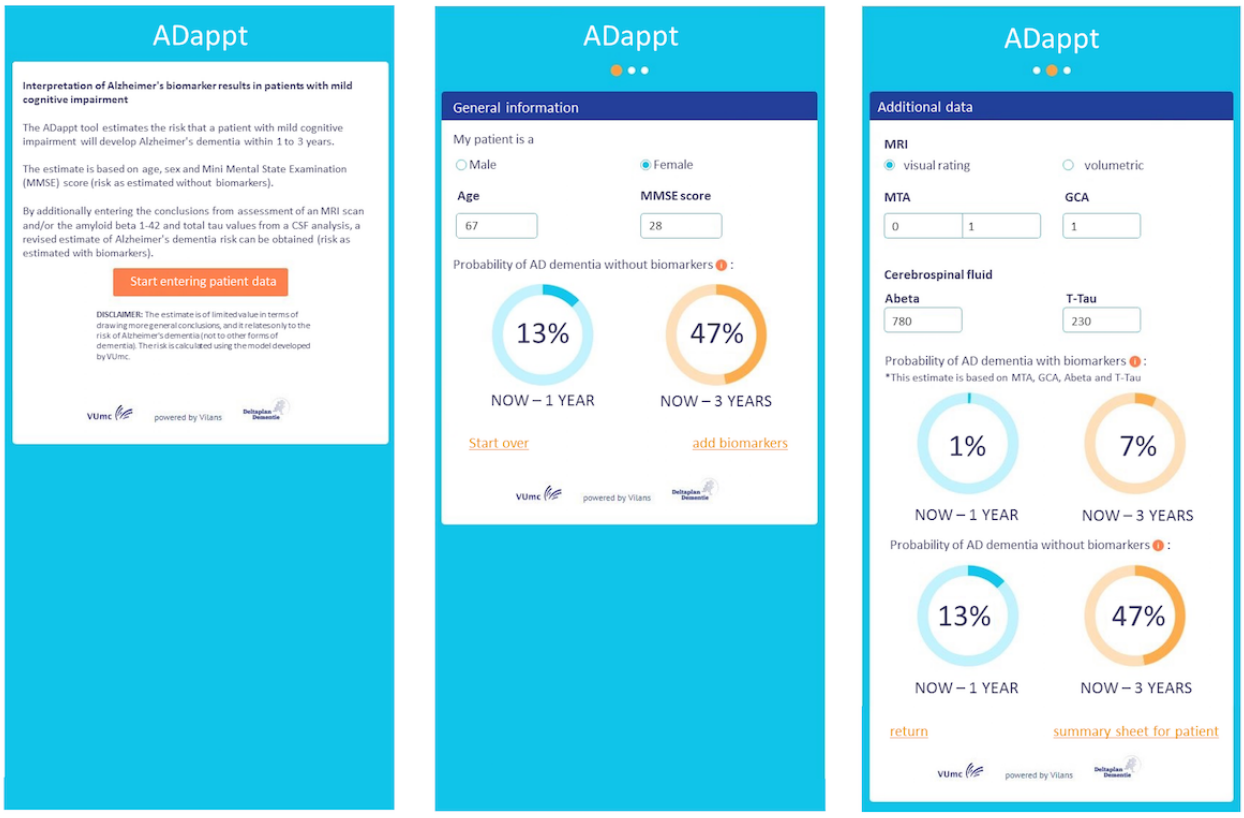


Table 1. Overview of themes for each focus group.

Group	Aim	Themes	Changes made based on the results
Focus group			
Clinicians	To explore the need for risk calculation and communication and preferences with regard to visualization	Module 1: Risk calculation. Reporting percentages is considered pleasant.; Reliability and validity; CIs should be added and it should be possible for clinicians to look up how the risk models were constructed and how they perform; The module should be user-friendly such that every professional is able to use it.; Module 2: A graphical representation of risk alone could be difficult for patients to understand and therefore would not be sufficient; Clinicians often show brain images to support the communication of test results; Clinicians provide patients with written information.	We included a link to the original paper that describes how the risk models were constructed; We accompanied the graphical presentation of risk with a textual explanation; The module allows summary sheet for patients to be printed
Patients and caregivers	To explore communication needs and to explore what kind of information should be communicated when disclosing (risk related) test results and how it should be visualized	Module 2: Risk Communication. Patients would like to know their exact progression risk. The explanation of risk should be simple. To compare their results with what is normal for their age. How should I discuss the results with family or friends?; Visualization: Patients like to see their brain images (MRI[a] or CT[b]) at home. Patients like to know which results have led to the presented risk and why. The preference for visualization of risk differs per person. How should I deal with the diagnosis? Are there things that I can do myself (lifestyle changes, tips and tricks)? Which steps do we need to take (case manager etc)?	We included an *a priori* risk as reference group for comparison purposes. The result page includes information on each diagnostic test and whether this result was abnormal. A summary is given at the end with the opportunity to include personal notes. We included 2 ways to visualize risk: a bar chart and an icon array. Users can switch between these 2
Panel			
Clinicians	To explore the preferences with regard to visualization of test results for patients	Clinicians like to communicate as *dichotomous'* as possible. However, biomarker results always have a gray area. This could be visualized by a *traffic light*; Clinicians would like to visualize risk in a line chart with time on the horizontal axes; The brain images (MRI or CT) could be visualized with a figure of the brain: normal versus atrophy; Clinicians emphasize that the module should be an aid, and that there should remain room for personal variation	We added a traffic light visualization for all diagnostic tests; An open text field provides the ability to personalize the result page based on the needs of clinicians and patients
Individual			
Interviews	To explore whether the storyline, visualization, and style of the printout page are clear	The printout contains too much and too complex information; The presentation of the *a priori* risk is confusing and sometimes daunting; Patients prefer to see their test results first followed by the risk; The graphical presentation of risk in 2 ways works well; The font is too small; The print of the results page is considered as valuable.	A total of 2 communication experts reviewed the text on understandable language; We removed the *a priori* risk from this module; We changed the flow of the printout: test results are presented first followed by risk; Colors and font were optimized

[a]MRI: magnetic resonance imaging.

[b]CT: computer tomography.

Phase 2: Design and Development

Test Functional Design

End users agreed on the proposed order and name of the tool. In general, the information in the module was considered to be clear. Suggestions for improvement included (1) a clear disclaimer that the module calculates risk of AD dementia only, (2) to use a different term instead of a priori and a posteriori risk, (3) adding value ranges, and (4) the module should also work when only CSF or MRI values were entered.

Phase 3: Usability and Acceptability

Questionnaire Feedback Prototype

The responses of the n=24 clinicians are summarized in Table 2. The applicability and user-friendliness of the module was rated highest. More than half of the respondents indicated that they would use the final version of the module in the future. The perceived reliability of the module was rated relatively low.

Table 2. Overview of first round of usability rating.

Questions	Rating
Is it clear where ADappt could be used for (rate 1-10)?	8.3
How user-friendly would you rate this tool (rate 1-10)?	8.3
How reliable would you rate ADappt (rate 1-10)?	6.4
Would you use the final version of ADappt in your daily clinical routine (% yes)?	58%

Module 2: Risk Communication Module

To facilitate explanation of the test results, we developed in co-creation (steps described below) a risk communication sheet. The final layout is shown in Figure 3. The final design of the summary sheet (module 2). Here we use the same example as in Figure 2. First, a general description of MCI is given, followed by the personalized results of this person. For each test, we give a summary of what kind of information is retrieved from the test, followed by the interpretation of the test result and how it effects the chance of AD dementia. Finally, we summarize the findings and give a verbal explanation (1 out of 100) of risk and visualization of this risk, either with an array grid or bar chart (not shown). Of note, the MRI is a stock image, not personalized.

Phase 1: Needs Assessment

Focus Group Clinicians

With regard to risk communication, clinicians mentioned that they often show brain images to patients to support communication of test results and that they provide patients with written information (findings and adaptations are presented in Table 1). In addition, clinicians confirmed that a graphical representation of risk only is not sufficient to explain a risk to patients and caregivers. Therefore, we accompanied the visual presentation of risk with a textual explanation.

Focus Group Patients and Caregivers

An important theme during the focus group with patients and caregivers was that patients would like to know their exact progression risk. Other themes with regard to risk were that explanations should be simple and that they would like to compare their results with a normal reference category. In addition, patients indicated to struggle with how they should communicate their diagnosis and test results with family and friends (Table 1). In terms of visualization, patients preferred to see their own brain images. However, in view of ever-more complicated privacy regulations, we decided not to include this in the summary sheet. Patients would also like to know how the test results contributed to the presented risk. Individual differences emerged with regard to the preference for the visualization of risk (bar chart or icon arrays). Therefore, we decided to incorporate both options in the module, to be used depending on patients' preference. Finally, patients and caregivers would like to be provided with information on how to handle the diagnosis, what they can do in terms of lifestyle changes and which steps they should take next (for example a case manager). As this is likely to be different for each patient, we included an open field at the end of the summary sheet that can be used by the clinician to include such information.

Phase 2: Design and Development

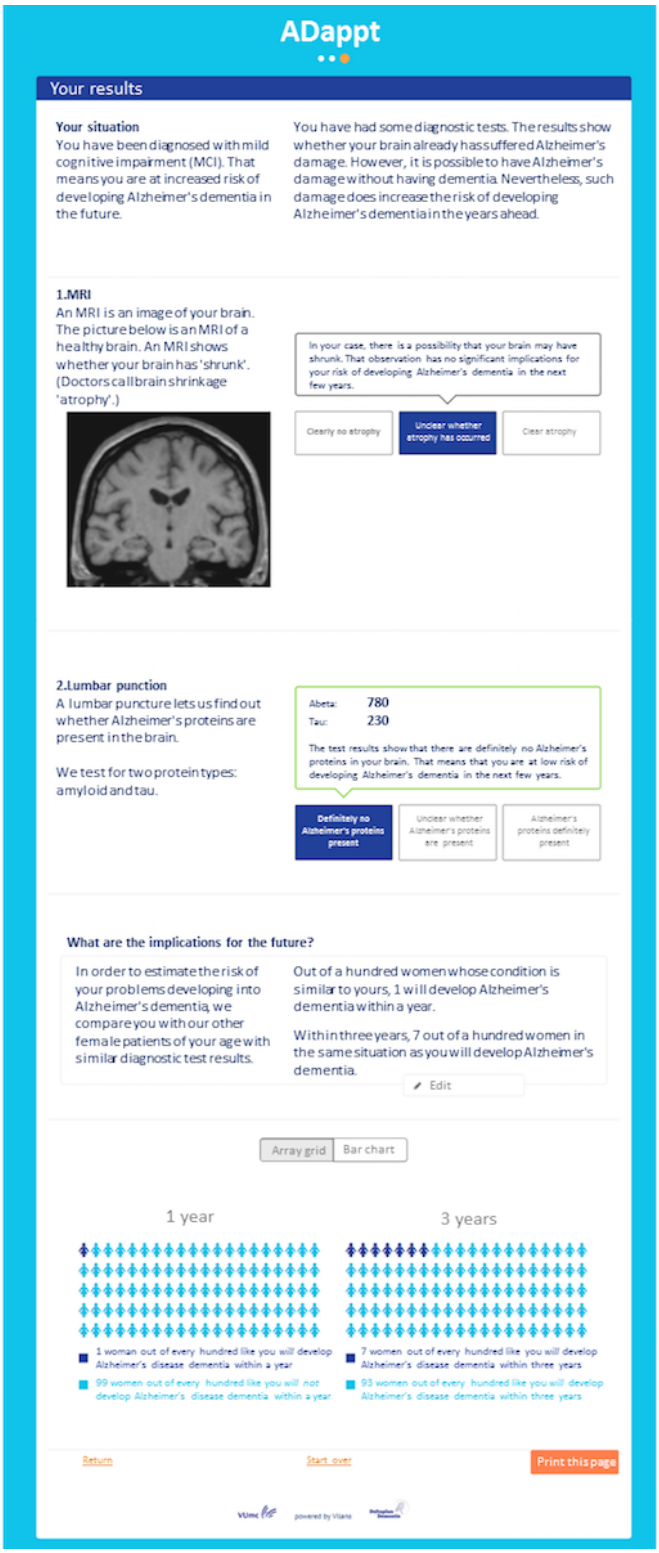
Panel Clinicians

One of the themes emerging from the panel discussion with clinicians is that they prefer to communicate test results in a dichotomous way (normal or abnormal, Table 1). However, biomarker results are originally continuous in nature, and in terms of interpretation, there is always a gray area. A possible way to visualize this is by using a traffic light. Therefore, we included a traffic light for all biomarkers on the summary sheet, with red indicating abnormal, green indicating normal, and gray indicating borderline results. As an alternative to including the MRI or CT images of patients, clinicians suggested to implement an example MRI image on the written summary for patients. For risk visualization, clinicians suggested to use a line chart with time on the horizontal axis. However, as the risk calculation module only provides valid predictions up to 3 years, a line graph might incorrectly imply that this line could be extrapolated to longer follow-up periods. For this reason, we decided not to make use of this suggestion. Instead, we included 2 options for risk visualization: a bar chart and an icon array. Finally, clinicians emphasized that the communication module should be an aid, allowing for tailoring of the communication to individual patients, rather than a strict protocol. This whish is met by providing an open text field in the summary sheet, where the clinician can add information.

Individual Interviews

During the individual interviews with patients and caregivers, the storyline of the printout was considered as too long and too complex. Therefore, 2 communication experts reviewed, optimized, and abbreviated the text (LV and ES). Moreover, we removed the a priori risk (ie, risk without biomarkers, see example in Figure 2) from the summary sheet for patients as this was experienced as confusing and sometimes daunting. Patients and caregivers only valued the probability based on the diagnostic tests. Patients would like to see their individual test results first, followed by their overall risk as a result of these individual test results. The graphical presentation of risk as either a bar chart or icon array worked well and the printout page was considered valuable. Themes and adaptations are summarized in Table 1.

Figure 3. Final design of the risk communication module (module 2). Here we use the same example as in Figure 2. First, a general description of MCI is given, followed by the personalized results of this person. For each test, we give a summary of what kind of information is retrieved from the test, followed by the interpretation of the test result and how it effects the chance of AD dementia. Finally, we summarize the findings and give a verbal explanation (1 out of 100) of risk and visualization of this risk, either with an array grid or bar chart (not shown). Of note, the MRI is a stock image, not personalized.



Module 3: Shared Decision-Making Module

Phase 2: Design and Development

Table 3 presents the conversation starter with example phrases for a clinician to engage patients and caregivers in each of the 4 steps of shared decision making (create choice awareness, provide information, explore preferences, and decide together [27,28]). In Table 4, we show example language that can be used to inform a patient on pros and cons with regard to imaging. Phrases for other diagnostic tests can be found on our website [32].

Table 3. Example phrases to start shared decision making.

Step	Aim	Example
Creating choice awareness	To make the patient aware that there is more than 1 way forward, that a decision needs to be made on whether and which diagnostic test to use, and that the best way forward depends on what matters most to the patient	"The aim is that we decide (together) which diagnostic test we will perform."
Provide information	To assess patients' preferences	"There is much to tell about the different diagnostic tests. Some patients would like to hear as much as possible, while other patients do not want to know too much. What do you prefer?"
	To inform on the different diagnostic test possibilities	"What would you like to know about the possibilities for diagnostic testing?"; or "There are 3 possibilities, namely…"
	To inform on the pros and cons in general or for a specific test	"Would you like to know more about the possible pros and cons?"
	To inform which results can be expected	"I will tell you something about the kind of results that you can expect when we perform a specific test"
Explore preferences	To explore preferences and considerations from the patient	"I have told you about the possibilities, what are your considerations?"
	To estimate the decision preferences of the patient. Does the patient want to be involved in the decision or does the patient want the clinician to decide	"Some patients would like to decide with the clinician which test to perform, while others would like the clinician to decide. What do you prefer?"
Decide	To make a shared decision; a balanced decision that both parties support, and communicate this	"We decide to do [X], because you indicated that [preferences patient]."
	To formulate an advice, in which the preferences of the patient are taken into account, and communicate this	"I propose [X], based on [preferences patient, guidelines, experience, preferences clinician]. Do you agree?"

Table 4. Example phrases for magnetic resonance imaging (MRI) and computed tomography (CT).

Reason why MRI or CT scan is suggested	Pros	Cons
"A scan of the brain is a common part of dementia diagnostics. With MRI[a] or CT[b] scan we visualize the brain. We can exclude treatable diseases. Moreover, we can view characteristics of dementia, such as shrinkage of the brain or wearing of the blood vessels."	• "Detecting treatable diseases, such as a brain tumor, brain infarct, or hemorrhage." • "Detecting characteristics of dementia." • "An MRI[a] scan shows more details than a CT[b] scan." • "A CT[b] scan is less cumbersome as the scan takes less time (10-15 min) and the CT[b] scanner is more spacious. Also, a pacemaker is not a problem."	• "A patient may not move for 30 min in the MRI[a] scanner." • "For some patients an MRI[a] scan may be an anxious experience (claustrophobia)." • "It is not always possible to perform an MRI[a], for example, if a patient has a pacemaker." • "A CT[b] scan shows les details than an MRI[a] scan."

[a]MRI: magnetic resonance imaging.

[b]CT: computer tomography.

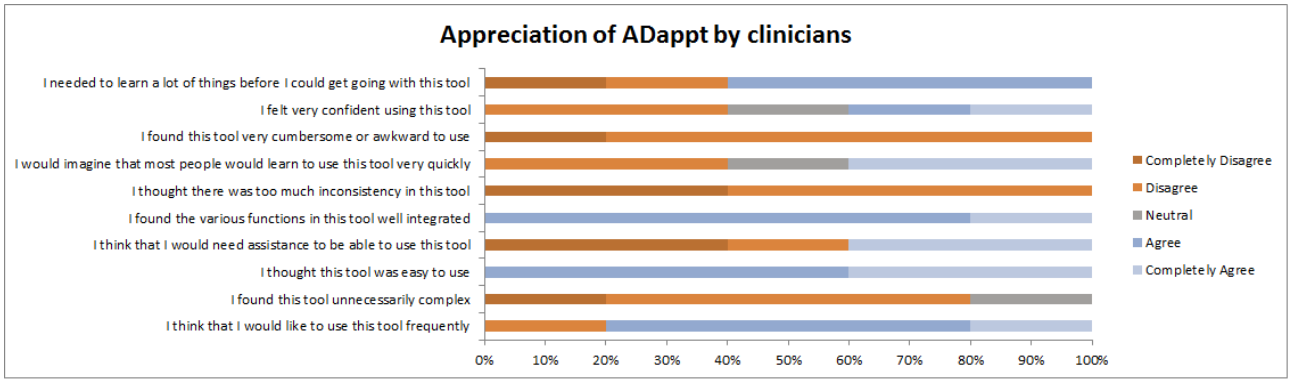
Pilot Study in 4 Local Memory Clinics

In total, 7 clinicians from 5 memory clinics commented on the ADappt tool and 5 of them completed the survey. The usability of the tool was rated with a score of SUS=4.4 (SD 0.5, max score=5; see Figure 4). Moreover, clinicians rated the tool as well integrated, easy, and consistent. A total of 3 clinicians used the tool in their daily practice, of which 1 used it on a regular basis during the pilot. Figure 1 summarizes the response frequencies of each question in the survey:

[…] it was very useful, because this patient had somewhat conflicting biomarkers, which did not point in one direction, so when using the app, it resulted in a much lower risk than that these people expected, and actually they went home very satisfied.

[…] I did use the website, but mainly the result page to provide the patient with more insight in what it could mean when it results in MCI and what the risk on dementia eventually is and that you can give them a printout to take home, that is very positively received also by the patient.

Figure 4. Overview of pilot results: responses of clinicians to each question of the system usability scale.



Clinicians experienced some technical problems while using the tool. For example, the site was blocked by the firewall in 1 of the hospitals, leading to the need to use it on a personal device. Some clinicians commented that they already feel time pressure during a consult and do not find the time to actually open the tool in the consult. A total of 4 patients (n=3 (75%) female, mean age 72 years [SD 2]) completed a short questionnaire after the consult in which the tool was used. The result page was valued as clear and useful by all. The result pages helped them to better understand the diagnosis and helped them explain the results to relatives and/or friends. These patients recommended the result page to other patients.

Discussion

This study reports the development and initial usability testing of ADappt—a Web-based tool to facilitate risk calculation and support clinician-patient risk communication and shared decision making in a memory clinic setting. We worked closely with end users, clinicians, patients, and caregivers, to identify initial requirements for the tool and make necessary changes to enhance the functionalities, usability, and information provided by the tool. Needs assessment (phase 1) uncovered the need of patients and caregivers for written summaries and information on prognosis. Clinicians expressed their need for visual aids to communicate results and prognosis. In the development phase (phase 2), we developed a risk calculation tool for clinicians and a risk communication tool (summary sheet) for patients and caregivers. In addition, a conversation starter was developed to support clinicians and patients in decision making around diagnostic testing.

Already in an early stage of usability testing (phase 3), the tool was considered clear and user-friendly, and a majority of memory clinic professionals indicated they would use such a tool in the future. However, clinicians appeared to have concerns about the reliability of the risk prediction tool. At the moment of testing, the algorithms were not yet published, and therefore a reference to a detailed description of the models was not included in the tool. To date, the module has been updated with the published algorithms [6]. For the tool to be used in real clinical practice, generalizability of prediction models in the risk calculation module is essential. Therefore, we are generating updated risk models based on data from a range of multi and monocenter cohorts and in alignment with the recently published National Institute on Aging and Alzheimer's Association (NIA-AA) criteria [5]. These updated models will be applicable to CSF biomarkers and volumetric MRI markers measured with different assays and platforms. In addition, we will add models based on amyloid PET. Another short-term update will be the translation of the tool into English.

Our small pilot study demonstrated that the tool, especially the printout page (risk communication module), was considered valuable by patients and caregivers. Although the usability of the tool was rated to be high by clinicians, only few clinicians actually used the tool in clinical practice. This was mainly due to practical reasons; clinicians experienced technical hurdles for the use of such a tool in clinical practice (eg, computers in consulting room firewalled). Despite these hurdles and that relying on computer algorithms may be counterintuitive for clinicians, experience from different disease areas shows that computer algorithms are welcome in clinical practice and are seen as the future of medicine. For example, in oncology clinicians use Adjuvant Online to calculate the risk of recurrence with and without adjuvant therapy for breast cancer patients [20]. Recently U-Prevent was introduced for clinicians to calculate cardiovascular risk and therapy benefit [33,34]. The major challenge for ADappt is its large-scale implementation. In an ideal situation, ADappt would be embedded in electronic patient file systems. Alternatively, ADappt can be used as a simple add-on help for both the clinician and patient to be quickly consulted on their mobile phone. In the short term, an e-learning could be useful to show how the clinicians can integrate the tool in their routine. Moreover, the amount of text in the tool was still experienced as a barrier by clinicians and could be further improved by using graphics instead of plain text.

The 3 modules of ADappt could aid clinicians and patients in a number of ways. In the diagnostic process for AD, it is currently not common practice to actively engage patients in diagnostic decision making [10,25]. ADappt provides a conversation starter and an overview of pros and cons per diagnostic test and could therefore help clinicians to engage patients and caregivers in diagnostic decision making [9]. In an observational study of ABIDE, we currently examine communication and decision-making processes during pre- and postdiagnostic clinician-patient encounters. This study will provide input to further improve the shared decision-making module, as soon as the results of this study become available [11].

Second, ADappt supports clinicians in the communication of test results to patients and contributes to personalized diagnostic care and harmonization of clinical practice. After diagnostic testing, the interpretation and communication of test results, especially when patients are not yet demented (ie, MCI) is not straightforward. The ADappt tool clearly shows whether a patient is unlikely to develop AD dementia in the following years and therefore could be reassured, or whether a patient is indeed likely to convert to AD dementia and should therefore be followed up, arranged care, or referred for participation in clinical trials. The importance of an appropriate diagnosis and prognosis of MCI is acknowledged in current guidelines. These guidelines state that an appropriate diagnosis of MCI is important for patients and caregivers to understand the cause of their complaints and to arrange care planning based on communicated prognostic probabilities [35]. Moreover, clear communication of the test results and the corresponding prognosis has been given high priority by patients and caregivers. Tools similar to ADappt can help in this regard. One of the strengths of this study is that we designed and co-created ADappt with the end users, that is, clinicians, patients, and caregivers in memory clinic settings, to optimize future use of the tool. Most suggestions and whishes were met in the design and development of the tool. Only 2 suggestions did not find their way into the tool immediately. First, a recurring theme was the use of CT or MRI images to support the communication of diagnosis and test results. Both clinicians and patients indicated that they would like to see a patients' CT or MRI image to be included on the summary sheet. However, this would require the summary sheet to make a link to, for example, the electronic patient file that is challenging, both from a technical and privacy perspective. As an alternative, we suggested that the clinician shows the patient their own MRI on screen in the consulting room, and we included an example MRI on the summary sheet. Second, in early phases of the development of the summary sheet, patients indicated that they would like to see their results in comparison with a reference class (ie, what is normal for my age). In the first design of the summary sheet, this reference class was presented as separate probabilities and patients could compare this with their personal risk. However, this led to confusion and patients suggested that this should be removed from the summary sheet. Another strength of the tool is its compatibility with the most recent versions of the most commonly used Web browsers and could be used on all commonly used devices (computer and mobile phone). Moreover, the tool is designed as a flexible platform with the idea that extra modules can easily be added in the future. This would also enable adding modules on lifestyle advice [36], extension to other biomarkers or settings, such as the general practitioner, or to advanced care planning.

Among the limitations is that other factors, such as cardiovascular disease on MRI, cardiovascular risk factors, and amyloid PET biomarkers are currently not accounted for in the risk prediction. Clinicians do consider these factors to be important for prognosis in risk prediction and should therefore be accounted for in the models. However, the algorithms incorporated in the tool had a different starting point—namely, how to extract maximum information from MRI and CSF biomarker values for an individual patient, given that the clinician decided to order these tests. For a user-centered development process, the number of participants in this project was adequate. However, to achieve more generalizable results with regard to implementation or cost-effectiveness, future validation should include larger samples and a different study design.

In conclusion, this study presents the first tool to support clinicians and patients in memory clinic settings with decisions on diagnostic testing, individual tailored interpretation of diagnostic test results, and communication of test results. At the moment, the tool is available for academic use only. The tool is developed in a multiphase design, where co-creation with end users was an important feature. Owing to its flexibility, it is possible to add extra modules, guidelines, or new prediction models in the future. Moreover, as the tool currently focuses on clinicians, we envision that in the future a similar platform would be valuable for patients and caregivers to facilitate them to engage in shared decision making and to aid them in managing their own health care trajectory.

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Conflicts of Interest

PS has acquired grant support (for the institution) from GE Healthcare, Danone Research, Piramal, and Merck. In the past 2 years, he has received consultancy/speaker fees (paid to the institution) from Lilly, GE Healthcare, Novartis, Sanofi, Nutricia, Probiodrug, Biogen, Roche, Avraham, and EIP Pharma. WMvdF performs contract research for Biogen MA Inc. Research programs of WMvdF have been funded by ZonMW, Health Holland, Pasman stichting, NWO, EU-FP7, EU-JPND, Alzheimer Nederland, Cardiovasculair Onderzoek Nederland, stichting Dioraphte, Gieskes-Strijbis fonds, Boehringer Ingelheim, Piramal Neuroimaging, Roche BV, Janssen Stellar, and Combinostics. All funding is paid to her institution. All other coauthors report no conflicts of interest.

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Abbreviations

ABIDE: Alzheimer biomarkers in daily practice
AD: Alzheimer disease
CSF: cerebrospinal fluid
CSS: cascading style sheets
CT: computer tomography
MCI: mild cognitive impairment
MRI: magnetic resonance imaging
PET: positron emission tomography
SUS: system usability scale

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Original Paper

Audience Response Systems and Missingness Trends: Using Interactive Polling Systems to Gather Sensitive Health Information From Youth

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Abstract

Background: The widespread availability and cost-effectiveness of new-wave software-based audience response systems (ARSs) have expanded the possibilities of collecting health data from hard-to-reach populations, including youth. However, with all survey methods, biases in the data may exist because of participant nonresponse.

Objective: The aims of this study were to (1) examine the extent to which an ARS could be used to gather health information from youths within a large-group school setting and (2) examine individual- and survey-level response biases stemming from this Web-based data collection method.

Methods: We used an ARS to deliver a mental health survey to 3418 youths in 4 high schools in the Midwestern United States. The survey contained demographic questions, depression, anxiety, and suicidality screeners, and questions about their use of offline resources (eg, parents, peers, and counselors) and Web-based resources (ie, telemental health technologies) when they faced stressful life situations. We then examined the response rates for each survey item, focusing on the individual- and survey-level characteristics that related to nonresponse.

Results: Overall, 25.39% (868/3418) of youths answered all 38 survey questions; however, missingness analyses showed that there were some survey structure factors that led to higher rates of nonresponse (eg, questions at the end of survey, sensitive questions, and questions for which precise answers were difficult to provide). There were also some personal characteristics that were associated with nonresponse (eg, not identifying as either male or female, nonwhite ethnicity, and higher levels of depression). Specifically, a multivariate model showed that male students and students who reported their gender as other had significantly higher numbers of missed items compared with female students (B=.30 and B=.47, respectively, P<.001). Similarly, nonwhite race (B=.39, P<.001) and higher depression scores (B=.39, P<.001) were positively related to the number of missing survey responses.

Conclusions: Although our methodology-focused study showed that it is possible to gather sensitive mental health data from youths in large groups using ARSs, we also suggest that these nonresponse patterns need to be considered and controlled for when using ARSs for gathering population health data.

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KEYWORDS

mental health; youth; surveys and questionnaires; health care; software

Introduction

Background

Audience response systems (ARSs) are hardware- or software-based systems that allow presenters to interact with participants in real time, with audience members responding to questions posed by the presenter on handheld devices, and, in most cases, having their anonymous answers displayed on screen to the entire audience. Early iterations of ARSs relied on "clicker" hardware, a handheld device that had to be purchased by or distributed to audience members and used radio frequencies to send responses to the presenter's computer-connected Universal Serial Bus (USB) drive. Owing to this hardware requirement, clicker systems were mainly marketed and adopted in higher educational contexts, where students would purchase the hardware and use it throughout the semester for quizzes and other class activities. However, the latest versions of ARSs (eg, Mentimeter and TurningPoint) are cloud software-based programs that allow for audience members to respond via their own connected devices, such as phones, tablets, or laptops. This transition from hardware- to software-based ARSs has increased the accessibility of these systems, expanding the possibilities of interactive education and real-time data gathering beyond traditional education environments. A notable feature of these ARSs is the confidentiality of audience members' responses [1], a feature that might be particularly beneficial when gathering data or providing education on sensitive topics [2,3]. As audience members' devices do not need to be registered (the survey is accessed via a weblink), participants can respond on provided devices or their own devices, without supplying any personal identifiers. In addition, unlike the older, hardware-based systems, the newest wave of ARSs neither have hardware costs associated with them nor do they have limits on the number of participants who can register their responses, which allows for large-scale, time- and cost-effective data gathering.

These innovations may be particularly useful to those in the health care industry, as it creates the potential to gather real-time health data on sensitive topics from a large number of participants. Indeed, there is some evidence that ARSs can be used successfully within the health care domain. In one of the first studies that employed this method, researchers used an ARS to provide information on anticoagulants to clinicians [4]. More recently, Tar-Ching et al [5] used an ARS to gather expert opinions on the barriers and priorities related to occupational health, and Toonstra et al [6] used an ARS to educate a diverse group of health care professionals on the safe rehabilitation of patients who were in intensive care units. Thus, ARSs have been used successfully for both educating health care professionals and gathering input from expert stakeholders. A study by Davis et al [7] showed that ARSs can also be used to simultaneously engage community members in health-related discussions and gather data during these health-related discussions. In their study, Davis et al [7] successfully used an ARS to educate community members and gather data about their knowledge of health disparities related to cancer.

Notably, most of the existing research on the use of ARSs within health care contexts has used adult samples, and only a few studies have focused on gathering health information from the youth. In their recent study, Gray et al [8] used an ARS to gather food intake and health (activity engagement) information from fourth- and fifth-grade children in the classrooms of 2 New York City schools. As compared with data gathered in paper-pencil surveys and data gathered 2 weeks later via the same ARS, the original data proved reliable. Meanwhile, MacGilleEathain [3] used an ARS to collect health data from secondary students in Scotland. In her study, adolescents responded to questions about sensitive topics (ie, sex and relationships), and she found the method "highly effective" (page 79) in gathering these types of data [3]. Combined, these studies suggest that ARSs can be employed successfully to gather health information within youth community settings. However, in both studies, students used clickers and not their own handheld devices, and both studies involved small groups of youths in classroom settings. Presently, there is no known research that has examined whether ARSs can be employed with youths using their own devices and in larger (nonclassroom) settings. In addition, although MacGilleEathain [3] suggested that ARSs might be used with the youth to gather data about suicidality, there is no known research that has examined the extent to which ARSs can be used successfully to gather data about sensitive mental health topics.

There is reason to believe that ARSs would be especially appealing to the youth, prompting high rates of survey response. The uptake of mobile technologies among adolescents (aged 13-17 years) in the United States is among the highest of any age cohort, with approximately two-third of the adolescents reporting that they have smartphone access (73%) and that they use social media (76%) [9]. In addition, because of their interactive features, ARSs have been lauded for their potential for audience engagement [1,4,10,11]. In support of this, a recent study comparing the effectiveness of ARSs with traditional hand raising in a classroom environment showed significant increases in student participation when using an ARS [10]. In addition, in an effort to improve end-of-semester course evaluation response rates, Turban et al [12] used an ARS and significantly improved rates from 55% with paper-based forms to 91% with ARS. Thus, the familiarity of the communication medium (ie, their own device) coupled with the anonymity and interactivity of the ARS may increase the likelihood that the youth will engage with an ARS-administered survey. However, some participants may not favor this response option. According to Almetria, Matusovich, and McCord [13], many college students prefer paper-and-pencil response options as opposed to electronic response options (eg, clickers or other software) for real-time experience surveys. In addition, Wyrick and Bond [14] found that as compared with paper-and-pencil surveys, sensitive questions delivered on the Web were 4 times more likely to be skipped by the middle and high school students in their sample. Consequently, as with other survey methods, a response bias may emerge in ARS surveys, whereby some individuals' data are not included in parts of the study, for reasons that are not random [15].

Owing to the novelty of the method, it is currently unknown whether personal characteristics predict systematic nonresponse patterns for mental health surveys administered via ARS to the youth. However, in previous research with women who had undergone breast reconstruction after mastectomy, nonwhites and those from lower socioeconomic status were less likely to complete surveys [16]. In addition, Cheung et al [17] found that youths with more mental health issues were less likely to respond to voluntary survey questions than youths with fewer mental health issues, which resulted in a sample bias that skewed health behavior prevalence data. Thus, it is possible that the same types of personal characteristics that predict complete nonresponse (eg, race and mental health issues) might also predict missingness in Web-based survey data collected via ARS. Missingness on Web-based surveys might also be related to item placement, and declining response rates over the course of surveys have been noted with ARSs [18]. Whether from audience fatigue or a decline in the novelty effect, some participants who respond in the early parts of the survey may drop out, potentially leaving a nonrepresentative sample for later questions. According to Jääskeläinen and Lagerkvist [18], who tested ARS response rates among students with introductory physics tasks, these "small drops are unimportant." However, when probing about sensitive mental health issues, this may not be true—respondents who drop out or choose not to respond over the course of a survey may be qualitatively different from those who complete the survey. This is the assertion that this study was designed to address.

Objectives

In sum, the aim of this study was to examine the extent to which an ARS could be successfully employed to gather mental health information from youths in a large nonclassroom setting, using a software-based ARS that required students to use their own handheld devices. Our metrics for successful employment included an analysis of overall response rates, as well as a missingness analysis focused on decreases in responses through the course of the survey and nonresponse based on specific demographic and sociobehavioral sample characteristics (ie, age, gender, ethnicity, and depression and anxiety screen scores).

Methods

Youth Sample Recruitment

The goal of this study was to recruit an ethnically, racially, and economically diverse sample of high school students to participate in our ARS-delivered survey. To do this, we contacted school administrators in Northeast Indiana for possible participation. A total of 4 high schools, each in a different school district, with a total of 5156 students, agreed to participate. See Table 1 for enrollment data for the participating schools from the Indiana Department of Education [19].

Table 1. Demographic characteristics of students at 4 partnering high schools.

Characteristic	High school			
	A (N=1254), %	B (N=1641), %	C (N=1267), %	D (N=994), %
Female	50.32	47.41	45.86	47.5
Male	49.68	52.59	54.14	52.5
American Indian	<1.00	<1.00	<1.00	0
Asian	<1.00	<1.00	5.52	2.9
Black	<1.00	<1.00	29.67	29.0
Hispanic	6.54	2.50	16.02	9.1
Multiracial	1.44	2.19	7.26	5.1
Native Hawaiian or Other Pacific Islander	<1.00	0	0	<1.00
White	90.19	93.78	40.81	53.8
Free/reduced price meals	37.48	35.95	67.56	62.7

Each high school's administration worked closely with our research team to plan and implement the consent process. As most high school students are minors (<18 years old), the consent process included communicating study details to parents or guardians. School administrators agreed to notify parents and guardians on our behalf through their standard means of communication. Schools used different methods to communicate with parents, including email, short message service text message, phone call, postal mail, printed paper copies sent home with students, or a combination of these. At schools for which standard communication modes included only electronic communication, printed paper forms were sent home with students for whom parental electronic communication was not established. Schools were required to communicate study details to parents at least one time and at least two weeks before the survey event date. All participating schools had existing protocols for the passive or "opt out" consent process, as they had used this method for other school-based activities. School administrators assumed responsibility for tracking those students who were not permitted to participate and providing them with an alternate activity (eg, time in the media room), using their standard procedures. On the day of the event, the high school principal was required to provide a signed, printed letter to the principal investigator, confirming that all parents had the opportunity to review the passive consent form and that all students whose parents opted out of the event had been accommodated with an alternative activity. Names of nonparticipating students and their parents were not shared with

research team members to ensure their privacy. All procedures were approved by the research institution's Institutional Review Board.

Audience Response System Survey

A multidisciplinary team of health services researchers, nurses, informaticists, and suicide prevention experts developed an age-appropriate, 38-question mental health survey embedded within a video-based program focused on mental health needs and resources. The resulting product was a survey *event*, designed to be held in a large gymnasium or assembly hall, featuring an emcee (a local celebrity), a disc jockey playing popular music, and a series of prerecorded video clips featuring teen actors giving testimonials about common adolescent stressors, describing Web-based mental health resources for the youth, and asking the survey questions. During the live event, the youths were given time to respond to each question on their own handheld device, which they were instructed to bring at least one day before the event. A total of 2 schools had school-issued devices; the other 2 schools had tablets available for students who did not have a personal device or forgot to bring one to the event. The 1-hour "Tech to Stress" event was engineered by a contracted company that assisted with technological needs alongside study staff and managed video content production. The ARS comprised a proprietary polling software running on a Structured Query Language-based platform on an individual server. An ad hoc network infrastructure was set up specifically for the event. The server was placed on a standalone Wi-Fi Protected Access-secured Wi-Fi network running dual band 802.11 N and G frequency standards. Multiple access points were deployed around the event area to maximize coverage, with extra care given to load balance the channels to avoid interference. A few of the schools turned off their regular wireless network transmissions in the area of the auditorium or gymnasium, as well as during the event, to help minimize interference. For added protection and security, the server was set on a separate subnet behind a network firewall to block access from those taking the survey from accessing the server directly and the data it contained. The students were not required to register their own devices in an identifiable way. The software assigned a random identifier to each device session in the event so that each individual's survey responses were linked to 1 random identifier. At the end of the event, the data were then exported from the server to an encrypted USB drive and completely removed from the server. After each event, the ad hoc network was dismantled, and the server no longer held any event survey data. The Parkview Health Legal Department vetted the contractor and the contractor's data security procedure. On the day of each school-wide event, students assembled into the auditorium or gymnasium, and they were given scripted instructions on how to register, connect to the polling technology, provide consent/assent, and complete demographic questions. Instructions were given on 2 video screens, and instructions were verbally given by the principal. If any of the participants had questions or technological difficulties, they were instructed to raise their hand so that study team members could assist them. Details about the "Tech to Stress Less" program are displayed in Table 2.

Table 2. Tech to Stress Less program components, description, and purpose.

Presentation step	Description	Purpose
Registration: 10 min (variable)	DJ[a] was playing music throughout. Students assembled into the auditorium or gymnasium, and they were given scripted instructions on how to register, connect to the polling technology, provide consent, and complete demographic questions. Instructions were given on 2 video screens, and instructed were verbally given by the principal. If any of the participants had questions or technological difficulties, they were instructed to raise their hand for assistance.	Obtain Consent; Provide instructions for polling procedure
Welcome: 2.5 min (variable)	DJ was playing music softly in the background throughout. Students were welcomed by a live speaker, using prescripted verbiage, who kicked off the event, followed by a high-energy musical performance, with music played by a DJ.	Promote participant engagement
Stress content: 20.75 min	Video content alternated with survey questions that participants answered with a personal device (laptop, tablet, and mobile phone). This section comprised prerecorded educational videos on stress (6.18 min) and testimonial videos of the youth talking about their stress (5.57 min), intertwined with survey questions introduced through video (9.00 min).	Presentation of adolescent stress and mental health concerns; Assess prevalence of mental health concerns
Tech content: 22.22 min	Video content alternated with survey questions that participants answered with a personal device (laptop, tablet, and mobile phone). This section comprised prerecorded informational videos on existing technologies (6.22 min), intertwined with survey questions introduced through video (16.00 min).	Educate about TMH[b]; Obtain youth ratings of TMH
Conclusion+final question: 2.5 min (variable)	Youth rated satisfaction with the event (0 to 10 scale)	Obtain ratings of event; Dismissal

[a]DJ: disc jockey.

[b]TMH: telemental health technologies.

Measures

In total, students were presented with 38 questions during this event. At the outset, students responded to 7 items to assess demographics (age, gender, and race), anxiety, and depression. *Depression and Anxiety* were measured using the Patient Health Questionnaire (PHQ)-4 [20], a validated, ultrabrief measure of depression and anxiety [20-22] that has been found to be a valid tool in the mass screening of young adults [23]. Students responded on a 4-point Likert scale (0=*not at all*, 3=*nearly every day*) about how often in the last 2 weeks they had experienced depression and anxiety symptoms. We computed scores for the subscales (depression Cronbach alpha=.76; anxiety Cronbach alpha=.82). According to the scale parameters, subscale scores from 0 to 2 are classified as normal to mild, and scores from 3 to 6 are classified as moderate to severe in their symptomology. The remaining items assessed previous mental health provider visits, suicidality (Youth Risk Behavior Surveillance System [24]; YRBSS_1 and YRBSS_2), stress, coping strategies, preferred telemental health tool features, use of telemental health tools, openness to using telemental health tools, comfort with face-to-face therapy, and satisfaction with the event. All items were closed ended. The order of questions was varied so that respondent fatigue would not unduly affect particular (later) questions. Specifically, for questions 15 to 30, the order of presentation was varied such that, for 2 schools, questions 25 to 30 were presented earlier (as questions 15 to 20), and questions 15 to 24 were presented later (as questions 21 to 30). Therefore, the question numbers listed below refer to the order in which the item was presented. However, when content was analyzed (eg, desire for anonymity), comparisons were made across different question numbers. All items are in Multimedia Appendix 1.

Data Analysis

All data were aggregated by research study personnel. Data analyses from the larger study are presented elsewhere (Toscos et al, in press). For this study, which was focused on the nuanced analysis of the ARS response rates, descriptive statistics were calculated for demographic, anxiety, and depression. PHQ scores for anxiety and depression items were dichotomized such that scores 3 and higher represented moderate-to-severe levels. Plots were constructed to show the overall percentage of missing responses per question. To examine missingness in these survey data, a count variable was created to represent the total number of missing responses for each participant. Here, a missing value was either a skipped response or, where available as an option, a “Prefer not to answer” response. In both cases, the student’s answer was coded as missing, whether it was from intentional or unintentional avoidance of answering the question. In total, 38 items comprised this count variable. A second count variable was computed to exclude the final 4 items to account for the technology issues that may have impacted response rates. Moving averages were calculated for percentage of missing responses for each set of 4 sequential questions. Moving averages were compared with individual item response rates to identify questions with higher missingness than items immediately preceding and following. In addition, as per Cameron and Trivedi [25], a generalized linear model using a negative binomial distribution was tested because of the use of count data and overdispersion. In this model, demographics, PHQ anxiety score, and PHQ depression score were entered as predicting number of missed responses. In post hoc tests, all pairwise comparisons among schools for number of missing items were conducted using Tukey adjustment for multiple comparisons. Analyses were conducted using IBM SPSS Statistics Version 24 (IBM Corp.) and SAS software 9.4. Copyright 2014 SAS Institute Inc. SAS and all other SAS Institute Inc product or service names are registered trademarks or trademarks of SAS Institute Inc, Cary, NC, USA.

Results

In total, 3418 high school students participated in the survey events. Of these, 49.56% (1694/3418) of the high school students were female, 46.84% (1601/3418) of the high school students were male, and 3.60% (123/3418) of the high school students responded “other” to gender. Mean age was 16.12 years (SD 1.22, range 13-19), and ethnicities were non-Hispanic white (60.47%, 2067/3418), black (12.96%, 443/3418), Latino (7.90%, 270/3418), Asian (2.43%, 83/3418), Native American (1.64%, 56/3418), South Asian or Indian American (0.76%, 26/3418), Middle Eastern (0.80%, 27/3418), and other or multiracial (6.85%, 234/3418); 6.03% (206/3418) of the high school students selected “prefer not to answer,” and 0.18% (6/3418) did not respond. The average PHQ depression score was 1.39 (SD 1.40), and average PHQ anxiety score was 1.63 (SD 1.51), with 23.71% (809/3412) and 30.80% (1051/3412) of the high school students meeting the minimum score for moderate-to-severe depression and anxiety, respectively. As shown in Figure 1, the number of missing responses steadily increased over the course of the survey event. To illustrate, overall missingness for Q12 was 13.63% (466/3418), overall missingness for Q23 was 20.28% (693/3418), and overall missingness for Q33 was 23.20% (793/3418). For the final item (satisfaction rating for the event) at schools 1, 2, and 4, 35.06% (905/2581) of the high school students did not respond. At school 3, percentage of missed responses was high for the final 4 items (71.09%, 595/837; 70.97%, 594/837; 71.57%, 599/837; 69.89%, 585/837) because of a technology issue. In terms of participants’ nonresponse for *specific items*, there were jumps in missingness (on the basis of difference between item moving average response rate and actual response rate, Figure 2) for the items assessing race, previous suicidality (YRBSS_2), stress, preference for learning to manage stress (q22 for schools 1, 2; q29 for schools 3, 4), and preference for anonymity if discussing problems on the Web (q26 for schools 1, 2; q31 for schools 3, 4). For these latter 2 items with high missingness, the number of missing responses was higher when the item was administered at a later point in the survey. The average number of total missed responses was 5.61 (range 0-32, SD 8.41, and n=2575), omitting school 3. Including school 3 and omitting the final 4 items involved with technology issues, total missed responses was 4.80 (range 0-33, SD 7.36). Of all participants, 86.92% (2971/3418) responded to 20 or more items, and 25.39% (868/3418) of the participants responded to all items. However, 13.08 % (447/3418) of the participants responded to 19 or fewer items. In a multivariate model, race, gender, school, and depression were significantly related to number of missed items,

whereas age and anxiety were not related to number of missed items (see Table 3). Male students and students reporting "other" gender had significantly higher numbers of missed items compared with female students. Similarly, nonwhite race and higher depression score were positively related to the number of missing survey responses.

Figure 1. High school survey nonresponse: percentage of missing responses by school (N=3418). PHQ: Patient Health Questionnaire; YRBSS: Youth Risk Behavior Surveillance System; MH-Prof: visit with Mental Health Professional.

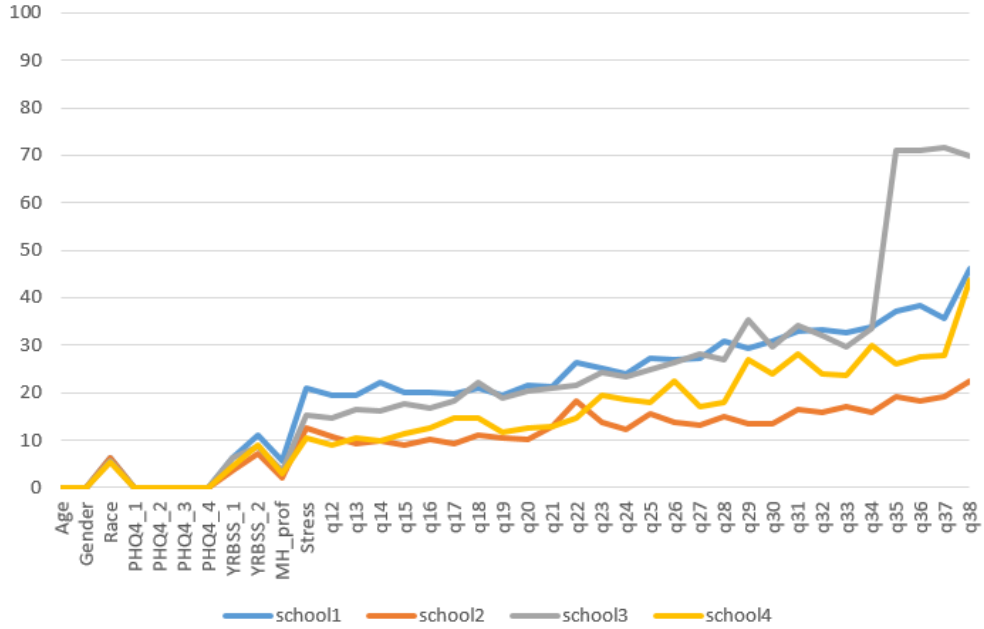


Figure 2. Percentage of missing responses and moving average of missed response percentage by item (N=3418). School 3 missing items omitted from q35 to q38 because of technology issue. PHQ: Patient Health Questionnaire; YRBSS: Youth Risk Behavior Surveillance System; MH-Prof: visit with Mental Health Professional.

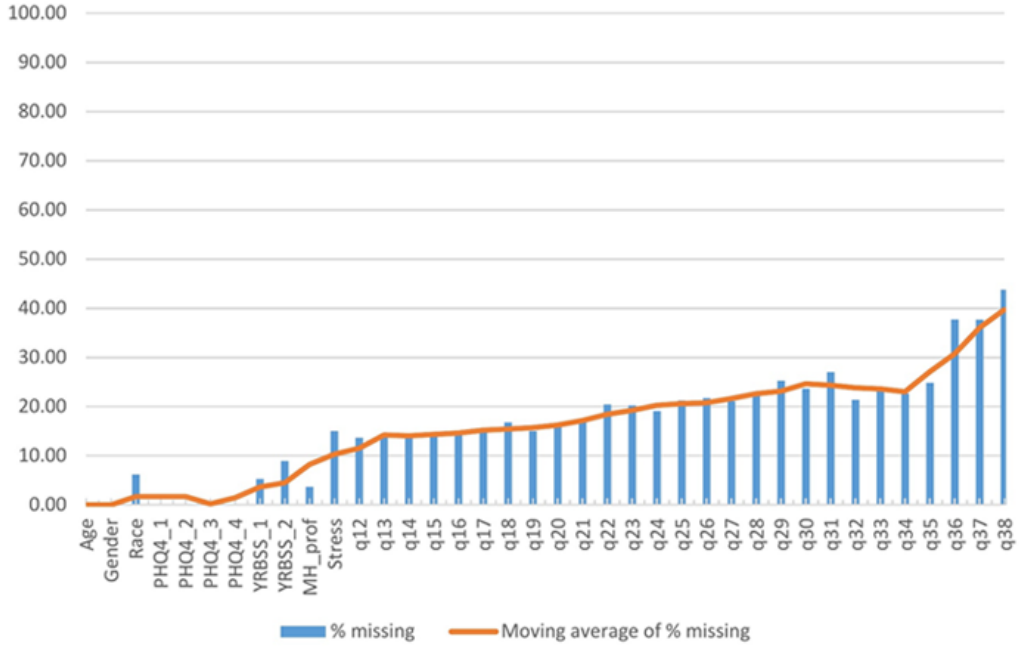


Table 3. Negative binomial generalized linear model results for combined demographics and depression score predicting number of missing items on high school survey (N=3206).

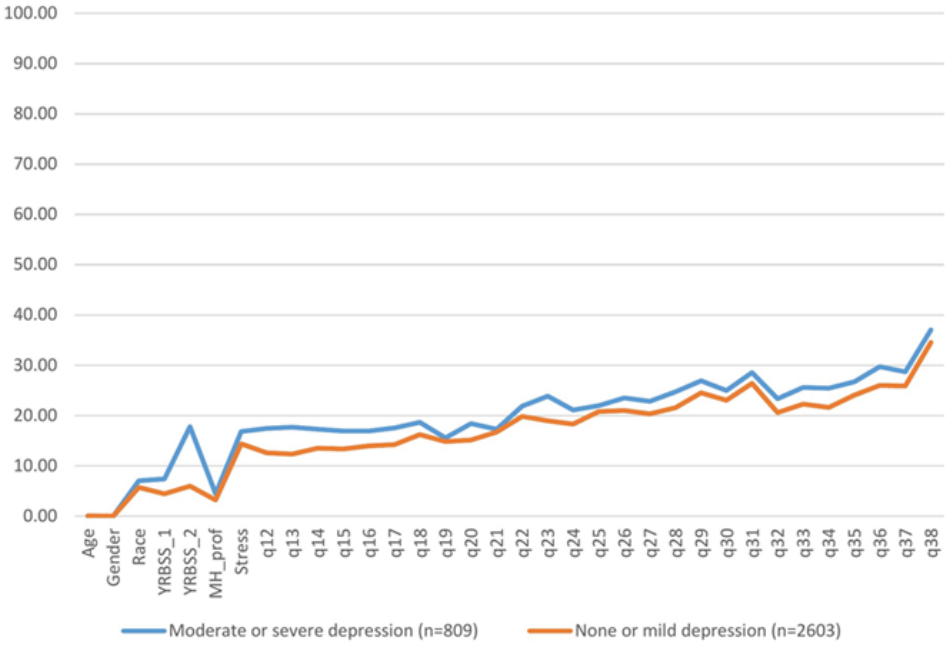
Predictor	*B* [a]	SE[b]	Wald 95% confidence limits	*P* value
Intercept	0.86	0.10	0.67, 1.04	<.001
Race (not white)	0.38	0.07	0.25, 0.52	<.001
Gender (male vs female)	0.32	0.06	0.19, 0.44	<.001
Gender (other vs female)	0.50	0.19	0.12, 0.87	.009
School (1 vs 4)	0.56	0.10	0.37, 0.75	<.001
School (2 vs 4)	–0.10	0.09	–0.29, 0.08	.27
School (3 vs 4)	0.33	0.09	0.15, 0.51	<.001
Patient Health Questionnaire depression	0.06	0.02	0.02, 0.11	.004

[a]*B*: unstandardized parameter estimate.

[b]SE: standard error.

As shown in Figure 3, the pattern of missed responses for depressed students was, although at a higher percentage, largely similar to nondepressed students, with a striking difference for the item assessing previous suicidality (YRBSS_2). In post hoc comparisons among schools on missingness, 4 of 6 comparisons were significant (school 1 vs 2: *P*<.001; school 1 vs 4: *P*<.001; school 2 vs 3: *P*<.001; school 3 vs 4: *P*=.002). However, school 1 and school 3 (*P*=.05) did not differ from one another, and school 2 and school 4 did not differ from one another (*P*=.69).

Figure 3. High school survey nonresponse: percentage of missing responses by item for depressed and nondepressed students (N=3412). School 3 missing items omitted from q35 to q38 because of technology issue. YRBSS: Youth Risk Behavior Surveillance System; MH-Prof: visit with Mental Health Professional.



Discussion

Principal Findings

A software-based ARS was successfully employed to gather mental health information from youths in a large nonclassroom setting at 4 high schools. Overall, 80% of youths responded to more than half of the survey items, and one-fourth of the youth responded to all items. This is encouraging, as it seems to be particularly challenging to gather health data from the youth. For example, in a previous study, a mailed survey to adolescents about their health needs (including depressive symptoms) yielded a 33% response rate, with only a modest improvement in response rate when phone call reminders were conducted as an additional strategy to enhance response rates [26]. Although response rate was not measured in this study (our missingness analyses included only students who logged into the system at least once), we were able to gather health data from a wide variety of youths with different socioeconomic and mental health backgrounds. There is some evidence that this can also be accomplished with paper-and-pencil surveys. The 2015 Youth Risk Behavior Surveillance survey, for example, which was administered in classrooms to students at 125 public and private high schools, boasted an 86% response rate [27]. The advantage of the ARS approach to data gathering over these

paper-and-pencil school-based collection methods is cost. Traditional research may have high costs (either financial or time or both) associated with the materials and data entry for mailed surveys, multiple waves of reminders and solicitation for electronic surveys, and outreach required to obtain large sample sizes [28]. Newer ARSs (eg, Mentimeter) have low annual fees associated with them (eg, US $100 or less), and students can connect via school (or portable) Wi-Fi or a cellular data connection. Thus, our sampling approach (surveying students en masse in a school setting) coupled with the ARS may provide a quick, relatively inexpensive data collection process for gathering data from the youth. Importantly, adolescents reported on sensitive mental health topics, demonstrating that ARS is a possible methodology for assessing these subjects. This aligns with previous research demonstrating that the privacy permitted by self-administered surveys facilitates disclosure of depressive symptoms and other nondesirable behaviors [29,30]. However, previous research has also shown that item response tends to decline over the course of ARS-delivered surveys [18], and item missingness tends to be higher for items that are too personal or intrusive [30,31]. Both of these trends held true for our sample. With regard to declining response rates, missingness increased steadily over the course of the survey: the percentage of students who skipped responses increased from a high of 17% for a question in the first half of the survey to a high of 35% for the last question of the survey. These findings emphasize the importance of item placement; critical survey items should be placed at the start of surveys when using ARSs to gather data from the youth. Additional analyses showed that some types of questions were skipped more than others, and examining the pattern of skipped responses revealed several themes. First, more sensitive questions (eg, about race, suicidality, and stress) were more likely to be skipped than the questions immediately preceding those questions, regardless of their place in the survey. This aligns with findings from Asgeirsdottir et al [30], who found, using their paper-pencil survey methods in Swedish high schools, that 10.8% of high school teens skipped questions about sexual abuse as opposed to less than 5% who skipped questions on other, less sensitive, topics (eg, family conflict, depressed mood, and anger). Kays et al [31] also found that college students were less likely to answer sensitive questions than nonsensitive questions; however, they also found that respondents were more likely to respond to sensitive questions via Web-based surveys than via the paper responses. Other spikes in nonresponse may have been because of the question requiring more cognitive effort or being a poorly constructed item (eg, preference for learning to manage stress), which resulted in more missing data when this item was administered later in the survey. Live survey administrators may want to consider giving additional prompts throughout the survey (eg, reassuring participants of their anonymity throughout or emphasizing the importance of completing sensitive questions) and increasing the specificity and relevance of items so that these spikes in missingness are minimized. The impact of adding these or other prompts on participants' response rates during live ARS surveys is a direction for future research. On an individual level, amount of missing data was related to specific demographic and sociobehavioral characteristics (ie, gender, ethnicity, and depression scores). Previous studies of nonresponse have found more nonresponse for blacks and Hispanics than whites [32,33]. This trend was also evident in our sample—on average, nonwhite students (including black and Hispanic students) skipped 17% of the items, whereas white students skipped only 11% of the items. Nonresponse rates were also related to gender: "other" selection for gender was related to the highest rates of nonresponse (27%). This finding is consistent with previous studies that have shown that males have greater levels of nonresponse than females [34,35]. Finally, depression level was related to nonresponse in our sample. A previous diary study showed that nonresponse was related to depressive symptoms, such that depressed individuals had lower compliance with multiple survey completions per day [35]. In addition, in a survey on alcohol consumption, excessive drinkers were less likely to respond to the survey [36]. Combined, these previous studies suggest that those with behaviors or symptoms that fit the stigmatized topic of interest may be less likely to respond to survey items. This was also true in our anonymous survey delivered over ARS—the interactive polling system and group survey approach did not appear to overcome these issues. With consideration for all of the individual characteristics that affected item response, statistical analyses of live survey response data need to account for these patterns of nonresponse and employ statistical corrections.

Limitations

Several limitations must be noted. First, we have limitations in the sample. Specifically, the sample included only adolescents enrolled in school, excluding home-schooled adolescents and adolescents who have dropped out, as well as students who were not present on the day the survey was administered. As previous researchers have suggested, both adolescents not enrolled in school and absent could differ from those present for the survey event [37]. In addition, some students experienced technological issues that precluded them from participating on individual questions and may have pushed them out of the survey, forcing the start of a new survey instance for some participants. For example, some students in school 1 experienced difficulty entering and remaining connected to the local Wi-Fi network, and some students in school 3 experienced technological issues that prevented them from answering the final 4 questions. These sampling issues, in addition to other malfunction issues that could have occurred without our knowledge (eg, low battery power in devices or devices freezing during survey participation), limit the generalizability of our findings. However, members of the research team noted that the technological issues appeared to be minimized in schools where students accessed the ARS survey with school-issued devices. As bring your own device (BYOD) programs gain popularity [38], researchers should explore the extent to which ARS survey responsiveness is related to whether participants use their own devices or school- or company-issued devices. It may be that those in underserved populations, who may have the greatest mental health needs, may also be the ones who do not have their own devices, prohibiting their response in a BYOD environment. This is an important issue to explore in future research. Second, some items used in the survey were researcher developed and not previously validated. As a result, item clarity or acceptability

could have influenced nonresponse rates. For example, the item "How would you most prefer to learn to manage your stress" had the response options "Learn about it in school; Ask a healthcare professional; Use as an app or website; Find other ways; Prefer not to answer." This item requires a respondent to project one's self into a hypothetical situation and select a most likely behavior from a list of predefined options. However, it is possible that all of these options were equally unappealing to the student, and as that was not an option provided, the student chose not to answer. Moreover, participants' selection of "other" gender did not clearly indicate gender identity for these students. Questions that more accurately assess gender—such as "What is your current gender identity?" and "What gender were you assigned at birth?"—as have been used in previous research [39], could be incorporated in future studies to explore this issue of gender and survey nonresponse more directly. Third, differences among schools (ie, behavioral norms, teaching atmosphere, and rural vs urban location) or survey administration events (ie, day of the week, time of year) were not considered in this research project. These unmeasured factors likely exerted some influence on missingness, as school was a significant predictor for rate of missing responses. Future research should consider environmental or contextual issues that could impact survey response rates. Fourth, it may be that some of the most vulnerable students in terms of mental health needs were not responding to survey items (either skipping or selecting "prefer not to answer"), which may bias the statistics so that the group appears more psychologically healthy than it really is. Although the anonymity of the system and ease of responding may have encouraged response for some of these individuals, the ARS does not completely eliminate this type of response bias. Future iterations of ARS research with adolescents should test ways to increase response rates in these populations, perhaps by offering these individuals more assurances of the anonymity of their data or providing other participation incentives. Finally, it is possible that the entertainment-based presentation might have motivated students to respond, which might have contributed to the high response rate. Alternatively, the videos and entertainment activities in a large-group setting may have had an opposite effect on some students, increasing rates of nonresponse or even promoting a social desirability bias in student responses, a risk that jeopardizes the validity of the main findings of the larger study. Thus, a limitation of this study is that we did not specifically ask students questions about the ARS and whether they felt the system was truly anonymous, whether our methods for data collection were engaging, or whether they felt that other methods of data gathering (eg, paper-pencil surveys or ARS in the classroom) would lead to a greater number of (or less biased) responses. Future research examining data gathering systems should focus on these points more directly. In addition, we did not ask or measure the extent to which students learned about Web-based resources for mental health (ie, content-related knowledge) from the process of participating in the ARS-delivered survey. These clarifying questions would provide helpful feedback about the best ways to introduce and use ARSs and which types of settings work best for which type of students. This is a valuable direction for future research.

Conclusions

Despite these limitations, this study demonstrated that an ARS can be used to gather sensitive mental health information from the youth, and we assert that these findings may be generalizable to different topical interests and community settings. Future research should investigate whether ARSs can be employed successfully to gather data on other health topics from adolescent samples. As software-based ARSs are beginning to emerge as cost-effective data gathering solutions outside of traditional education and business environments, there is great opportunity to further develop the methodology and data collection procedures for gathering health information from adolescents, as well as adult participants, in different types of community settings.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey items and response set.

[PDF File (Adobe PDF File), 75KB - formative_v3i3e13798_app1.pdf]

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Abbreviations

ARS: audience response system
BYOD: bring your own device
PHQ: Patient Health Questionnaire
USB: Universal Serial Bus
YRBSS: Youth Risk Behavior Surveillance System

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Original Paper

Web-Based Prescription Opioid Abuse Prevention for Adolescents: Program Development and Formative Evaluation

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Abstract

Background: The unprecedented number of youths engaged in nonmedical use of prescription opioids (POs), as well as the myriad negative consequences of such misuse, emphasizes the importance of prevention efforts targeting this public health crisis. Although there are several science-based, interactive drug abuse prevention programs focused on preventing the use of nonprescription drugs in youths, to our knowledge, there are no science-based interactive programs that focus on the prevention of PO abuse among adolescents.

Objective: The aim of this study was to develop and conduct a formative evaluation of a science-based interactive Web-based program focused on the prevention of PO abuse among adolescents aged 12 to 17 years (Pop4Teens). This study was conducted to prepare for a randomized controlled trial designed to evaluate the effectiveness of Pop4Teens compared with an active control website, JustThinkTwice.com (Drug Enforcement Administration), in impacting knowledge and attitudes about POs and perceptions of risk associated with the abuse of POs, as well as intentions to use and actual use of POs.

Methods: We conducted 6 focus groups with 30 youths (a mean of 5 per group: the eligibility being aged 12-19 years) along a continuum of exposure to POs (in treatment for opioid use disorder, in general treatment for other substance use disorder, prescribed an opioid, and opioid-naïve) and writing sessions with 30 youths in treatment for opioid use disorder (12-19 years) to inform the development of the Web-based prevention tool. Feasibility and acceptability of a prototype of the Web-based intervention were then assessed through individual feedback sessions with 57 youths (drawn from the same populations as the focus groups).

Results: We successfully completed the development of a Web-based PO abuse prevention program (Pop4Teens). Analyses of focus group transcripts informed the development of the program (eg, quiz content/format, script writing, and story editing). Selected writing session narratives anchored the planned scientific content by lending credibility and informing the development of compelling storylines intended to motivate the youth to engage with the program. Feedback session data indicated that the Web-based tool could be potentially useful and acceptable. In addition, feedback session participants demonstrated significant increases in their knowledge of key topics related to the prevention of PO abuse after the exposure to sections of the Web-based program.

Conclusions: The opioid crisis is predicted to get worse before it gets better. An effective response will likely require a multipronged strategy inclusive of effective evidence-based prevention programs acceptable to, and accessible by, a majority of youths.

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KEYWORDS

opioids; prevention and control; adolescent; randomized controlled trial; internet

Introduction

Background

Nonmedical use of prescription opioids (NMUPO) among adolescents—use of a prescription without or inconsistent with a doctor's order—is an escalating public health concern. Despite a plateauing of this type of drug use among youths in the past several years, 14.0% (2068/14,765) of a sample of high school students in a nationally representative study in 2017 endorsed lifetime misuse of prescription opioids (POs) [1]. Recent investigations underscore the gravity of the negative and potentially lifelong consequences associated with early-onset PO misuse. Strong associations between younger age of opioid initiation and heightened risk of opioid use disorders later in life have been demonstrated across a gamut of retrospective and longitudinal studies [2-4]. One study's epidemiologic calculation suggests that for roughly 8 million adolescents (12-21 years) who engaged in NMUPO between 2002 and 2013, approximately 42,000 to 58,000 met the criteria for opioid use disorder— *during each year* —within 12 months after the onset of their nonmedical use [5]. This conversion rate from experimentation to opioid use disorder reveals the addictive potential of this class of drugs. In addition, a prospective nationally representative study of high school seniors demonstrated that prescribed opioid use before high school graduation is independently associated with a 33% increase in the risk of future opioid misuse after high school. Notably, this association is concentrated among youths who had little to no history of drug use and disapproving attitudes toward illegal drug use at baseline [6].

NMUPO is also a strong predictor of heroin use onset among adolescents and young adults [4,7-9]. In a national study of youth aged 12 to 21 years, those who reported past NMUPO had a 13-fold increased risk of heroin initiation compared with those with no previous history of such use [10]. Young people who use POs nonmedically are also significantly more likely to experience major depressive episodes (MDEs) [11], as well as sexual violence [9,12], compared with their nonabusing peers.

Further underscoring the urgent need for prevention of NMUPO among the youth, recent statistics show that drug overdose is now the leading cause of death for adults aged under 45 years in the United States, driven largely by opioid-related overdoses, which accounted for most of the 63,632 lethal overdoses in 2016 (65.99% (41,997/63,632) [13,14]. Between 1999 and 2016, the drug overdose death rate increased by 268.2% among those aged 15 to 19 years (N=7,921 adolescent deaths 1999-2016) [15]. Though the effects of introducing opioids to the developing brains of adolescents may be harmful in ways that are not yet well understood, the most immediate consequences are likely to impact cognitive, social, and emotional development [16,17]. For example, some data show that treatment-seeking adolescents with opioid use disorder demonstrate working memory impairment [18], as well as daily drug using/seeking routines that leave little room for healthy social development and alternative interests [19]. In addition, in a recent study using a nationally representative dataset, youths who engaged in NMUPO were 120% more likely to experience an MDE in their lifetime [20]. The current National Institutes of Health (NIH) initiative, the Adolescent Brain Cognitive Development Study [21], designed to prospectively study the risk and protective factors influencing substance use and its consequences among a cohort of 9- to 10-year-olds (for 10 years) will likely add much to our understanding of developmental consequences. The number of youths currently engaged in NMUPO, as well as the possible consequences of such misuse, unequivocally emphasizes the importance of prevention strategies targeting this public health crisis.

Nationwide efforts to provide a comprehensive response to this crisis include the following: the development and deployment of interventions such as prescription drug monitoring programs to reduce inappropriate prescribing of opioids and enable the early identification of persons demonstrating problematic use [22], increasing the number of prescribers who receive training on pain management and safe opioid prescribing [23-25], and expanding access to abuse-deterrent formulations to discourage abuse [26]. There are also numerous efforts underway to improve access to, and insurance coverage for, evidence-based treatment for individuals with opioid use disorders [25,27]. The availability of the opioid antagonist naloxone hydrochloride (NARCAN), which reverses the potentially fatal respiratory depression caused by heroin and other opioids, is increasing among law enforcement and laypersons alike across the country [28]. However, limited attention has been given to the development of evidence-based prevention programs to deter opioid misuse among the youth. The prevention program that we have developed and plan to evaluate in an upcoming randomized controlled trial is the first of its kind, to our knowledge, as existing prevention programs do not incorporate scientific knowledge about risk factors for PO abuse.

Risk factors for PO abuse differ from other drugs/illegal drugs in significant ways: the vast majority of nonmedical PO users report obtaining these medications for the first time from friends or family [29], lowering the threshold to access in terms of both response effort and costs; the perceived risks (eg, health and legal) associated with the misuse of these medications are significantly attenuated compared with other drugs of abuse because of their prescription and approval for medical use [30,31]; and opioid prescriptions for acute pain episodes set the occasion for either the misuse of leftover medications [6,32,33] or enticement of those youths who are prescribed opioids into diverting (eg, selling, trading, and sharing) their medication for monetary or social gain [34].

Irrespective of the specific risk factors associated with the use of a particular class of drugs, effective drug abuse prevention programs generally educate the youth about how specific drugs work (mechanism of action) and typically focus on one of 2

broad categories of skill training [35]: social influences and training skills necessary to resist peer, family, media, and other social influences known to promote drug use [36] and the provision of more general skills training necessary for social competency and the ability to cope with stressful life situations [37]. Numerous qualitative and quantitative reviews of the prevention science literature have demonstrated that substance abuse prevention programs based on these approaches generally increase protective factors, reduce risk factors, and produce marked reductions in drug use among the youth [38]. In addition, programs based on social influence and general skills training models have been shown to be effective when delivered via interactive, activity-oriented programs and not traditional, didactic instructional techniques [39,40].

Digital platforms may provide a particularly appealing and effective approach for prevention efforts designed to reach adolescents. The traditional means of reaching the youth are hindered by the costs associated with teacher/clinician-delivered interventions as well as manifold issues that impede delivering interventions with fidelity. However, interventions delivered via digital platforms (eg, laptop, mobile phone, or computer) boast of benefits that have greater appeal to the youth [41], significantly reduced costs [42], standardized content delivery [42], the potential for delivery across a multitude of settings [43], and minimizing teaching and/or clinical staff burden compared with traditional methods [44]. Underscoring the opportunity afforded by digital platforms, as of 2018, 93.9% (698/743) of teens reported going on the Web daily—including 44.9% (334/743) who said they go on the Web *almost constantly*. These numbers are largely a function of mobile device usage and/or ownership with nearly 95.0% (706/743) of teens endorsing one or the other [45].

Published scientific literature on digital platforms for interventions targeting adolescent substance abuse is burgeoning [41,46].The number of publications describing technology-based substance abuse prevention programs that aim for universal application, that is, intended for all youths who endorse no past alcohol or substance use, is significantly smaller. These programs have demonstrated effectiveness in 3 contexts: primary care [47], schools [48,49], and homes [50-53]. They target the prevention of different classes of drug use, for example, alcohol [49,50,54], cannabis [49,51], and tobacco [48] and generally comprise interactive internet-based activities that function to increase drug-related knowledge and shape user attitudes and normative beliefs around substance use in ways that result in abstinence or delayed onset of use [51]. All programs referenced herein were found to be effective in reducing intentions/expectations to use and/or endorse use.

Thus, although several science-based interactive drug abuse prevention programs have been developed to prevent the use of nonprescription drugs in youths, to our knowledge, there are no published studies featuring science-based interactive programs focused on the prevention of PO abuse among adolescents. As described below, the scientific evidence underpinning the Web-based adolescent prevention program content that we described in this paper comes from the literature on computer-delivered interventions [41,55,56], computer-assisted instruction technology [57-59], and identified risk factors for PO use among the youth [5,6,8,9,30,33,60].

The data presented in this paper are from a completed Phase I of a Small Business Technology Transfer (STTR) grant from the National Institute on Drug Abuse (NIDA; R41DA023731) as well as a NIDA STTR Phase II grant (2R42DA023731–02). These efforts extend our previous study, developing and evaluating science-based digitally delivered substance abuse prevention programs for the youth, with a focused goal to prevent PO misuse among the youth.

Aims

The aim of the research reported herein was to develop and conduct a formative evaluation of a science-based Web-based interactive program focused on the prevention of PO abuse among adolescents. This program is composed of 8 modules addressing the following topics: What are POs?; misconceptions that POs are safe and nonaddictive; misconceptions that using POs without a prescription is not illegal; risks of PO misuse; nonmedication alternatives for pain management; refusing offers to misuse POs; refusing requests by others for a PO prescribed to you; and how to know if you or someone you know may be addicted. This study was conducted before conducting a randomized controlled trial to evaluate the effectiveness of the Web-based PO abuse prevention program, Pop4Teens, compared with an active control, the JustThinkTwice.com website (Drug Enforcement Administration), in impacting attitudes about, knowledge and perceptions of risk associated with the abuse of POs, as well as intentions to use and actual use of POs. The results of the randomized controlled trial will be published separately once the trial is completed.

Methods

Design

Our iterative development process spanned Phase I (when 3 modules were developed, ie, *introduction*, *what are POs*, and *misconceptions that POs are safe and nonaddictive*) and Phase II (when the remaining modules were developed—see above). We did not include the *introduction* module in the final product as it had become redundant because of the inclusion of the content of subsequent modules. These activities included the conduct of the following: 6 focus groups with youths along a continuum of exposure to POs (in treatment for opioid use disorder, in general treatment for other substance use disorder, prescribed an opioid, and opioid naïve); writing sessions with youths in treatment for opioid use disorder to inform the development of the Web-based prevention tool as well as to increase the overall credibility of the content; and one-on-one feedback sessions with youths (drawn from the same populations as the focus groups) . We conducted focus groups to help shape program content development and feedback sessions to obtain systematic feedback on the beta version of the Web-based intervention.

Participants

Participants for focus groups and individual feedback sessions were recruited from a treatment program focused on the treatment of opioid-dependent youths, a community-based

adolescent substance abuse treatment program, and the community via advertisements/flyers for Phase I and either a community hospital setting or a treatment facility for opioid-dependent adolescents and young adults for Phase II. Participants for the Phase II writing sessions were recruited exclusively from the latter. Participants in focus groups and writing and feedback sessions in both Phases I and II were compensated $30 for their time (see Table 1 for details on activities, eligibility criteria, and sample sizes).

Table 1. Overview of aims and participant activities by phase.

Small Business Technology Transfer[a] Phase – Aim	Primary aims	End user activity	Eligibility criteria	Sample size (n)
I – 1. (2010-2011)	Develop pilot content of a Web-based PO[b] abuse prevention program for High school-aged Youth	FG[c] 1	Youth 14-18: not in substance abuse treatment / opioid naive	6
		FG 2	Youth 14-18: in treatment for wider substance abuse issue	5
		FG 3 (Interview)[d]	Youth 14-18: in treatment for opioid dependence	1
		Individual feedback sessions	Youth 14-18: along a continuum of exposure to opioids (paralleling groups from FG 1, 2 and Interview)	30
II – 1. (2014-2016)	Complete development of ALL components of a Web-based PO abuse prevention program/Integrate all components into a unified, Internet-based multimedia package to be run cross-platform	FG 1	Youth 12-19[e]: in treatment for prescription opioid dependence	8
		FG 2	Youth 12-17[f]: not in substance abuse treatment/ opioid naïve	6
		FG 3	Youth 12-17: prescribed an opioid in the past year	4
		Writing sessions	Youth in treatment for opioid dependence	30
		Individual feedback sessions	Youth 12-19: along a continuum of exposure to opioids (paralleling groups from FG 4, 5 and 6)	27
II – 2. (2017-2018)	Conduct a randomized, controlled trial to evaluate the effectiveness of a Web-based PO abuse prevention program	Randomized, controlled trial	Youth 12-17, English literate, whose parents provide consent (w/ access to Internet)	400 (planned)

[a]A program that expands funding opportunities in the federal innovation research and development arena.

[b]PO: prescription opioid.

[c]FG: focus group.

[d]We were able to recruit only 1 adolescent who met the eligibility criteria and consequently conducted an in-depth interview instead of a focus group.

[e]The eligible age range was broadened for youth in treatment for PO dependence due to the fact that most youth do not enter treatment for opioid dependence before 16 years of age.

[f]The target age range for Phase I (14-18) was determined to be too old in light of scientific literature related to prescription opioid misuse among youth published between the funding of Phases I (2010) and II (2014). In the interests of (1) locating our work within the larger corpus of effective prevention efforts targeting adolescent substance abuse in general (Hale et al, 2014), (2) attending to epidemiological work (Meier et al, 2012) cautioning against designing prevention initiatives that focus on the later high school years, and (3) seeking to help youth on the younger tail of initiation of prescription opioid abuse avoid the potentially significant negative long-term consequences of early experimentation (McCabe, 2007), we adjusted the range to youth between the ages of 12-17 for Phase II.

Procedure

All relevant institutional review board approvals were obtained before the commencement of each phase of the research. Adolescents' parent/guardian provided consent for their child (if aged <18 years) and adolescents provided assent (if aged <18 years) or consent (if aged ≥18 years) to participate (with the exception of the writing session, for which we obtained a waiver of assent/consent because of its anonymity).

Focus Groups

We conducted the first series of 3 audiotaped 90-min focus groups with the youths to determine how to best present the information in the program to the target age group. The youths provided input on all aspects of the program content, including the structure and style of the program. Participants were asked to brainstorm and systematically fine-tune the various components of this program during these focus groups, which were conducted before the planned pilot program content was developed.

Focus groups were conducted in a semistructured group interview format, in which the content of the discussion was guided by a list of key topics relevant to the 3 modules developed in this phase of the development of the tool (eg, *What are POs?*; *What do you think they do?*; and *Why do you think doctors prescribe opioid medications?*). The youths were asked a series of questions regarding the extent to which the language, video, characters, graphics, and presentation style and structure to be used in presenting the desired material (described below) were (1) understandable, (2) engaging, and (3) relevant to their experience and the experience of those their age. All data obtained from focus groups were qualitative in nature and were used to shape program development in a manner that is developmentally appropriate for and acceptable to the target audience.

The second series of 3 focus group discussions (designed to inform the development of the remaining 6 modules using a similar process as described in the previous section) were structured by questions probing the following: misconceptions that using POs without a prescription is not illegal, risks of PO misuse, and how to know if *you or someone you know* is addicted (focus group 1: youths in treatment for opioid dependence); assessments of credibility and compelling nature of stories written by youths in treatment (focus group 2: opioid-naïve youths); and what teens need to know if prescribed an opioid (physical, emotional, and social effects), impact of experience on the future use of POs, and how to respond if approached to share POs (focus group 3: youths prescribed an opioid).

Writing Sessions

To strengthen the credibility of the prevention program, we recruited youths in treatment for their opioid dependence from a therapeutic substance abuse treatment center to write stories describing topics of potential interest to program users, as well as topics paralleling planned scientific content: their lives just before using POs the first time, their motivations to use POs the first time, how quickly the time elapsed between using POs the first time and then losing control of their use, their experiences of realizing that they had a problem with POs, and also, how to know if you or someone you know is addicted to POs. The need to protect the writers' anonymity constrained the content of the narratives. Treatment center staff led the writing sessions to ensure no stories revealed the identities of the authors or those of others around them. Writing sessions occurred in small groups at times that were convenient for them throughout a day of their treatment experience. They were instructed to choose a pseudonym to put at the top of their paper, along with age and race, and to tell their story *without risking the identity of friends or family members*. There were no time limits on the writing sessions other than those naturally imposed by treatment program schedules. The staff reviewed the narratives for any identifying information before sharing the anonymous files with the research team. Our team used some of these stories to anchor the Web-based program, as well as to generate scripts for actors to portray some of this content in video clips conveying planned content (eg, risks of PO use and refusing requests from others for a PO prescribed to you). Input from the focus groups, as well as the stories that best fit with the planned content (eg, risks associated with opioid misuse), was incorporated into the development of the beta version of the Web-based program.

Feedback Sessions

During the iterative development process in each phase, we also conducted one-on-one feedback sessions with the youths to (1) enable them to access the program modules on a study phone, tablet, or laptop and (2) systematically provide feedback on the beta version of the Web-based program. After completing a brief demographic form, participants completed a 2- to 5-item presession knowledge test to probe baseline familiarity with the content of the section topic to be reviewed. An example of a multiple choice question from a knowledge test is, "Prescription opioids vary in strength and the effects are 'dose related,' meaning _____."

Participants then completed the Web-based module at their own pace, answered the knowledge test items again, and completed a brief 17-item feedback survey inclusive of 12 visual analog scale (VAS) items and 5 open-ended response items. Possible values for VAS scores ranged from 0 to 100 mm and were anchored in terms of the variable of interest probed in the item. For example, for the first item—"How interesting was the section of the program you just completed?"—0 was anchored by the phrase *not interesting*, whereas 100 was anchored by *very interesting*. Most participants reviewed 2 modules in a single feedback session and completed separate pre- and postsession knowledge tests and feedback surveys for each module (see Multimedia Appendix 1 for the 17-item feedback survey).

Analysis

We transcribed the focus group audiotapes and reviewed the transcripts while listening to the audiotapes to ensure accuracy. The focus group data were thematically analyzed to inform the development of the program. For the feedback sessions, mean VAS scores were calculated for each item. Paired *t* tests were used to compare pre- and postsession knowledge test accuracy data, collapsed across modules and participants. Feedback session data were used to inform program refinement before the launch of the trial, for example, feedback on program content and interactive features.

Results

Participant Characteristics

Participants across development activities were predominantly non-Hispanic white males. Of those queried, only a small handful had previously participated in any drug prevention program geared toward POs. Of the youths in treatment for opioid dependence use disorder, the average age of first opioid use was 14.7 years (SD 1.2) for youths in focus groups and 15.75 years (SD 2.4) for youths in writing sessions and half had transitioned to heroin use before seeking help with their opioid use (see Table 2 for more detail).

Table 2. Program development participant' demographic characteristics.

Characteristic	Phase I		Phase II		
	Focus groups #1-3 (n=12)	Feedback sessions (n=30)	Focus groups #1-3 (n=18)	Feedback sessions (n=27)	Writing sessions (n=30)
Age (years), mean (SD)	16	16.53 (1.1)	16.77 (2.2)	16.37 (2.2)	21.83 (2.0)
Gender, n (%)					
Female	5 (42)	13 (43)	11 (61)	11 (41)	9 (30)
Male	7 (58)	17 (57)	7 (39)	16 (59)	21 (70)
Ethnicity, n (%)					
Non-Hispanic	—[a]	27 (90)	16 (89)	26 (96)	13 (87)[b]
Race, n (%)					
White	—	15 (50)	15 (83)	24 (88)	—
Black	—	6 (20)	—	1 (4)	—
Mixed/other	—	9 (30)	3 (17)	2 (8)	—
Previous experience w/ PO[c] Drug Prevention Program, n (%)	1 (7)	1(3)	—	1 (4)	—
Age at first PO use, mean (SD)	—	—	14.7 (1.2)[d]	—	15.75 (2.4)
Transition from PO heroin use, n (%)	—	—	6 (86)[d]	—	12 (41)

[a]Data not collected.

[b]Denominator is 15.

[c]PO: prescription opioid.

[d]Applies only to youth in focus group #1 (n=8).

Focus Groups

The first series of 3 focus groups were focused on gleaning an understanding of what the youths know about POs, as well as misconceptions that POs are safe and nonaddictive. The youths were generally very well informed about the indication for POs. However, they were equally uninformed in their assessment of their addictive potential and associated risks of overdose. Analysis of data from the second set of focus groups among the youths in treatment for opioid dependence highlighted the following themes: the latency between first use of opioids and loss of control is so brief that most youths report not even noticing (range: 3-8 months); self-medication of unwanted feelings, combined with low threshold access to prescribed medication, is the primary reason for many youths to first use POs; and POs are perceived as the second most dangerous drug (next to heroin) among the youth who have experimented with many substances. The transcript data from the second focus group of opioid naïve youths suggest that based on their reading of the stories written by the youths in treatment, they believe the program should avoid moralizing; *laundry-list-style* detailing of negative consequences; and normalizing other drug use when highlighting the severity of prescription and other opioid (eg, heroin) abuse. The analysis also suggests that the youths believe the program should include stories of how *average* kids have gotten into trouble with POs to highlight the nondiscriminatory dimension of opioid abuse among the youth (eg, a star athlete and a kid from a happy family).

Finally, the youths prescribed an opioid in the past year who participated in a focus group reviewed the refusal skill scripts drafted by research team members and provided written edits. The youths provided valuable insights on how to increase the credibility of the refusal skill script for those who may want to know how to refuse requests by others for an opioid prescribed to *you*. Specifically, the youths feel that if anyone approaches you to share or sell your prescription pain medication, the overwhelming message needs to be one of consternation and affront that someone would consider asking for something that you need to manage your injury.

Writing Sessions

The writing session stories varied in length from 2 paragraphs to 5 pages of written text, single-spaced. Members of our research team identified narratives for program inclusion by comparing rankings based on the quality of the writing, as well as the extent to which narrative content matched planned content (eg, if a youth wrote about the challenges of saying *no* when offered a Percocet, this content parallels the planned module on how to refuse offers to misuse an opioid). Once the narratives were selected, we worked with a multidisciplinary media company to audition and identify actors to read the selected youth narratives to be recorded for program inclusion.

Feedback Sessions

Each of the participants recruited for individual feedback sessions reviewed 2 modules/program sections on one of the following platforms: mobile phone, tablet, or laptop. Feedback sessions were conducted individually, such that the participants

individually interacted with the computer program. Scores indicate that participants made significant knowledge gains. For the modules developed in Phase I, the mean number of correctly answered items on the knowledge pre- and posttests was 3.65 (SD 1.46) and 4.4 (SD 0.75; t_{19}=3.866; P<.001) for youths in treatment for opioid dependence, 2.5 (SD 1.27) and 4.4 (SD 0.68; t_{19}=7.292; P<.001) for youths in general substance abuse treatment, and 3.1 (SD 0.72) and 4.4 (SD 0.75; t_{19}=5.94; P<.001) for opioid naïve youths, respectively. For the 6 modules developed in Phase II, the mean number of correctly answered items on the knowledge pre- and posttests was 3.54 (SD 0.88) and 4.0 (SD 0.78; t_{23}=−2.696; P<.05) for youths in treatment and 3.3 (SD 1.21) and 4.13 (SD 0.86; t_{29}=−5.473; P<.001), for opioid naïve youths, respectively. See Figure 1 for a review of these data in terms of percent correct in the pre- and postknowledge test. Participants also rated the program sections positively. As shown in Figure 2, several of the responses to the 12 VAS items on the feedback session survey instrument fell between 80 and 100, indicating that participants found the modules to be *easy to use*, *understandable*, and *useful as part of a drug prevention program* and they also *liked using technology* and *liked the videos*. The remaining scale scores (eg, *interesting*, *useful*, *new information*, *answer questions*, *applicable to others you know*, *comparable to other information or treatment on this topic*, and *helpful [in terms of] change[ing] behavior*) fell between 60 and 80, with the exception of 1 item that probed the applicability of the content to one's own life. This item had a mean score of 49 among opioid naïve youths (SD 27.03), which is not surprising given that the program is anchored by stories of youths in treatment for opioid dependence. In addition to the VAS items, participants were asked the following open-ended questions: "What did you like most about the program?"; "What did you like least?"; and "What suggestions might you make to improve the program?". Participants in both groups overwhelmingly liked the *stories* (eg, "I mainly liked the person story about a young adult that actually experienced an addiction problem. It makes the program more real because it is based on a real person") and *videos* (eg, "I liked the three videos I viewed because at times when they were a bit corny and funny, they got the point across in a relatable and effective way") the best. The youths in treatment ranked the stories as most preferred, and opioid naïve youths ranked the videos as most preferred but each group predominantly referenced these 2 features as the *best*. What the youths liked least was unanimous: the *quizzes* were least liked across all groups of youths (eg, "I liked the quiz the least because it kept asking the same questions"). Suggestions for improvement were largely feedback on how to improve the quizzes (eg, "Don't' time the questions" and "Make quizzes less repetitive").

Figure 1. Pre- and postknowledge test scores: Phases 1 and 2 (P1, P2).

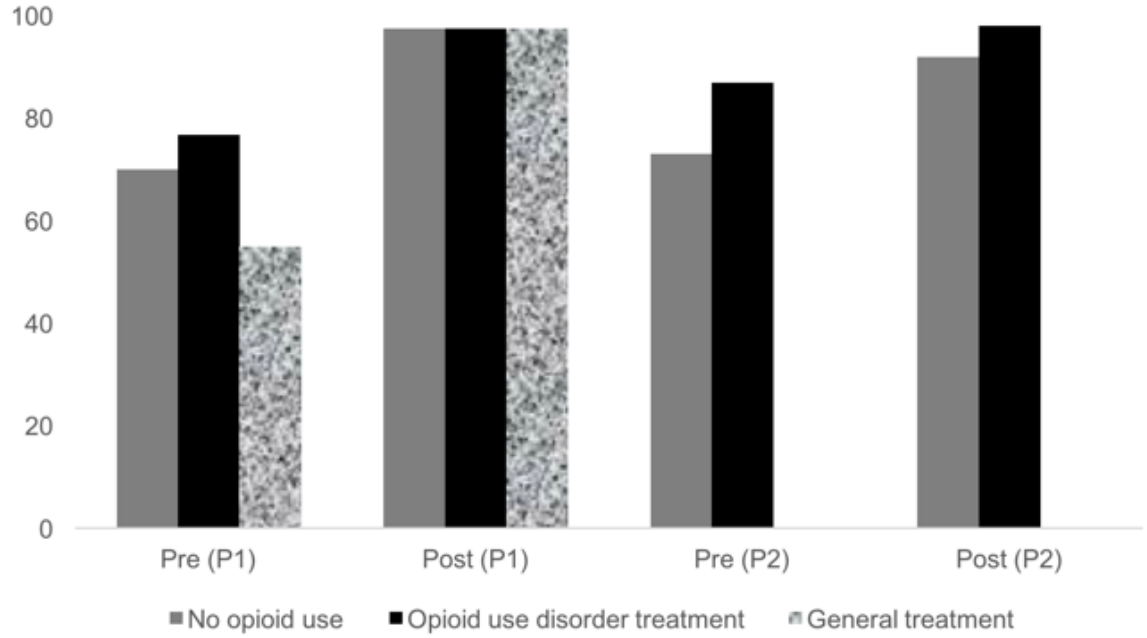
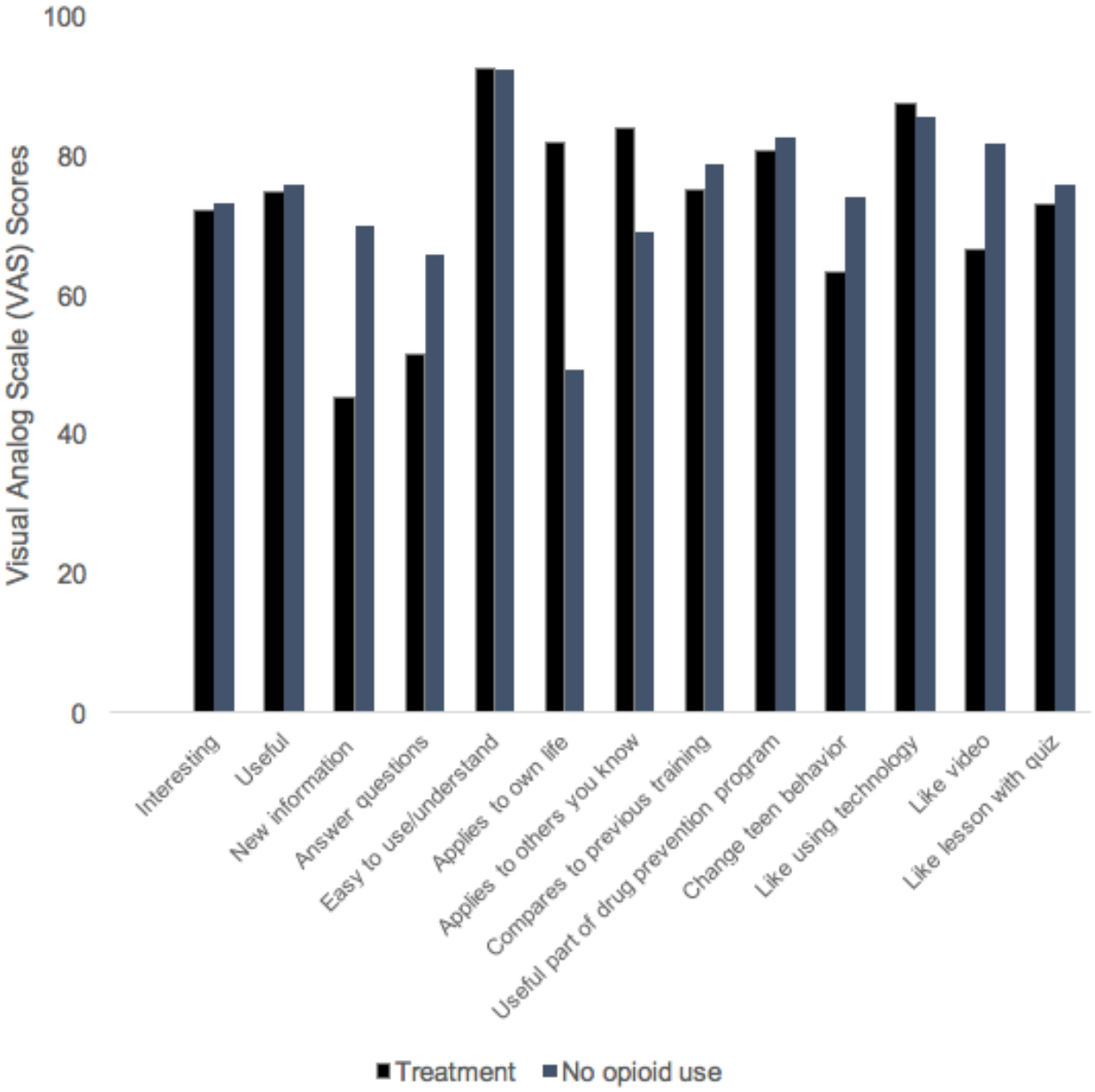


Figure 2. Feedback survey results.



Development Product: Pop4Teens Program

On the basis of the information gleaned from the development activities, our technology team completed the final version of the Web-based intervention to be run cross-platform (ie, on mobile devices, tablets, and laptops). The 4 cornerstones of the Pop4Teens program are as follows: 8 stories of real youths in treatment for opioid use disorders and their companion lessons, videos, and quizzes. The stories provide an entrée to the program and potentially strengthen the credibility and compelling nature of the content by offering real-world experiential information on motivations to use POs for the first time, how quickly the time elapses between using POs the first time and losing control of use, experiences of realizing that the youths had a problem with POs, and how to know if you or someone you know are addicted to POs (see Multimedia Appendix 2). Lessons are bullet-point scientific summaries that accompany individual stories to reinforce content (see Multimedia Appendix 3). A total of 6 short (approximately 5-min) videos were the products of scripts that we created based on planned skill-building content as well as feedback from focus group youths. Working with a multimedia production company, we auditioned and identified actors to act out 3 separate skill-based scenarios: how to refuse offers to misuse opioids, how to refuse requests by others for a PO prescribed to you, and how to nonmedically manage pain through controlled breathing and relaxation exercise. In addition, the program includes 2 informational videos (*What are prescription opioids?* and *Misconceptions that prescription opioids are safe and nonaddictive*) developed during Phase 1 of the STTR grant mechanism (see Multimedia Appendix 4). Finally, the lessons provide the source material for the quiz questions (see Multimedia Appendix 5).

Discussion

Principal Findings

Though time consuming, there is no substitute for enlisting potential end users in the development activities for Web-delivered intervention programs, for example, user-centered design [61] and behavioral science–informed user experience design [62,63]. A key element in the development of new technologies for behavior change is whether it suits its purpose and meets users' needs and expectations [64]. Through the engagement of youths along a continuum of exposure to opioids through focus groups and writing and feedback sessions, Pop4Teens reflects the perspectives of these youths with the goals of maximizing acceptability, engagement, usability, utility, relevance, credibility, and, ultimately, effectiveness in reaching program outcomes.

Focus group input helped shape the Pop4Teens program in significant ways, several of which warrant underscoring. First, the research team had chosen select stories produced by the youths (ie, youths in treatment on their loss of control) for inclusion in the program. However, after enlisting the input of opioid naïve youths on these top-ranked stories, several were swapped for alternatives that were less *laundry-listy* of negative consequences or edited to remove what opioid-using youths found to be the normalization or minimization of other drug use. Second, the importance of the input from youths who had been legitimately prescribed an opioid that directed the emotional tone of how to respond if/when a friend requests to use medication prescribed to them for an injury cannot be overstated. The participants in this focus group were unanimous in their feeling that the response needs to be one of indignation and affront because in their collective experience, most friends/acquaintances do not accept *no* for an answer and often persist in their pressure to divert medications. This information was critical in the development of the skill-based video on the same topic. Third, the pervasive input from youths in treatment for opioid use disorder on the latency between first use and loss of control of PO misuse functioned to make this a point that we highlight repeatedly in the program. The youths in this focus group wanted to make sure we conveyed strongly that these drugs are not similar to other drugs of experimentation because of their addictive potential and loss of control.

The decision to enlist youths in treatment to share their stories was based on the voluminous literature on the social learning theory [65] which suggests that behavior change resulting from interactions with peers may be more likely than interactions with others (eg, in this case, adults, experts, and scientists) because peers are perceived to be more credible role models and enhance self-efficacy. Including youths in treatment to write about their experiences of losing control of PO misuse as part of the development process ultimately served a dual purpose. On the one hand, feedback session data support the stories' inclusion to increase engagement with the program. On the other hand, the youths who provided their stories widely reported being grateful for the opportunity to turn a very dark period in their lives into something potentially positive and lifesaving for other youths. Finally, feedback session data demonstrate the promise and potential effectiveness of a Web-based approach to preventing opioid misuse among teens, given the statistically significant increases in participant knowledge between pre- and postsession module reviews as well as the overall positive assessment of the program.

The widespread use of technology among the youth highlights the important opportunities for delivering effective technology-based universal prevention interventions such as Pop4Teens to this group. Applicability of this technology-based tool may include its use across a range of settings, including primary care [48], schools [50,66,67], and individual homes [52,54,68-70]. In the primary care setting, Pop4Teens could conceivably be suggested to the youth as part of universally targeted care approaches within primary care practices across the country. For example, once a young person turns 12 years of age, the program could be part of a package of behavioral health recommendations that are considered part of the annual visit and thus recommended until the youth turns 17 years of age. In school settings, where most prevention interventions are delivered, Pop4Teens could be adopted as a stand-alone unit on POs (especially in communities hardest hit by the epidemic) or could be used in conjunction with other intervention content to expand the current drug prevention programming. Finally, the Pop4Teens tool might conceivably become a tool that parents and youths could access for free without barriers, off the internet.

Conclusions

The opioid crisis is predicted to get worse before it gets better [71]. An effective response will likely require a multipronged strategy inclusive of improved regulation and monitoring of opioid prescribing, increased support for effective nonopioid approaches to pain management, and increased availability of affordable, evidence-based treatment options for the millions of Americans battling opioid use disorders. Effective, evidence-based prevention programs to help young people steer clear of the enormous sink hole into which tens of thousands have stumbled, including those who will not emerge, and the others who struggle mightily to claw their way out are also needed. Pop4Teens is the first science-based interactive Web-based program focused on the prevention of PO abuse among adolescents. Results from an ongoing randomized controlled trial evaluating Pop4Teens will help determine whether a tool of this type is effective in the prevention of PO misuse among adolescents. We plan to publish outcome data upon completion of the trial in 2019.

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Productions for their media expertise and execution of the audio and video components of the program; Lori Loeb at Dartmouth College for helping the team conceptualize the prevention program's site architecture; and the health care team at the Center for Comprehensive Pain Management and Palliative Care at Capital Health Medical Center—serving chronic pain sufferers who are prescribed opioids—for helping begin structuring the planned content.

Authors' Contributions

LAM conceived the study and grant application and led the planning of the study. LAM, MG, and SKM participated in its design and helped draft the protocol. SKM and SS conducted focus groups and feedback sessions. LAM and SKM wrote the core content (lesson summaries, scripts, and quiz questions). MG led the computerization of the program. JB assisted with conceptualizing how to implement the recruitment and data collection for the randomized controlled trial. SB recruited participants for the randomized controlled trial and is monitoring data collection and incentive delivery. All authors read and approved the final manuscript.

Conflicts of Interest

LAM is affiliated with both HealthSim LLC (the business that received the NIH STTR grant and developed the Web-based intervention described in this paper) and Dartmouth College. This relationship is extensively managed by her academic institution, Dartmouth College.

Multimedia Appendix 1

Feedback session survey.

[DOC File, 32KB - formative_v3i3e12389_app1.doc]

Multimedia Appendix 2

Stories.

[PNG File, 144KB - formative_v3i3e12389_app2.png]

Multimedia Appendix 3

Lessons.

[PNG File, 142KB - formative_v3i3e12389_app3.png]

Multimedia Appendix 4

Videos.

[PNG File, 181KB - formative_v3i3e12389_app4.png]

Multimedia Appendix 5

Quizzes.

[PNG File, 70KB - formative_v3i3e12389_app5.png]

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Abbreviations

MDE: major depressive episode
NIDA: National Institute on Drug Abuse
NIH: National Institutes of Health
NMUPO: nonmedical use of prescription opioid
PO: prescription opioid
STTR: Small Business Technology Transfer
VAS: Visual Analog Scale

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Original Paper

A Web-Based Physical Activity Portal for Individuals Living With a Spinal Cord Injury: Qualitative Study

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Abstract

Background: The population with a spinal cord injury (SCI) largely remains inactive following discharge from rehabilitation despite evidence on the benefits of physical activity. These individuals need to develop skills to self-manage their condition in order to prevent secondary comorbidities and rehospitalization. A Web-based physical activity portal can address this need. Few Web-based interventions incorporate theoretical frameworks, behavior change techniques, and modes of delivery into their design.

Objective: This study aimed to identify the preferred features of a Web-based self-management physical activity portal through stakeholder engagement with individuals with a spinal cord injury and health care professionals (HCPs).

Methods: An interpretative phenomenology methodology and participatory design, along with an integrated knowledge translation approach, were used to conduct this study. Convenience sampling was used to recruit individuals with an SCI living in the community, who were either interested or already engaging in physical activity, and HCPs working with individuals with an SCI, from three city-based rehabilitation sites. Individual 1-hour sessions involving navigation of an existing website and a semistructured interview were conducted with all participants. Individuals with an SCI completed a demographics questionnaire prior to the individual sessions, while demographic information of the HCPs was collected during their interviews. Additionally, all participants were asked a question on their intention to use or recommend a portal. An in-depth thematic analysis was used to derive themes from participants' responses.

Results: Thirteen individuals with an SCI and nine HCPs participated in the study. Five core themes emerged: (1) knowledge: guidance and barrier management; (2) possibility of achievement: the risks and benefits of physical activity and modelling; (3) self-regulation strategies: action planning, goal setting, tracking, rewards, and reminders; (4) interactivity: peers and professionals; and (5) format: appearance, language, and ease of use. The mean (median) ratings of the likelihood of promoting and using a Web-based portal tailored to individuals' needs were 9.00 (8.78) and 7.75 (7.88) for HCPs and individuals with an SCI, respectively.

Conclusions: This study highlights features of an online self-management platform that can provide individuals with an SCI the motivation and volition to engage in physical activity. These findings will inform the design of a Web-based self-management physical activity portal to increase physical activity adherence and behavior change.

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KEYWORDS

spinal cord injuries; self-management; internet; exercise; motivation; volition

Introduction

Persons living with a chronic disability, especially those with limited mobility, are at an increased risk of developing secondary comorbidities, many of which are preventable [1]. With the rise in the prevalence of these conditions, individuals are expected to effectively manage their condition to ensure a high quality of life and longevity [2-5]. One response to this concern is the increasing development of self-management systems, specifically those that are Web-based. Due to continual technological advances, the internet has changed the way in which individuals seek and receive health services and information [6]. There are now a variety of online resources that have the potential to support health and well-being. Moreover, research has reported increased levels of condition-related information searching among chronic disease populations, including diabetes, depression, and chronic obstructive pulmonary disorder (COPD) [7,8]. These technologies have been recognized as a vital component for adherence to chronic disease management and the prevention of secondary health concerns [1,3,5].

Although great variability exists, Web-based self-management systems largely include components addressing multiple facets of disease management [9]. One major area of concern that can have a significant impact on medical, symptom, and lifestyle management is physical activity. In fact, the World Health Organization and the Center for Disease Control and Prevention have described physical inactivity as a leading risk factor for chronic conditions and death [10]. Conversely, regular physical activity has been shown to decrease the development of secondary comorbidities [10]. In effect, there is a need for health promotion efforts pertaining to physical activity engagement among individuals living with a chronic condition [1].

A spinal cord injury (SCI) is one such condition that requires comprehensive self-management interventions to improve the quality of life of members of this population. Individuals with an SCI are discharged from rehabilitation hospitals following increasingly shorter lengths of stay. The SCI population largely remains physically inactive after discharge, despite available physical activity guidelines and knowledge of the benefits of physical activity [11-13]. As seen in other chronic conditions [5], these individuals acquire fewer skills to self-manage their condition upon reintegration into the community, as information regarding their injury becomes less accessible [14,15]. In their systematic review of meta-analyses, Rogers et al [16] found that most of the self-management programs on the internet that demonstrated effectiveness in randomized controlled trials are unavailable for use to the general public. Therefore, these individuals are at an increased risk of developing secondary comorbidities, such as autonomic dysfunction, loss of motor control, depression, and fatigue [12,17], often resulting in rehospitalization [15]. To address this inactivity and the development of secondary health conditions, knowledge must be mobilized beyond academics and into the hands of individuals living with chronic conditions via optimal delivery mechanisms to enhance information uptake [12,18].

Additionally, the vast majority of reviews that evaluate the effectiveness of Web-based self-management interventions have focused on chronic conditions, specifically, those with a more progressive nature such as obesity, type 2 diabetes, and COPD [4,8,19]. Although physical activity is undoubtedly important for individuals with and those without disability, the SCI population presents with a unique need for support and resources, as the rapid, often immediate, onset of an SCI necessitates intense rehabilitation services early on and a high level of resilience to cope. In effect, there is a need for novel research that systematically explores and describes effective technologies to be included in an online self-management program for individuals with an SCI and other populations with similar needs. Furthermore, only a small number of available Web-based interventions are grounded in theoretical frameworks and incorporate behavior change techniques (BCTs) and modes of delivery (MoDs) into their design [20-22]. Theories are valuable in understanding the factors that influence one's health behaviors [23]. Additionally, incorporating BCTs and MoDs into the design of online self-management programs can inform adherence and behavior change [24-28].

The Health Action Process Approach (HAPA) is a framework that effectively addresses the intention-behavior gap [29] and has been applied in rehabilitation with clinical populations [23]. It posits that individuals require *motivation* to develop the intention to engage in a behavior, followed by *volition* to elicit a behavior [29]. It proposes that characteristics of Web-based interventions, including BCTs and MoDs, should be adapted to one's stage of readiness to engage in a behavior. Thus, the framework provides a theoretical foundation to guide the development of self-management programs to increase adherence behaviors [30]. It has demonstrated good applicability in increasing adherence to physical activity among individuals with obesity and type 2 diabetes [19,23,31,32] as well as in creating physical activity interventions for individuals with an SCI [33,34].

According to the HAPA framework, *goal setting*, *action planning*, *provision of feedback on performance*, and *self-monitoring* are among the most effective BCTs linked to changes in health-related behavior [24-26]. The BCTs *barrier identification/problem solving* and *providing rewards on behavior change* have also been correlated with improvements in clinical and psychological outcomes as well as health behavior [27]. In terms of MoDs, *access to an advisor /contact with clinicians* was found to have small-to-medium effects on behavior [32] and has been linked to intervention adherence [26,28]. A thematic synthesis of qualitative studies by Dwarswaard et al [2] showed that individuals with chronic conditions require support from health care professionals (HCPs) to manage their condition. The collaboration between patients and HCPs is vital for self-management support [2]. Alternately, several studies have postulated that high attrition rates and

minimal health behavior change during Web-based health-related programs may be associated with minimal or no contact with experts [35,36].

SCI Action Canada is an Ontario-based online self-management physical activity portal for individuals with an SCI, created in 2008 [37]. This website was developed to mobilize strategies to inform, teach, and enable individuals to initiate and maintain a physically active lifestyle [38]. It comprises various BCTs in line with the Health Action Process Approach framework [33,39] as well as multiple MoDs [38]. *SCI Action Canada* 's content includes evidence-based physical activity guidelines, education on the benefits and safety precautions related to physical activity, tailored exercises and information based on the level of injury, and strategies to plan physical activity and overcome potential barriers. However, certain interactive features such as the possibility to contact a clinician as well as select customizable features that the user can individualize to their current condition and preferences are not incorporated in the website. Despite the evidence presented on the effectiveness of BCTs and MoDs in self-management portals, a knowledge gap remains regarding which Web-based features best meet the unique needs of individuals with an SCI and potentially other populations with shared characteristics and recovery trajectories.

Moreover, few studies have embedded a participatory or user-centered design that incorporates the perspectives of both HCPs and individuals with an SCI in the initial development of such a site [40,41]. This iterative research design constitutes a collaborative approach in which individuals who can impact or be impacted by an intervention are involved throughout its development. The inclusion of end-users in initial designs of a Web-based portal has been shown to enhance usability, adherence, and behavior change associated with its use [42]. Jafari et al [43] found that a participatory design approach was essential in determining the aspects needed in the creation of personalized, internet-enabled education for patients with diabetes. Furthermore, a participatory design study by Allin et al [44] demonstrated that engaging users as codesigners, codevelopers, and informants in the formation of an online platform may promote self-management.

In their study, Munce et al [15] used a cross-sectional design to explore preferred content modules, including exercise, pain, and nutrition management, as well as program delivery formats including the internet, DVDs, and a telehealth system to include in a program for individuals with an SCI. They suggested the creation of a tailored self-management program to increase users' knowledge acquisition postdischarge from rehabilitation; their study was the first to examine these concepts using feedback from individuals with an SCI. This research study builds on Munce and colleagues' [15] novel findings by examining specific Web-based components of a self-management portal focused on physical activity.

To our knowledge, this study is the first to explore the needs, learning styles, and preferences of key stakeholders, including individuals with an SCI and HCPs, specifically in the development of a Web-based self-management program. Thus, the objective of this study is to identify needs and preferences of individuals with an SCI and HCPs with regard to the features of a Web-based self-management physical activity portal that have the potential to enhance one's motivation and volition to engage in physical activity.

Methods

Statement of Ethics

Approval for this project was granted by the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research study.

Research Design

This qualitative study used a constructivist paradigm with an interpretive phenomenology methodology, and an integrated knowledge translation approach to inform the objective of this research. This approach acknowledges the unique life experiences of individuals with a disability as well as the clinical experience of HCPs. It additionally permits an exploration through the analysis of first-person narratives constituting participants' experiences, views, and needs. An in-depth content analysis was subsequently used to systematically determine participants' preferred design features of an online physical activity platform. A participatory or user-centered design, which supports cocreation through the involvement of key stakeholders, was also applied.

Recruitment

Convenience sampling was used to recruit individuals with an SCI and HCPs. Recruitment took place at three rehabilitation sites in the province of Quebec: Rehabilitation Site 1 was a Montreal-based secondary inpatient and outpatient rehabilitation hospital, Rehabilitation Site 2 was a Montreal-based tertiary inpatient and outpatient rehabilitation hospital, and Rehabilitation Site 3 was a Quebec City–based secondary and tertiary inpatient and outpatient rehabilitation hospital with postdischarge physical activity programs.

Recruitment of individuals with an SCI was done via the telephone. The researchers contacted interested persons with an SCI from Montreal and Quebec City. The eligibility criteria were as follows: age ≥18 years, discharged from inpatient services from one of the three rehabilitation sites, ability to communicate in English or French, ability to independently make informed decisions, access to the internet and an email address, and ability to use a computer independently or with assistance.

HCPs were recruited from the affiliated institutions through presentations to clinical teams to explain the objective of the study and the required time to participate. Interested HCPs contacted the researchers via email.

Procedure

After obtaining informed consent, two trained researchers conducted individual 1-hour sessions with HCPs and individuals with an SCI at the individual's affiliated rehabilitation site or in their home. Prior to their scheduled session, the individuals completed a demographics questionnaire.

In the first part of the session, participants spent 30 minutes navigating selected content on the *SCI Action Canada* website. Using a think-aloud approach, participants verbally expressed their immediate positive and negative thoughts on how the content and structure of the website may influence the motivation and volition of persons with an SCI to engage in physical activity. The two researchers tracked the content that participants independently navigated through, with the use of a comprehensive checklist containing the BCTs and MoDs integrated in the website. They also prompted participants to navigate through the features they overlooked. The website navigation session was recorded using Camtasia software, version 8 (TechSmith, Okemos, MI), provided by McGill University.

Subsequently, the two researchers conducted semistructured interviews comprised of open-ended questions during the second part of the session. Participants responded to questions regarding physical activity engagement following an SCI. Individuals with an SCI were asked about the type, frequency, and social aspect of, as well as barriers to, their involvement in physical activity since their injury. HCPs were asked about their experience with physical activity prescription for their patients and expounded on strategies to improve physical activity adherence within the SCI community. All participants explored the importance of physical activity for individuals with an SCI. They were also asked to provide feedback on the website navigation portion of the session, including the site's ease of use, appeal, and delivery format, as well as perceived usefulness of embedded and absent physical activity resources. Furthermore, the individuals were asked to rate their likelihood of integrating a Web-based portal into their physical activity practice, on a scale of 0 (unlikely) to 10 (very likely). Using a similar scale, HCPs were asked to rate the degree to which they would promote such a physical activity platform in practice. All interviews were audio recorded using Camtasia software.

The length of each session ranged from 46 to 90 minutes. All sessions were transcribed verbatim. Pseudonyms were assigned to each participant. Quotations from French-speaking participants were translated to English for the purpose of this paper. In addition, the demographics questionnaire, interview guide, and navigation checklist used throughout the study were reviewed by a team of stakeholders, which included three clinical researchers, a knowledge translation specialist from *SCI Action Canada*, a coordinator for a Quebec adapted sports organization, and a consultant living with an SCI who promotes community integration.

Data Analysis

Descriptive statistics were used to summarize the characteristics of all participants and the responses on questionnaires for individuals with an SCI. All transcripts from the site navigation and interview sessions were reviewed. An in-depth thematic analysis was conducted by four members of the research team to derive common themes. Content analysis was guided by participants' rich feedback on the perceived ability of select Web-based features to impact the motivation of the individuals to initiate and maintain engagement in physical activity. The two authors who conducted the interviews also maintained field notes with thematic logging of significant moments during and after the individual sessions, which served as a component of data triangulation to contribute to the analytical process. Codes representing core concepts were identified in the transcripts. Through extensive discussion surrounding emerging commonalities, subthemes were formed and then grouped under "umbrella" key themes. All derived themes have connections to BCTs and MoDs, as outlined by Abraham and Michie [45]; this was paramount to contribute to the evidence and overall rhetoric surrounding their value as embedded components of Web-based self-management portals aimed at ameliorating health-related behaviors. The four researchers who carried out the analysis met regularly to resolve any discrepancies in order to ensure consistency of the findings. Data saturation was achieved at 21 participants. The median and mean ratings attributed to the likelihood of integrating a Web-based portal into physical activity practice or promotion were calculated.

Results

Participant Characteristics

Thirteen persons with an SCI, seven from Montreal and six from Quebec City, agreed to participate in the study. Ultimately, data collected from 12 individuals were included in the study, as data from one participant, whose condition turned out to be inaccurate, were removed. The majority of the sample was male (n=10) between the ages of 19 and 68 (mean 46.8, SD 17.1) years. Most of these individuals had a nontraumatic SCI (n=8) and a level of injury located between T1-S5 (n=6). Most participants were discharged from rehabilitation for more than 12 weeks (n=9). Ten of the participants had been participating in physical activity for over 6 months. Lastly, most subjects spent at least 2 hours per day navigating the internet, in general (n=8). Demographic information of these individuals is presented in Table 1.

Nine HCPs, six from Montreal and three from Quebec City, agreed to participate in the study. They had an average of 13.7 (SD 11.9) years of experience working with the SCI population. Additional demographic information of the HCPs can be found in Table 2.

In total, 5 themes with 14 subthemes emerged (Textbox 1).

Table 1. Characteristics of the individuals with a spinal cord injury.

Characteristic	n (%)
Age (years)	
16-30	2 (17)
31-45	2 (17)
46-60	5 (42)
61-75	3 (25)
Gender	
Male	10 (83)
Female	2 (17)
Affiliated rehabilitation site(s)[a]	
Site 1	6 (50)
Site 2	4 (33)
Site 3	6 (50)
Level of injury	
C1-C4	3 (25)
C5-C8	3 (25)
T1-S5	6 (50)
Severity of injury	
Complete	5 (42)
Incomplete	7 (58)
Nature of injury	
Traumatic	4 (33)
Nontraumatic	8 (67)
Time since discharge from inpatient rehabilitation services (weeks)	
0-4	1 (8)
5-8	1 (8)
9-12	1 (8)
>12	9 (75)
Number of months participant engaged in physical activity	
≤6	2 (17)
>6	10 (83)
Hours per day participant spent on the internet, in general	
<1	1 (8)
1 to <2	3 (25)
2 to <3	5 (47)
3 to <4	1 (8)
>4	2 (17)

[a]Total N>12, as several participants attended more than one rehabilitation site.

Table 2. Characteristics of the health care professionals.

Characteristic	n (%)
Profession	
Physiotherapist	3 (33)
Occupational therapist	3 (33)
Kinesiologist	1 (11)
Physical rehabilitation therapist	1 (11)
Dietician/nutritionist	1 (11)
Gender	
Male	2 (22)
Female	7 (78)
Affiliated rehabilitation site	
Site 1	3 (33)
Site 2	3 (33)
Site 3	3 (33)
Years of work experience with the spinal cord injury population	
1-10	4 (44)
11-20	2 (22)
21-30	2 (22)
>30	1 (11)

Textbox 1. Characteristic of Web-based interventions, themes, and subthemes.

Behavior change techniques

- **Knowledge**
  - Guidance
  - Barrier management
- **Possibility of achievement**
  - Risks and benefits
  - Models
- **Self-regulation**
  - Action planning
  - Goal setting
  - Tracking
  - Rewards
  - Reminders

Modes of delivery

- **Interactivity**
  - Peer
  - Professional
- **Format**
  - Appearance
  - Language
  - Ease of use

Knowledge

Participants preferred resources that enhance their knowledge of physical activity in terms of guidance and barrier management.

Guidance

Participants identified the importance of including resources that guide them in their physical activity participation. These resources consisted of home-based exercise tutorials, safety suggestions, and evidence-based physical activity guidelines. Furthermore, participants preferred having access to practical materials from a reliable source.

> *Oh I like this(home-based exercise tutorials). This tells you how to do it, right? I like that. You know why I like that? Cause it's stuff I can do at home and I don't need anybody.* [ISCI 13, female, 52 years]

> *It's important to engage in physical activity, but it must be done safely. People often fail to consider certain aspects of physical activity.* [HCP 05, female, occupational therapist, rehabilitation site 2]

Barrier Management

Participants identified cost and availability of exercise equipment, and physical accessibility as barriers to their physical activity participation. They suggested having access to information on tangible solutions to overcome these barriers.

> *That's interesting, you know, (information on) overcoming obstacles because people often tell me "Ah! But you're training, you're lucky, you're moving your abdominals, you're moving your legs, and this and that" ...People have difficulty overcoming obstacles because there are no two people with the same disability, so it can be helpful to provide information on overcoming obstacles.* [ISCI 10, male, 31 years]

> *You know, the equipment, notably adapted bicycles, is so expensive, so, [access to equipment] can be difficult without financial support. Over here [RS3], we have resources that can lend adapted bicycles, a cycling club...there are several resources, but they need to be advertised.* [HCP 07, female, occupational therapist, rehabilitation site 3]

Possibility of Achievement

All participants, especially persons with an SCI, suggested including features that will inspire them to achieve their physical activity goals.

Risks and Benefits

Participants disclosed the importance of being aware of the benefits of physical activity participation and the negative consequences of remaining sedentary.

> *I think there should be more information on the benefits of physical activity...or the risks associated with not engaging in physical activity. You know, a little like what they do with cigarette packages: "If you smoke, you will develop this disease", so on the site [it would say] "if you don't move, you will become overweight, you will experience shoulder pain, you will end up in a power wheelchair and become dependent on others". So, maybe not to say it this explicitly because it may offend certain users, but to really explain the benefits of physical activity and risks of a sedentary lifestyle.* [ISCI 10, male, 31 years]

> *Although I think [risks and benefits] can be motivating, they must be clearly outlined: you know "Essentially, physical activity improves this, and this, and decreases this" ...and also to explain that individual with an SCI are more at risk of developing other types of health problems and must be extra careful. Physical activity certainly helps maintain a healthy body weight, it can reduce risks of diabetes, it can reduce several things, so it's very important.* [HCP 05, female, occupational therapist, rehabilitation site 2]

Modelling

Examples of individuals with an SCI successfully engaging in physical activity within a community setting, in the form of photos, testimonials, and a mentor, was a recurrent topic. The majority of the participants explained that these forms of modelling provide a tangible outlook on a physically active lifestyle.

> *When I see this photo [individuals with aN SCI participating in an exercise class], I'd like to do it like him. It's very good...it [would] make me so happy. I want to do it like him.* [ISCI 02, female, 26 years]

> *Providing examples of active [individuals with an SCI] in the community, like success stories or testimonies or [saying] where individuals started and where they are now, and the benefits they have acquired...often speaks to clients; it gives them an idea, a vision of the future and of what it looks like to be an active person with an SCI.* [HCP 06, female, kinesiologist, rehabilitation site 2]

Self-Regulation Strategies

Many participants conveyed a preference for self-regulation tools such as action plans, goal setting and tracking, rewards, and reminder systems to support their engagement in physical activity.

Action Planning

Participants expressed that an action plan—a detailed organization of when, where, and how physical activity can be incorporated into one's weekly schedule—provides a sense of structure.

> *I personally have an action plan embedded within my schedule because it is as important as medical appointments...To reinforce, to integrate [physical activity] in a calendar is super pertinent.* [ISCI 12, male, 53 years]

On the other hand, a number of the individuals stated that their action plan did not need to be written down or input on their phone or computer, as it was already ingrained in their lifestyle.

> *My schedule is in my head. The definition says it: it's a routine. it's over and over again.* [ISCI 03, male, 43 years]

Goal Setting

Participants desired a goal-setting system as an interactive Web-based feature to formulate specific, meaningful, and realistic physical activity objectives that follow a safe progression.

> *[A goal setting system] gives importance to physical activity. [Just like] organizing a trip, giving time to organize my things, it gives physical activity the same importance as these things.* [ISCI 12, male, 53 years]

> *[Gradually progressing goals] is important because when objectives are not progressive, people are intimidated, and they get injured, and finally they abandon it because the way they started was not necessarily realistic.* [ISCI 07, male, 63 years]

Tracking

Participants discussed the importance of having a tool that monitors their physical activity progress. Participants reported that this tool would enable them to measure their improvements and follow-up on their objectives in order to stay accountable to their physical activity plan.

> *It would be very interesting to access the history of your past physical activities and exercise programs, to see if there has been progress* [ISCI 05, male, 59 years]

> *[To follow] the physical activity you have accomplished in real time, to know what you have accomplished and what is left to accomplish a given objective, I always think of a circle that becomes filled in as you complete more and more hours of physical activity.* [ISCI 09, male, 19 years]

Rewards

Some of the individuals with an SCI favored incorporating a reward system on a website to reinforce the habit of engaging in physical activity. These individuals reported that they enjoy rewarding themselves for engaging in physical activity with a positive extrinsic stimulus.

> *If I do my full 40(swimming)laps, I get a piece of cake. If I don't, I don't get it. That's me...Because I'm telling you, when I'm really tired and I don't want to do the 40 laps and I think of that piece of cake, I'm*

going to go [do the 40 laps]. [ISCI 13, female, 52 years]

However, some participants did not agree with the idea of a reward system, as they felt the health benefits of physical activity are a sufficient reward.

When you participate in physical activity, you do it for yourself. Your [reward], you will get it when you reap the benefits...Improving your condition is the best reward you can get. [ISCI 07, male, 63 years]

All the benefits it can bring, maintaining a healthy weight, energy levels, decreasing stress, that is what's important to me. I think the individual who wants to be active has to do it for themselves and not for a reward system. [HCP 07, female, occupational therapist, rehabilitation site 3]

Reminders

Some of the individuals explained that having a reminder system to participate in physical activity can serve as a form of encouragement or compensate for memory difficulties.

It's good. It will make me, maybe feel like somebody is pushing me to work; yeah, it's good. Like support. [ISCI 02, female, 26 years]

However, others suggested that this type of system should be optional, as reminders can become a stressor for them.

Personally, I hate it. I hate it! It's like...I think we have so much pressure from everything else. I wouldn't like to have reminders, but I'm sure some people would like it. [ISCI 05, male, 59 years]

Interactivity

Participants highlighted the value of having access to features that enable interaction with peers and professionals, as it would provide a sense of support.

Peer

Participants reported that they would value platforms to share resources and anecdotes, such as discussion forums or chat groups, which provide guidance and help foster a sense of belonging.

It (a network) is super important. If you don't have one, you don't have much. I often say "If i had not met all these people (with an SCI), I would be isolated and depressed," so it's super important. [ISCI 09, male, 19 years]

It could be a forum with questions, but also a forum where they can exchange information: "I would like to start a basketball team, but I am missing participants. Who would be available?" [HCP 05, female, occupational therapist, rehabilitation site 2]

Professional

Persons with an SCI expressed the importance of having access to a HCP by phone, email, or Skype, following discharge from rehabilitation, as it would enable them to seek reassurance with their physical activity plan or answer any questions they may have. Ultimately, they reported that having this type of access contributes to a continuum of care upon discharge.

It's an alternative (to a consult with your doctor) if you encounter a physical problem. If you feel a burning sensation or there is an exercise you don't understand, having the help of a clinician is interesting because the clinician can help determine if the problem is related to your injury or if it is another health issue. [ISCI 05, male, 59 years]

I think that it would be very useful because when you finish your rehabilitation, like myself, you feel a sort of mourning, an emptiness, and you're all by yourself. It would be good if there was a way to provide people with the opportunity to have contact with a clinician before they finish their rehabilitation; it could be something that can be continued after. [ISCI 04, male, 68 years]

However, some of the individuals who received all their rehabilitation services from the same institution preferred contact with a professional with whom they are familiar.

If you have a question, instead of calling a technician, you can come (to the rehabilitation site) and see someone who cared for you and can answer your questions, someone who knows you better than someone over the phone. Otherwise, you will need to explain [your situation] to the person you call [and...] start all over again. [ISCI 07, male, 63 years]

Format

Participants reported that the way in which content is structured and delivered, in terms of the appearance, language, and ease of use, influences their level of interest in using a Web-based platform.

Appearance

The majority of participants conveyed that they are primarily visual learners, and as such, are drawn towards photos, videos, colorful diagrams, and succinct text.

Pictures, videos - I'm very visual, so they help. I don't like text as much. So pictures, videos, and demonstrations are for sure always fun and practical. [ISCI 09, male, 19 years]

Colour coding is always more interesting. It makes it less dull to read. It's fun to at least having colour coding, which makes it more appealing to the eye. It's more structured. [ISCI 05, male, 59 years]

Language

Participants communicated the importance of having clear and concrete explanations that use lay and positive language. Participants also stressed upon the fact that all resources should be available in French.

[Terms such as] "muscular reinforcement" and "aerobic capacity" can be [confusing] for someone who is less knowledgeable. You know, give more concrete examples. [ISCI 10, male, 31 years]

> *[When] it says there are English documents, I'm already less inclined to visit them because they are in English. I'm sure that the majority of our clientele (in Quebec) would feel that way* [HCP 09, male, physical rehabilitation therapist, rehabilitation site 3]

> *It seems a little negative. You know "Lack of time, I can't participate in physical activity..." I would tend to rephrase the messages more positively. It feels very critical...We all have our reasons whether or not to participate in physical activity, good or bad. Maybe change it a little...to be more positive.* [HCP 09, male, physical rehabilitation therapist, rehabilitation site 3]

Ease of Use

Participants identified the need for a user-friendly website, comprised of structured, easily accessible content, as it renders the navigation experience more alluring and time-effective.

> *When you go on a website, you try to find information rapidly to accomplish something specific, [...because] we are all pressed for time. Sometimes it's hard to find information we want on a website, so it would be good to group the information in a succinct way.* [ISCI 12, male, 53 years]

> *[It's important] for links to be easily accessible to seek information that is relevant to me - [not to have to toggle back and forth between pages]. I would suggest using links to help quickly access relevant information.* [HCP 09, male, physical rehabilitation therapist, rehabilitation site 3]

Likelihood of Using a Web-Based Portal Tailored to the Needs of Individuals with a Spinal Cord Injury

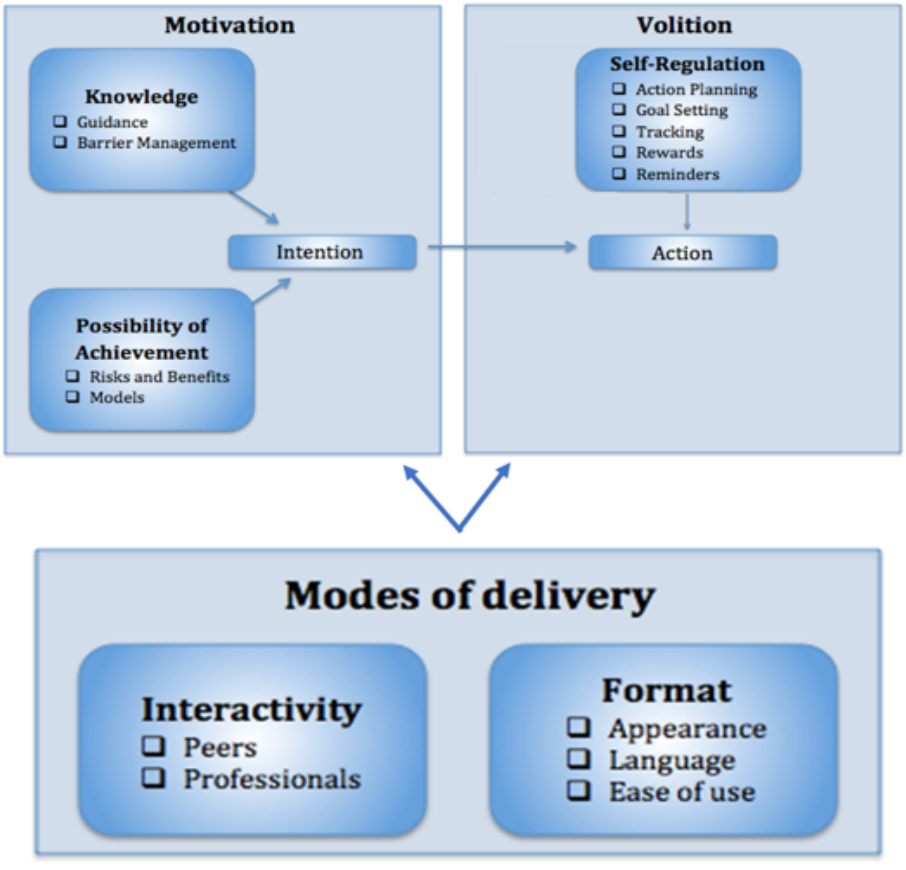
The mean and median ratings from both groups of participants were calculated for the likelihood that they would promote and use a Web-based portal tailored to the needs of individuals with an SCI. The mean and median ratings for HCPs were 9.00 and 8.78, respectively. The mean and median ratings for individuals with an SCI were 7.75 and 7.88, respectively.

Discussion

Principal Findings

The aim of this study was to highlight the Web-based features that have the potential to influence the motivation and volition of individuals with an SCI to self-manage their participation in physical activity. This is the first study of its kind to use an in-depth qualitative research design to understand the needs, preferences, and lived experiences of members of the SCI community and HCPs in the preliminary stages in the development of a Web-based self-management program. Through an in-depth inductive thematic analysis, 5 core themes and 14 subthemes emerged. The first three themes (*knowledge*, *possibility of achievement*, and *self-regulation*) align well with the two phases of the Health Action Process Approach framework and thus BCTs, while the last two themes (*interactivity* and *format*) align with MoDs (Figure 1).

Figure 1. Diagram demonstrating how the resulting five themes relate to behavior change techniques and the phases of the Health Action Process Approach framework, and the how mode of delivery impacts these phases and behavior change techniques.



Tools that enhance one's *knowledge* and convey a *possibility of achievement* can provide persons with an SCI the motivation to form an intention to participate in physical activity [46]. Participants expressed an interest in resources that offer guidance on their condition and physical activity, strategies to overcome barriers, and information on the risks and benefits. Inclusion of BCTs that improve knowledge of one's condition has been attributed to increased levels of self-efficacy and physical activity behavior [24,25,37]. Participants also identified that *models* of individuals with an SCI successfully practicing physical activity help reinforce the intention to adopt healthy behaviors, as they contribute to a positive outlook on their condition through relatability [13]. This BCT has also been linked to improved clinical and psychological outcomes [24,47].

Participants expressed that *self-regulation* tools such as *action planning*, *goal setting*, and *tracking* are conducive to initiating and maintaining physical activity. These BCTs have demonstrated effectiveness in increasing one's physical activity engagement and sense of control in various populations by transforming their intention into a behavior [24,25,30,47,48]. Participants' perspectives, however, were mixed regarding the value of having *reminders* and *rewards* on a website. Although a number of the individuals and HCPs expressed that reminders have the potential to keep oneself engaged in physical activity, others perceived this function as burdensome and stressful. These findings are echoed in the literature: One systematic review demonstrated that a reminder system had the largest favorable effect on physical activity levels [36]. Conversely, Williams and French [47] associated this system with decreased self-efficacy among study participants, while a systematic review reported small and nonsignificant effects on physical activity when interventions contained reminders [24]. In terms of *rewards*, a portion of this study's participants viewed positive reinforcements as a necessity to their physical activity practice compared to others who stated that the health benefits from regular physical activity engagement are enough of a reward on their own. Interestingly, two studies have found that a system that rewards participants based on effort or progress positively influences one's self-confidence with respect to their physical activity participation. However, these same studies did not report significant effects where interventions rewarded participants only for successful behavior. We suggest that focusing on smaller short-term progress may increase one's sense of self-efficacy regarding physical activity engagement [27,47,49].

Additionally, participants identified the importance of including *interactive* features on the website. For example, some participants suggested that online access to HCPs may afford individuals with an SCI a sense of reassurance and support needed to cope with setbacks in physical activity. In fact, having access to a HCP over the phone was found to increase adherence to physical activity among individuals in both the motivational and volitional phases of behavior change [26,38]. In contrast, others mentioned that online access to HCPs would not be a necessary feature, as they have sufficient contact with an HCP in their community. Participants also expressed a preference for online discussion forums where they can interact with *peers* (fellow persons with an SCI), exchange knowledge, and integrate within the active SCI community. In their study, Allin et al [44] highlighted the importance of including these community-type resources on a Web-based platform.

Furthermore, our findings reveal that the way in which information is displayed on a Web-based platform (*format*), including the *appearance*, *language*, and *ease of use*, influences the degree to which individuals are drawn to and potentially utilize Web-based resources. Recent studies have stressed the importance of addressing features and functions including usability, readability, and visual esthetics to assure end-users' engagement in Web-based interventions [50,51]. However, research remains limited on the specific elements that constitute effective Web design [50]. More research on the impact of *format* on behavior change is needed to contribute to evidence supporting its value in online self-management portals. Ultimately, the interactive features and format of the website contribute to the degree of appeal of the BCTs identified by the first three themes and therefore have an influence on individuals' motivation and volition to engage in physical activity.

Our research builds upon Munce and colleagues' [15] cross-sectional study, which explored general components of self-management programs for individuals with an SCI. They reported, among others, participants' desires for portals to be internet-based and to include a physical activity component. Although numerous Web-based self-management portals exist, website quality remains low and few incorporate theoretical frameworks, BCTs, and MoDs into their design [20,21].

The *SCI Action Canada* website is one of the most developed Web-based self-management systems that currently exists. Its design was guided by the HAPA framework and thus incorporates various BCTs and MoDs that have been linked to increased physical activity engagement among individuals with an SCI. As such, it was used as a starting point for our research, anticipating that several areas of improvement would emerge from our results, which was the case. First, the content should be updated and enhanced to reflect the needs and preferences of the SCI community. Second, interactive features, including contact with peers and professionals through the same system, should be embedded within the website. Third, while not currently incorporated into health care, introducing self-management tools to patients early on in their recovery process is an integral step to ensure a continuum of care.

Murray et al [52] found that new technology has the greatest likelihood of becoming implemented if it aligns with the organizational objectives and expertise of existing HCPs and positively influences their relationships with patients. Dwarswaard and colleagues [2] also demonstrated that individuals living with a chronic condition expect HCPs to play a vital role in their self-management, which was similarly expressed by our study subjects. Given the sudden onset of an SCI and the trajectory and intensity of rehabilitation services, embedding HCPs into this process to ensure a continuum of care is critical. This can inform the need for a self-management portal to be presented and endorsed by HCPs before discharge as well as the incorporation of interactive features on the system to ensure users feel supported in the long-term.

This study's findings support the need to include numerous persuasive technologies in a Web-based physical activity portal.

Our results align with the literature, which has found that multimode tailored interventions that incorporate video, audio, discussion forums, and chat enhance interactivity, skills, and knowledge building, thus positively influencing patient engagement and health-related outcomes [27,35,53,54]. Furthermore, previous interventions that included multiple BCTs had larger influences on behavior change than those that incorporated fewer change techniques [24].

Finally, the robust user-centered design permitted us to delve into specific Web-based components favored by members of the SCI community. As such, this study supports the need to engage persons with an SCI and HCPs early on in the design of an online self-management portal. In addition, the high ratings of these key stakeholders on the likelihood to use a website tailored to one's needs illustrate not only the willingness of participants to use such a website, but also the degree to which it is valued in improving one's self-management in physical activity. As such, the educational and material resources included on the proposed self-management portal should be made easily accessible and cater to individualized needs [14,38].

Limitations

First, when considering the generalizability of this study's findings, it is important to note that the majority of the individuals who participated (83%) reported that they have been engaging in physical activity for more than 6 months. In addition, most participants (n=8) spend at least 2 hours on the internet daily. The characteristics of our sample may be attributed to the self-selective nature of our recruitment strategy, as members of the SCI community with an interest in physical activity likely shared an interest in this study's topic. As such, the results may not be representative of individuals with an SCI who are in an early stage of physical activity engagement or who lack access to Web-based resources. Moreover, due to our methodology and small sample size, we were unable to derive conclusive similarities or discrepancies in the findings between subjects, despite reaching saturation with 21 participants. Although this was not part of our initial objective, future research will involve conducting further analyses with more study subjects to determine subgroup clusters as we continue to develop the platform. A strength of this more engaged and technologically savvy sample, however, is that they were able to reflect on the motivational strategies they use or have used in their experience with physical activity to provide valuable feedback on Web-based persuasive technologies. These insights will guide us in shaping a platform integrated into care in a way that attracts less active individuals with an SCI to initiate behavior change and maintain engagement when discharged back to the community. Further research is needed to consider the perspectives of individuals with an SCI at a rudimentary stage of physical activity engagement.

Second, some participants reported that they did not have sufficient time to navigate the website, which may have influenced their exploration of the available resources. These participants may not have been able to conceptualize the impact of certain Web-based features they initially overlooked due to the time limit. Third, participants were asked to comment on several BCTs (eg, reward system and goal setting system) that have been shown to be effective in the literature but were not embedded within *SCI Action Canada*. Participants likely formed an opinion based on the hypothetical value of these tools without having had a genuine opportunity to interact with them on a website. Fourth, due to time and resource constraints, only persons with an SCI living in urban areas were recruited. As their perspectives may vary from those who live in more rural settings, the findings may be more applicable to an urban context.

Conclusions

To our knowledge, this is the first study to highlight the Web-based features that should be considered in the design of a Web-based self-management platform targeting physical activity. The Health Action Process Approach, as well as BCTs and MoDs, add value to the promotion of physical activity engagement, as they shed light on the potential for Web-based features to enhance the motivation and volition of persons with an SCI. The in-depth analysis and report of the needs and preferences of both individuals with an SCI and HCPs in this study serve as an essential preliminary step in the design of an online physical activity portal. Once a prototype is created, its ability to influence adherence and behavior change will need to be evaluated. Lastly, our study contributes to the growing body of knowledge on disability and chronic disease management. Many of the challenges in the self-management of physical activity experienced by individuals living with an SCI in the self-management of physical activity are similarly experienced by members of related disability populations. As such, we highly encourage fellow researchers to utilize and build upon our robust methodology as a platform to deepen the understanding of the needs and preferences of other disability populations in the interest of promoting and enhancing quality of life. Further research is therefore warranted in this area.

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Conflicts of Interest

None declared.

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Abbreviations

BCT: behavior change technique
HAPA: Health Action Process Approach
HCP: health care professional
MoD: mode of delivery
SCI: spinal cord injury

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Original Paper

The Internet-Based Cognitive Assessment Tool: System Design and Feasibility Study

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Abstract

Background: Persistent cognitive impairment is prevalent in unipolar and bipolar disorders and is associated with decreased quality of life and psychosocial dysfunction. The screen for cognitive impairment in psychiatry (SCIP) test is a validated paper-and-pencil instrument for the assessment of cognition in affective disorders. However, there is no digital cognitive screening tool for the brief and accurate assessment of cognitive impairments in this patient group.

Objective: In this paper, we present the design process and feasibility study of the internet-based cognitive assessment tool (ICAT) that is designed based on the cognitive tasks of the SCIP. The aims of this feasibility study were to perform the following tasks among healthy individuals: (1) evaluate the usability of the ICAT, (2) investigate the feasibility of the ICAT as a patient-administered cognitive assessment tool, and (3) examine the performance of automatic speech recognition (ASR) for the assessment of verbal recall.

Methods: The ICAT was developed in a user-centered design process. The cognitive measures of the ICAT were immediate and delayed recall, working memory, and psychomotor speed. Usability and feasibility studies were conducted separately with 2 groups of healthy individuals (N=21 and N=19, respectively). ICAT tests were available in the English and Danish languages. The participants were asked to fill in the post study system usability questionnaire (PSSUQ) upon completing the ICAT test. Verbal recall in the ICAT was assessed using ASR, and the performance evaluation criterion was word error rate (WER). A Pearson 2-tailed correlation analysis significant at the .05 level was applied to investigate the association between the SCIP and ICAT scores.

Results: The overall psychometric factors of PSSUQ for both studies gave scores above 4 (out of 5). The analysis of the feasibility study revealed a moderate to strong correlation between the total scores of the SCIP and ICAT (r=0.63; *P*=.009). There were also moderate to strong correlations between the SCIP and ICAT subtests for immediate verbal recall (r=0.67; *P*=.002) and psychomotor speed (r=0.71; *P*=.001). The associations between the respective subtests for working memory, executive function, and delayed recall, however, were not statistically significant. The corresponding WER for English and Danish responses were 17.8% and 6.3%, respectively.

Conclusions: The ICAT is the first digital screening instrument modified from the SCIP using Web-based technology and ASR. There was good accuracy of the ASR for verbal memory assessment. The moderate correlation between the ICAT and SCIP scores suggests that the ICAT is a valid tool for assessing cognition, although this should be confirmed in a larger study with greater statistical power. Taken together, the ICAT seems to be a valid Web-based cognitive assessment tool that, after some minor modifications and further validation, may be used to screen for cognitive impairment in clinical settings.

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KEYWORDS

screening; memory; executive function; bipolar disorder; depression; cognitive impairments; neuropsychological tests; computer software; speech recognition software

Introduction

Background

Cognitive impairment is prevalent in patients with unipolar disorder (UD) and bipolar disorder (BD) even during periods of remission, and it has a negative impact on the quality of life and psychosocial functioning. Nevertheless, cognitive function is rarely assessed in the clinical treatment of these affective disorders because of the time requirement for cognitive tests, which often exceeds the limited health care resources.

To date, there is no patient-administered tool that provides a brief and accurate screening for objective cognitive impairment using gold-standard, performance-based cognitive tasks for patients with affective disorders. The International Society for Bipolar Disorder (ISBD) Targeting Cognition Task Force recently recommended the systematic assessment of cognition in the clinical management of these patients using objective, performance-based cognitive tests [1]. However, validated tests with sensitivity to cognitive impairments in affective disorders only exist in paper-and-pencil or computerized formats, which must be administered by health care professionals. One such test for affective disorders is the screen for cognitive impairment in psychiatry (SCIP). The SCIP is a short (<15 min) paper-and-pencil test administered by trained health care professionals and comprises 5 subtests: (1) list learning (LL), (2) consonant repetition (CR), (3) verbal fluency (VF), (4) delayed list learning (DLL), and (5) visuomotor tracking (VMT) tests. These tests assess verbal recall, working memory, VF, delayed recall, and psychomotor speed, respectively [2]. The ISBD Targeting Cognition Task Force recommends the SCIP for cognitive screening in patients with BD based on recent validation studies [3,4]. In particular, studies point to the validity and reliability of the SCIP for detecting cognitive impairment in BD [5] and UD [6].

Nevertheless, even such brief screening for cognitive impairment in the clinical setting may require too much time and training of health care professionals to be realistic for all patients. This highlights the need for a patient-administered digital tool that provides a brief and valid assessment of cognition with objective cognitive tests, such as the SCIP, for affective disorders.

Previous Studies

Our study is mainly concerned with digital cognitive test batteries, and it partly deals with the application of automatic speech recognition (ASR) in psychiatry. An overview of the related works is presented in the following 2 sections.

Digital Cognitive Test Batteries

In this section, validated digital tools developed for cognitive assessment are presented. Cognitive training tools are, therefore, excluded.

CANTAB Mobile [7] is a validated patient-administered tool to screen for dementia. This app examines memory impairment in patients aged 50 to 90 years using the paired associates learning test. Central nervous system vital signs (CNSVS) is a computerized neurocognitive test battery developed to evaluate cognitive impairment in mental disorders, including UD. The CNSVS has 7 tests, including verbal and visual memory, finger tapping, symbol digit coding, the Stroop test, a shifting attention test, and a continuous performance test [8]. According to the findings by Gualtieri and Johnson, CNSVS is suitable for cognitive assessment and screening of normal subjects. Another test battery is Cogstate, which is aimed to screen patients with Alzheimer's disease but has been used to assess other neuropsychiatric disorders. A recent clinical study on Cogstate [9] aimed to examine cognitive impairment in UD patients compared with healthy controls in terms of psychomotor speed, alertness, visual memory, working memory, verbal memory, and learning and executive functions. Cogstate measures showed impairment in attention and verbal memory and learning, whereas no difference was found in psychomotor speed, visual attention, and working memory in UD patients versus controls. This contrasts with the literature on moderate impairments within these domains in UD and it could be because of the ceiling effects of the Cogstate. The THINC-it is a more recent cognitive assessment tool designed specifically for UD patients that measures attention, working memory, and executive function. This application is the first Web-based patient-administered cognitive screening tool developed for UD and thus represents an important step toward more common assessments of cognition in the clinical management of UD. The THINC-it uses gamified cognitive tasks to engage patients in taking the tests. For example, the *Trails* game is adapted from the trail-making test part B. According to the latest study [10], 100 healthy controls were tested for temporal stability and reliability as well as the validity of the THINC-it. Overall, high stability and reliability and moderate validity were found.

Automatic Speech Recognition in Cognitive Assessment Applications

Recently, ASR has been utilized to examine verbal impairment in mental disorders. Semantic VF as a determinant factor in mild cognitive impairment (MCI) has been automated through

ASR in recent studies [11-14]. Troger et al [14] applied ASR to examine semantic VF in dementia via a telephone-based approach, showing the feasibility of automated analysis in screening for dementia. Toth et al in their recent study [13] derived nonverbal acoustic features, such as the duration of pauses, from ASR among the Hungarian population. Their findings revealed significant differences between healthy individuals and MCI patients in terms of their acoustic features of delayed recall.

The Gaps in the Literature

The limitations of THINC-it are twofold. First, of the cognitive domains assessed by THINC-it, only psychomotor speed shows a moderate correlation with the standardized tests. Second, THINC-it does not examine verbal memory, although this cognitive measure is a predictor of a long-term psychological functional outcome in UD and BD patients [15]. CANTAB Mobile and CNSVS do not assess verbal memory as well. The lack of verbal memory assessment might be partially because of uncertainty about how to measure it via a digital tool. Moreover, the tests suggested by CANTAB and CNSVS for use in affective disorders have not been specifically developed to screen for cognitive impairment in UD and BD patients and may thus not have optimal sensitivity for impairments in these groups.

Internet-Based Cognitive Assessment Tool

We developed the internet-based cognitive assessment tool (ICAT) with the perspective that it can be administered by patients themselves at home. Specifically, the ICAT is a Web-based cognitive test battery that examines immediate and delayed verbal recall, working memory, executive function, and psychomotor speed in 5 short tasks. Speech recognition technology has become advanced enough to be used in various applications. Moreover, ASR requires minimum technology and resources for remote examination. Therefore, ASR is utilized in 2 ICAT subtests to assess immediate and delayed verbal recall.

Goals of This Study

The objective of this paper is threefold: first, to present the ICAT as a Web-based cognitive test battery designed based on the cognitive tests included in the SCIP; second, to present 2 studies assessing 2 aspects of the ICAT—(1) its usability and (2) its feasibility evaluated by correlation analysis between the SCIP and ICAT subtests and total scores; third, to evaluate the accuracy of the ASR for immediate and delayed verbal recall.

Methods

Design Methods

The ICAT user interface (UI) was designed in a user-centered design process involving computer scientists, health informaticians, psychiatrists, and psychologists. Overall, the design process took 5 months and was performed in 4 consecutive stages, as explained below.

Phase 1: Brainstorming Design Sessions

The essential components of the ICAT system as a patient-administered system were brainstormed in 3 weekly meetings. In addition, the technical opportunities and limitations of computerizing the SCIP subtests were investigated.

Phase 2: Personas and User Interface Design

To identify design requirements and system functionalities, 2 personas were prepared based on the inputs received from psychiatrists and psychologists, who provided the practical lived experiences of the patients. A flowchart was created based on the personas to determine the navigation through different components (eg, homepage, instructions, and cognitive assessment tasks), and UI wireframes of each page were drawn.

Phase 3: Mock-Up

The wireframes were presented as a slideshow and thoroughly discussed by the ICAT team members during user experience (UX) prototyping sessions. During these sessions every aspect of the ICAT was (re)designed, including the layout and graphical design of each page, the instructions, the use of speech recognition, the feedback to the users, the use of input modalities (ie, keyboard and mouse), and the informed consent pages. During the design process, the original SCIP tasks were significantly modified for administration on Web-based technology in a browser, particularly considering support for a PC-based setup with keyboard and mouse. In this phase, the homepage of the ICAT contained a welcome page and a speaker test (see Multimedia Appendix 1).

Phase 4: Prototyping

The low-fidelity mock-up of the ICAT was gradually turned into a functional prototype using Web technology for graphical rendering in a browser but with no storage or persistence. This prototype was used for the initial assessment during UX prototyping sessions involving PH, KWM, LVK, and JEB. The slideshows created during phase 3 were expanded to 4 pages in the low-fidelity mock-ups (see Multimedia Appendix 1); the first page was added to determine how the patient would be notified to take the test, and the fourth page was the consent form. The final prototype was used to deploy the ICAT application on a Web platform.

System Description

The ICAT includes the following 3 overall sections, which are presented one after another to the user: (1) the homepage, including an introduction, general instructions, and an informed consent form; (2) the technical setup (speaker and microphone test), and (3) cognitive assessment tasks. The ICAT supports both English and Danish, and users can hence select their preferred (native) language before proceeding to the general instructions. For readability, the lengthy instructions were divided into multiple pages. The terms of use in the consent form clarifies the purpose of the study, what data are gathered, and how the user's data will be handled. All of this complies with the European data protection law (general data protection regulation, GDPR). As the ICAT makes extensive use of ASR, the second section (technical setup) ensures that the microphone and speakers are properly configured. See Multimedia Appendix

1 to check the final design of the ICAT homepage and technical setup, respectively. The third section of the ICAT contains a set of 5 short tasks, each including a test introduction and task-specific instructions. These 5 tasks were modified versions of the following:

- SCIP LL
- SCIP CR
- Wechsler Adult Intelligence Scale letter-number sequencing (WAIS LNS)
- SCIP DLL
- SCIP VMT

All of the ICAT subtests were adapted from the SCIP except for the third subtest that was replaced with a modified version of WAIS LNS. A detailed description of each ICAT task can be found in Table 1. The ICAT WAIS LNS and VMT subtests present a practice set to the users beforehand. The practice sets were adapted from their corresponding clinically administered tests. In total, the 5 tasks of the ICAT take 20 to 30 min to complete.

Table 1. Description of the internet-based cognitive assessment tool subtests.

Task features	Task 1: list learning[a]	Task 2: consonant repetition[b]	Task 3: Wechsler Adult Intelligence Scale letter-number sequencing[c]	Task 4: delayed list learning[d]	Task 5: visuomotor tracking[e]
Measure	Verbal memory (immediate recall)	Working memory	Working memory	Delayed verbal memory (delayed recall)	Psychomotor speed
Scoring criteria	Total number of correctly recalled words for 3 trials	Total number of correctly recalled letters	Total number of correctly sorted sequences	Total number of correctly recalled words	Total number of correct matching letters
Score range	0–30	0–24	0–21	0–10	0–30
Practice test	No	No	Yes	No	Yes

[a]An audio file containing a list of 10 words is played to the patient. Following that, the patient recalls as many words as possible and speak them aloud. This task is repeated 2 more times (3 trials in total) using the same word list.

[b]First, a sequence of letters is played via an audio file. Then, the patient should sort a set of numbers in descending order within a certain time period (this task is only for delaying the response). After time is up, the patient recalls and types the letters that were read to him or her earlier.

[c]A set of letter-number sequences are displayed on the screen one by one. Each sequence is played via an audio file to the patient. Following that, the patient sorts the numbers and letters of the sequence and types them.

[d]In this task, the patient should recall the same words that were played in the first list learning task and speak them aloud. No audio is played for the patient in this task.

[e]A table including 6 letters and their matching codes (a combination of circles and asterisks) is shown to the patient. In 30 seconds, the patient enters the matching letters of 30 random codes one by one.

Modified Elements of the Screen for Cognitive Impairment in Psychiatry Tasks

List Learning and Delayed List Learning Tasks: Utilizing Speech Recognition

During the initial design of the ICAT LL and DLL subtests, users were supposed to type the recalled words. However, typing was not a suitable input technique for 3 reasons. First, typing influences human visual short-term memory that may help the users in practicing the words. Hence, practicing could significantly increase the users' scores in the second and third trials of the LL task. Second, typing skill depends on the people's age and previous typing experience. Third, misspelled words may cause a problem when scores are automatically calculated. To clarify the latter, the SCIP administrator reads the words aloud and gives scores based on what he or she hears from the patient. Hence, giving a score to a misspelled word is unclear. An editing option for the ASR transcript could allow users to check and modify it after a recall phase. However, this approach would display the words to the users, which would then significantly improve their verbal scores because (1) all trials of the LL subtest use the same set of words and (2) it would not comply with the SCIP administration manual. By considering these major issues, the alternative to typing was to utilize ASR. Figure 1 shows the UI of the ICAT LL subtest including a user's sound wave received from the microphone device during a recall phase. Figure 2 displays the number of recalled words calculated based on the real-time ASR when the user stops speaking. The ICAT DLL task has an interface and functionality similar to the LL task except that no audio file is played for the users.

Figure 1. Screenshot of a sound wave received from a user's microphone device during a recall phase of the internet-based cognitive assessment tool list learning task.

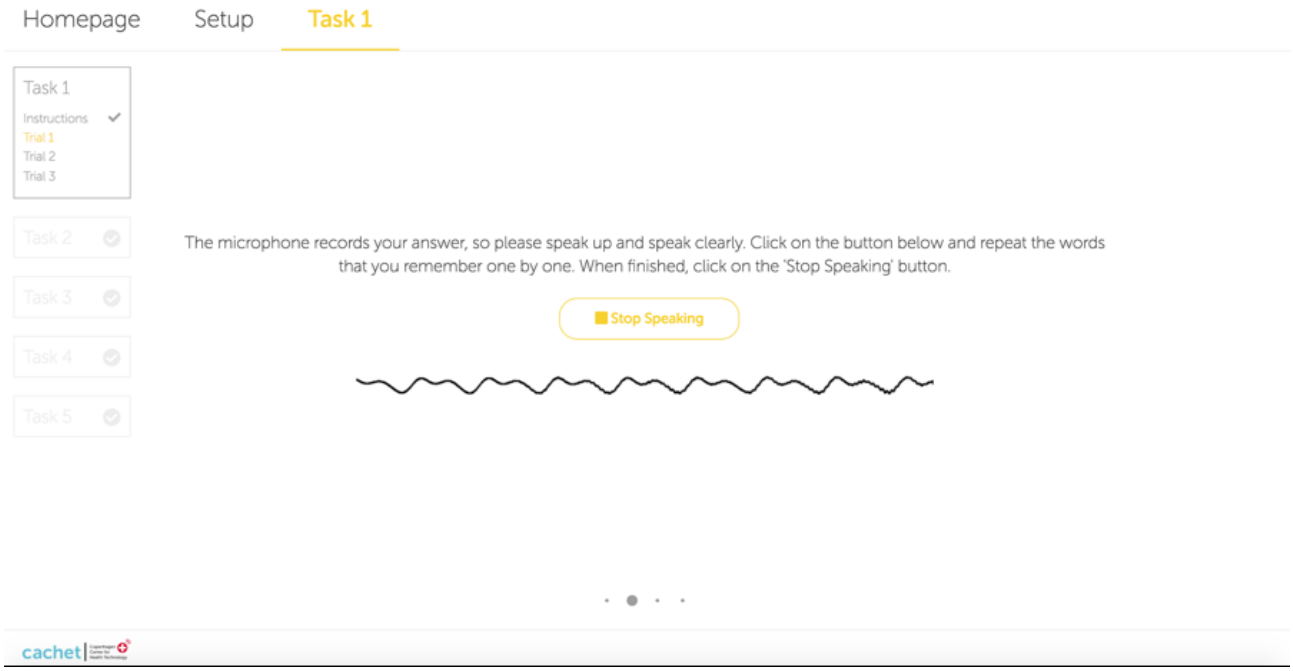
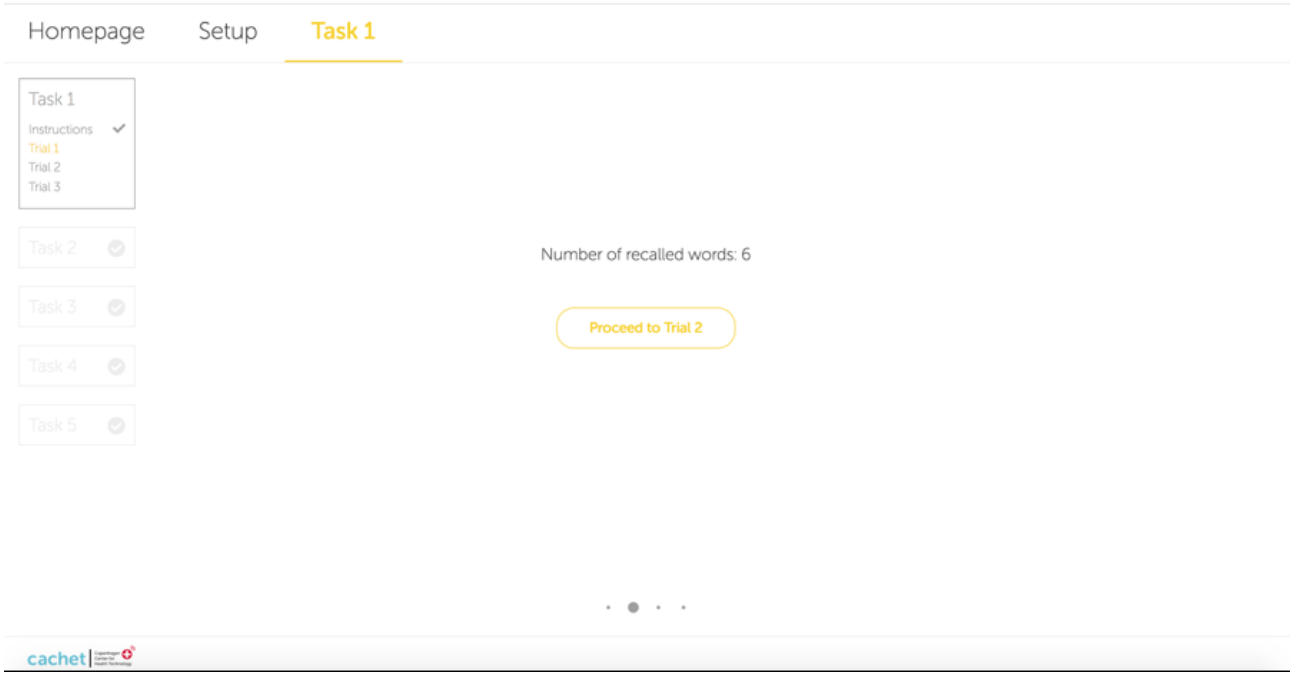


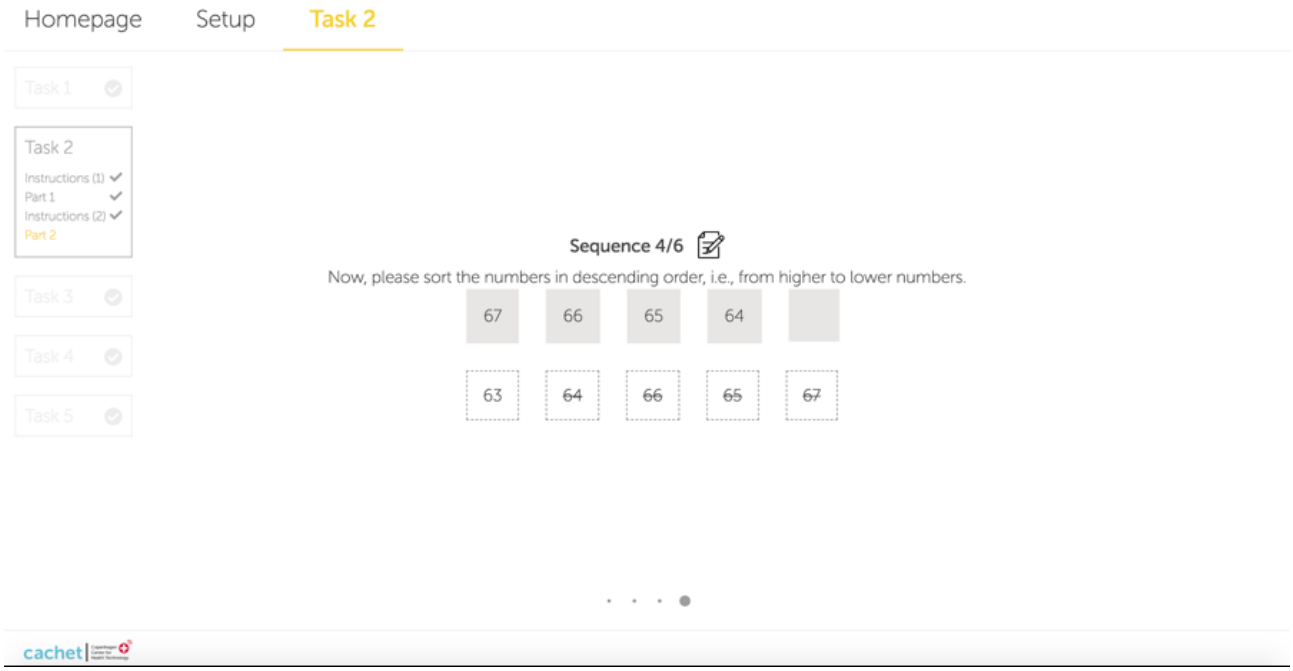
Figure 2. Screenshot of the number of recalled words recognized by automatic speech recognition when the user stops speaking in the list learning task.



Consonant Repetition Task: Sorting Numbers Using Drag-and-Drop

During the SCIP CR task, the test administrator asks the patient to count backwards by starting from a specific number for a time period. We replaced this face-to-face countdown with a sorting module in the ICAT CR subtest, where the users should drag each number and drop it into its correct place. The numbers displayed on the user's screen should be placed in descending order. Figure 3 shows a sample drag-and-drop task where users should sort a sequence of numbers from 67 (highest) to 63 (lowest) within a certain time limit. Each sequence includes 5 numbers, and if the user sorts them correctly, the next set automatically appears on the screen.

Figure 3. Screenshot of the internet-based cognitive assessment tool consonant repetition task where the user should sort the numbers in descending order by dragging and dropping the numbers into their correct place.



Wechsler Adult Intelligence Scale Letter-Number Sequencing Task: Replacing Verbal Fluency

The SCIP subtest for the assessment of the VF requires the patient to generate as many words as possible that start with a specific letter, for example, *F* in 30 seconds. The third subtest of the ICAT uses WAIS LNS because the SCIP VF task could not be implemented adequately in the technology. Hence, VF was replaced with WAIS LNS, which measures executive function. Figure 4 shows an example of an incorrect response to a stimulus during a practice test of the ICAT WAIS LNS subtest.

Figure 4. The internet-based cognitive assessment tool Wechsler Adult Intelligence Scale letter-number sequencing task includes a practice set with 5 sequences to prepare the user for the actual test. This screenshot shows that a user sorted a sequence incorrectly.

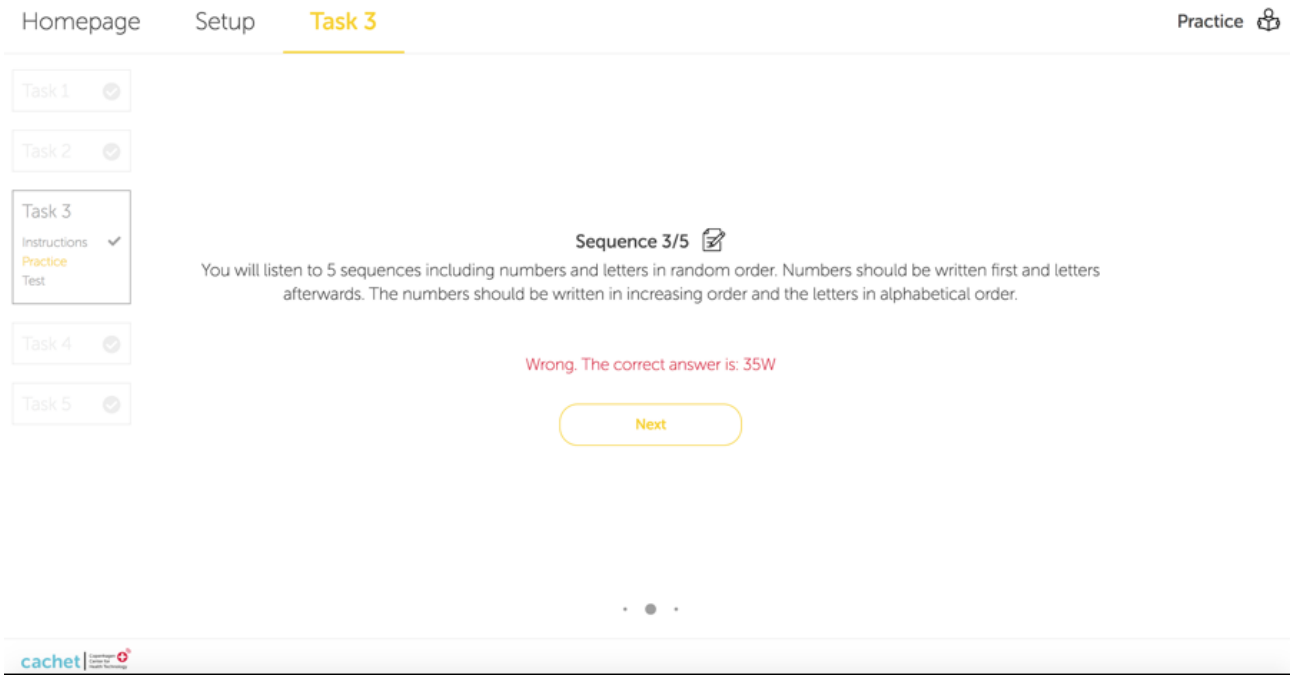
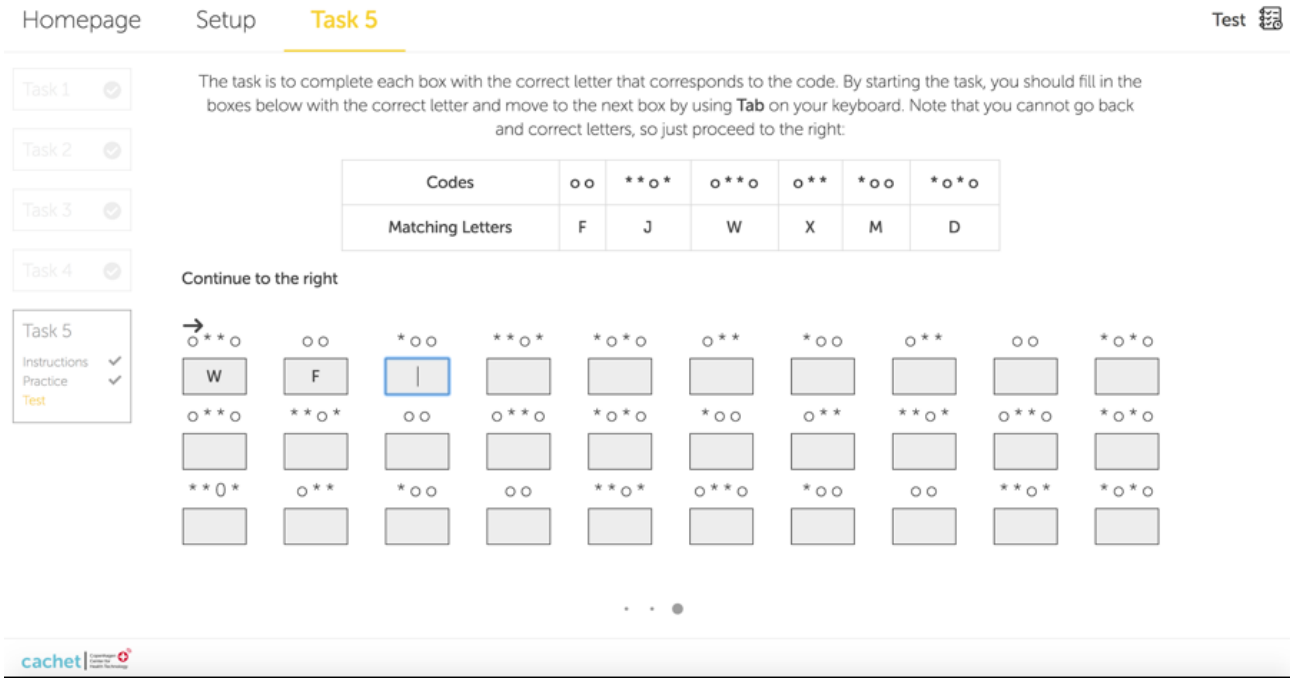


Figure 5. The user interface of the internet-based cognitive assessment tool visuomotor tracking task, where the user should enter the matching letter for each symbol as fast as possible.



Visuomotor Tracking Task: Changing Morse Codes

A table of 6 letters and their corresponding codes is written for the patients during the test, and they are required to write down the matching Morse code of 30 letters on a paper within 30 seconds. Owing to slow typing, especially among elderly people, we decided to ask users to enter the matching letter of each code in the ICAT VMT task. The Morse codes of the SCIP VMT task were modified from dots and dashes into a different combination of circles and asterisk symbols because of the learning effect for those participants who are already familiar with the Morse codes. The earlier design of this task can be found in our previous publication [16]. According to the former design of this task, a countdown clock was displayed to the user during the test, but it was later removed to prevent distraction. Figure 5 shows the current design of the ICAT VMT task.

Technical Specifications and Apparatus

The low-fidelity mock-up of the ICAT was created in the Balsamiq desktop app [17]. The front end of the ICAT was built using React (version 15.4.0) developed by Facebook incorporation company. The Copenhagen Center for Health Technology—CACHET Research Platform (CARP), which implemented an open mobile health (mHealth) data storage unit [18], was used as the data back end, and ICAT-specific JavaScript object notation (JSON) schemas for the cognitive functions were designed according to the open mHealth specifications. Google's ASR service [19] was used in the LL and DLL subtests, which require Google Chrome to run the application. CARP and the ICAT system are deployed on secure servers at the Technical University of Denmark. For the evaluation and feasibility studies, ICAT tests were administered using a MacBook Pro (Retina 15 inch) laptop and an external mouse for those who were not comfortable with the MacBook touchpad. Pearson correlation analysis was performed in SPSS.

Usability and Feasibility Studies

The local ethics committee for the Mental Health Services, Capital Region of Denmark, determined that their permission for the study was not needed because it involved no testing of biomedical products nor involved any invasive procedures. A total of 2 studies were conducted: the first study was a usability test, which we will refer to as Study 1, and the second is a feasibility study, which will be called Study 2 in the rest of this paper. Participants of both studies signed an informed consent before the data collection. The informed consent was compliant with the GDPR regulation to protect the personal data of the users. In the following sections, we elaborate on the participants and procedures of the studies individually.

Participants

All participants were healthy individuals. Study 1 included healthy students and individuals from the campus of the Technical University of Denmark and the city of Copenhagen. The inclusion criterion was English or Danish language skills, and the exclusion criterion was any hearing disability because some of the ICAT tasks used audio files. Study 2 included healthy participants who were recruited from blood banks at hospitals within the Capital Region.

Procedure

The age and gender of the subjects were collected before conducting both studies. Study 1 was conducted during June and August 2018. The study leader (PH) first asked the native language of the participant. Then, PH introduced the ICAT system to the participant and briefly explained the purpose of the study. The think-aloud method [20] was used during the test. The participants were not supposed to receive assistance during the test except for login issues. Study 2 was conducted during August and September 2018. Each participant first performed the Danish version of the SCIP (SCIP-D) as

administered by research assistants in the Neurocognition and Emotion in Affective Disorders group (AEJ, KO) and then completed the ICAT test.

The usability of the ICAT UI was evaluated in both studies by the poststudy system usability questionnaire (PSSUQ) [21]. Upon completing the ICAT test, the PSSUQ questionnaire was sent to the subjects' email via Google Form, and the study leaders conducted a brief follow-up interview with the participant. During the interview, the participants were asked to mention any general or task-specific issues or suggestions. Participants could also type further comments at the end of the PSSUQ form. The voice of the users was recorded during the ICAT test and the follow-up interviews. The manually generated transcripts of the participants' verbal responses during the ICAT LL and DLL subtests were obtained from their recorded files.

Metrics

Usability Factors

PSSUQ includes 19 items, each rated on a 5-point Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree). The psychometric factors of the PSSUQ are (1) overall usability, (2) system usefulness, (3) information quality, and (4) interface quality.

Word Error Rate

Previous studies used word error rate (WER) as the performance measure of ASR [11,12,14]. If N is the total number of words, D is the number of deletions, S is the number of substitutions, and I is the number of insertions, then, WER = (S+D+I)/N. WER is calculated by comparing ASR transcripts to the manually generated transcripts for English and Danish responses during the ICAT LL and DLL subtests.

Correlation Analysis

Pearson 2-tailed correlation analysis was performed at the .05 significance level for both the SCIP and ICAT subscores and total scores of the participants of Study 2.

Data Exclusion

The ICAT data of the WAIS LNS subtest were lost for 3 participants of Study 2. The correlation analysis was, therefore, performed for 16 participants.

Results

User Statistics

Study 1 included N=21 subjects—9 females and 12 males, with an average age of 31 years (SD 12). Of the Danish-speaking participants, 7 were native Danish speakers and 2 were citizens of Copenhagen who had spoken Danish for at least 10 years. As for the rest of the participants, 1 was a native English speaker and 11 spoke other languages. Study 2 included N=19 subjects—13 females and 6 males, with an average age of 36 years (SD 15). All participants of this study had Danish as their native language.

Internet-Based Cognitive Assessment Tool Test Scores

The scores obtained by the participants of both studies in tasks 1-5 are shown in Figures 6-10.

Figure 6. Boxplots of the internet-based cognitive assessment tool and screen for cognitive impairment in psychiatry subscores of the participants of both studies in task 1.

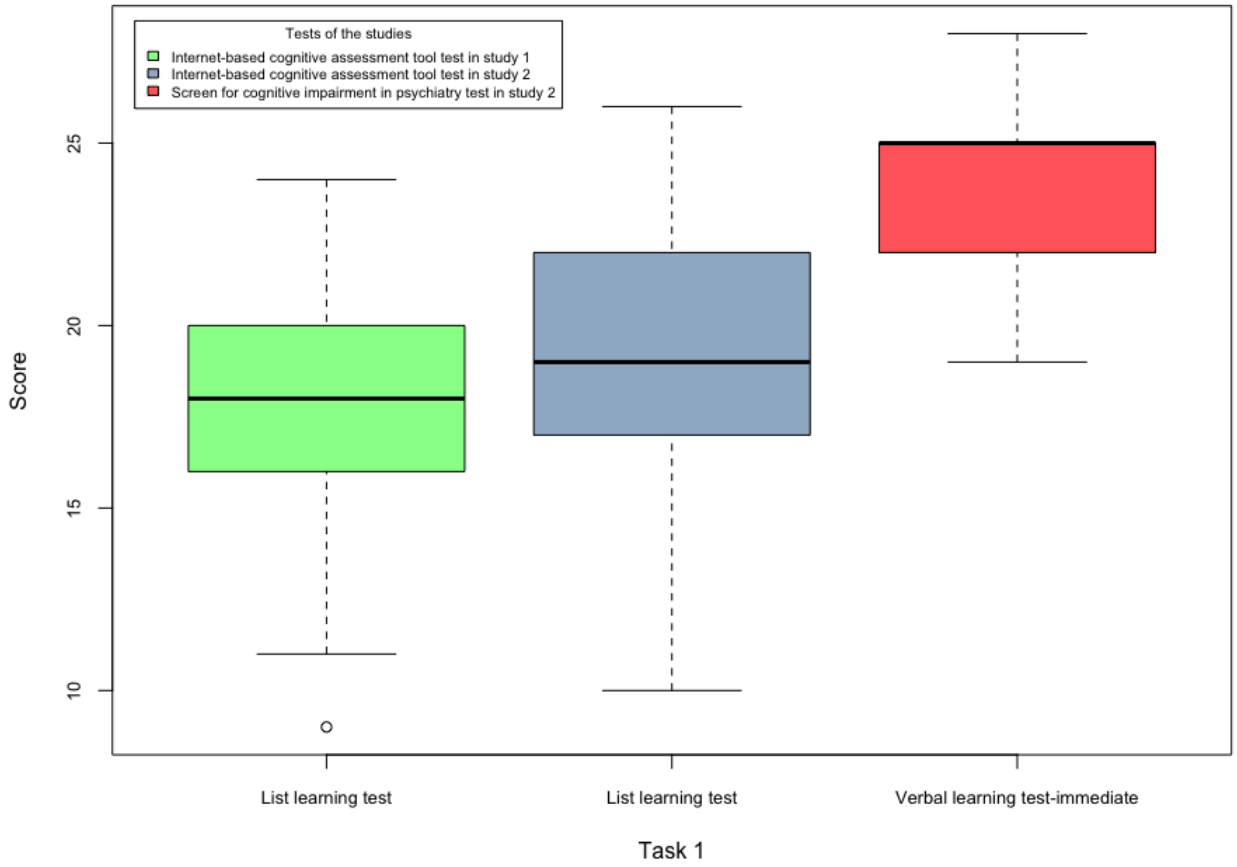


Figure 7. Boxplots of the internet-based cognitive assessment tool and screen for cognitive impairment in psychiatry subscores of the participants of both studies in task 2.

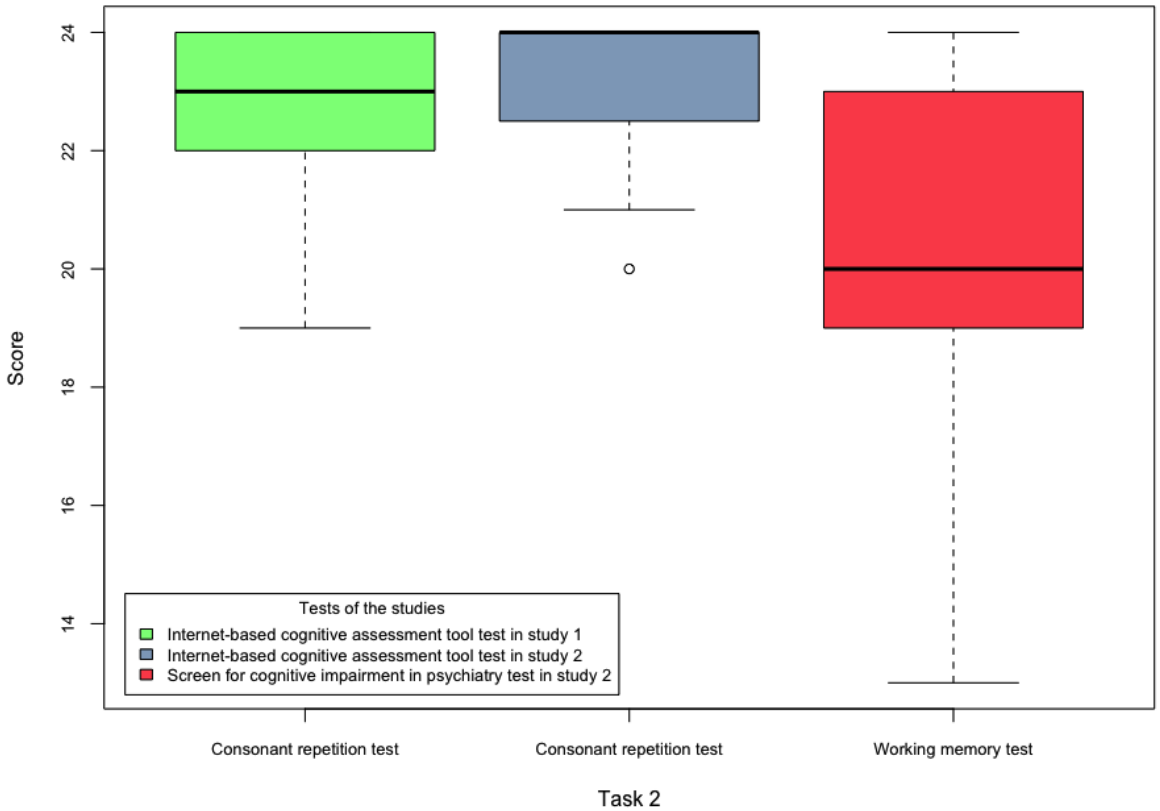


Figure 8. Boxplots of the internet-based cognitive assessment tool and screen for cognitive impairment in psychiatry subscores of the participants of both studies in task 3.

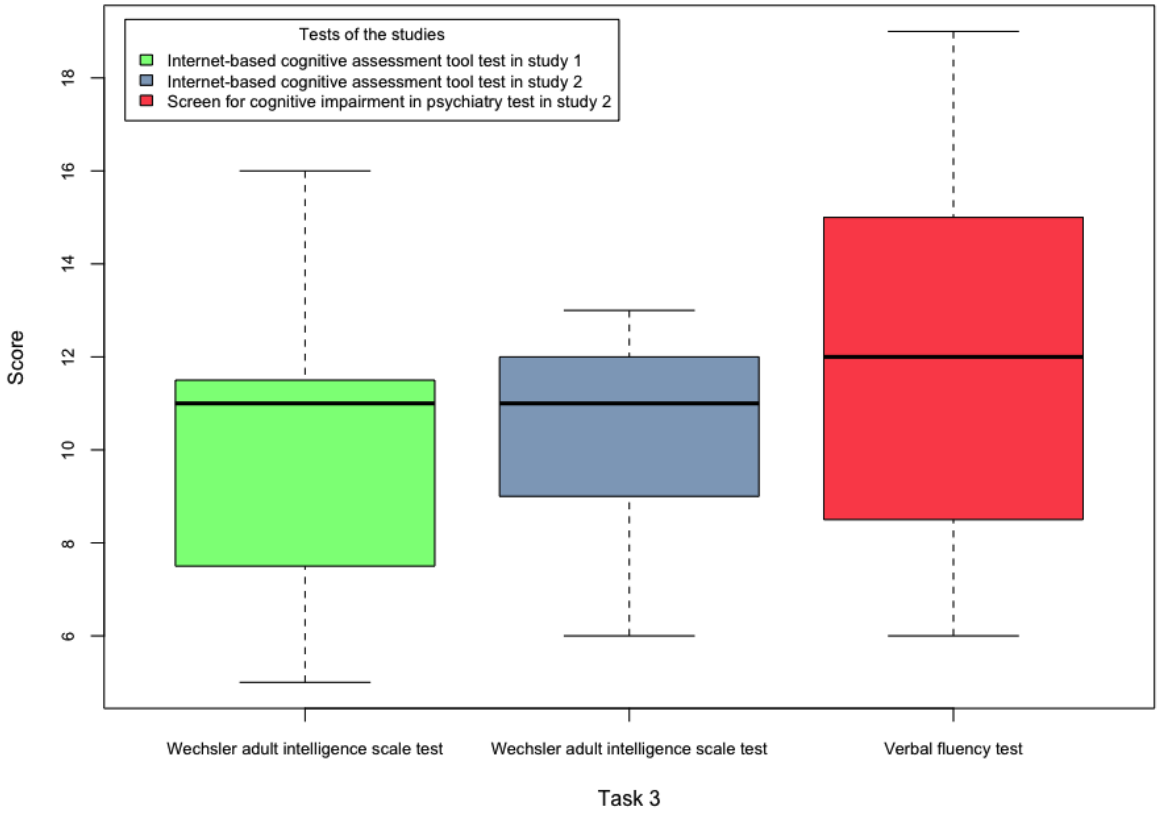


Figure 9. Boxplots of the internet-based cognitive assessment tool and screen for cognitive impairment in psychiatry subscores of the participants of both studies in task 4.

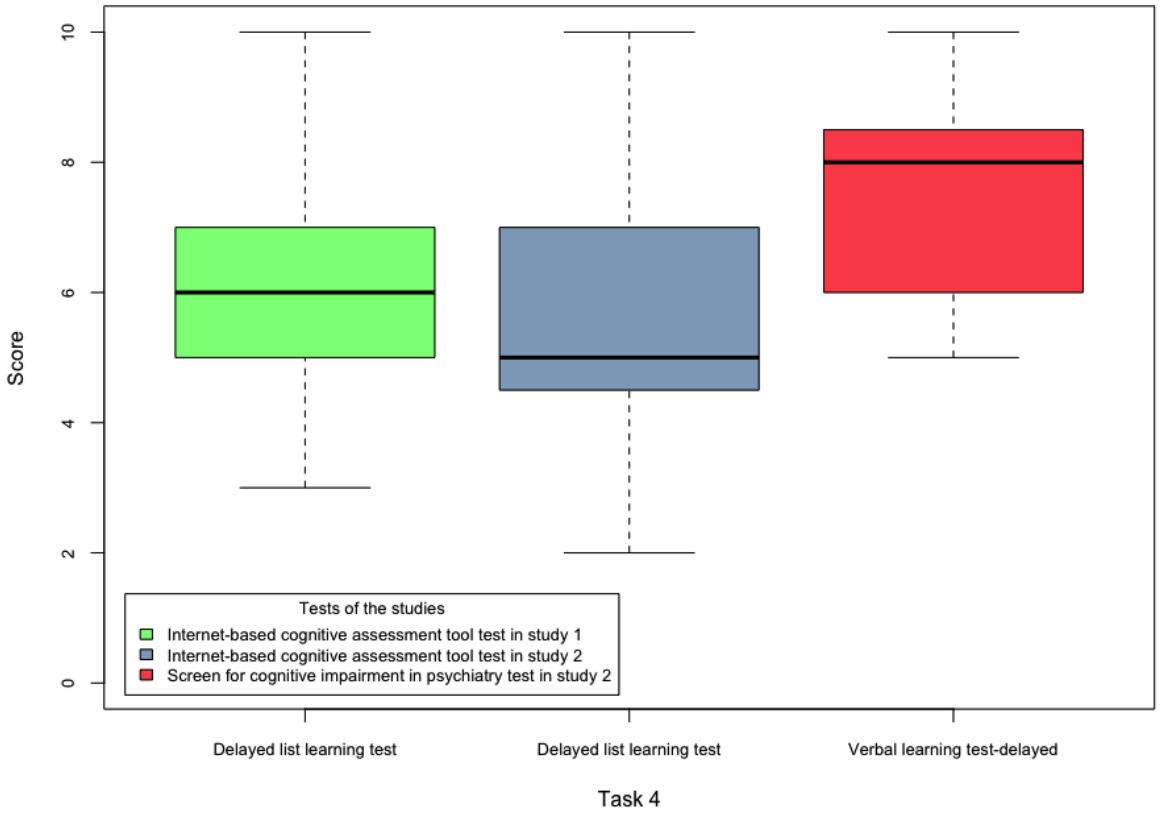
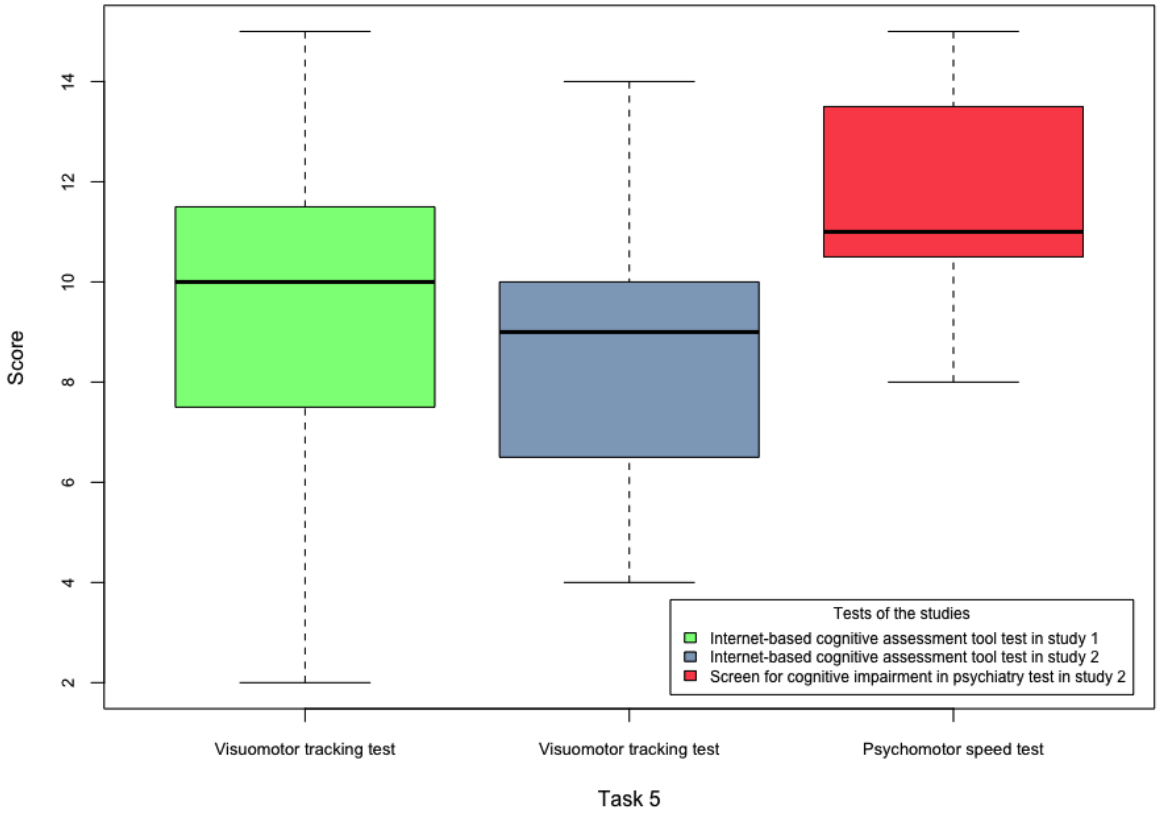


Figure 10. Boxplots of the internet-based cognitive assessment tool and screen for cognitive impairment in psychiatry subscores of the participants of both studies in task 5.



Usability and Feasibility Outcomes

Of the total number of subjects in both studies (N=40), 37 participants submitted the PSSUQ. The psychometric factors of the PSSUQ results (Table 2) are reported for each study separately because the objectives and procedures of those studies were different. Moreover, the PSSUQ results are calculated for Danish and English test participants. According to the reports collected from the follow-up interview and additional comments received via the PSSUQ form, some of the participants reported some issues and gave some suggestions regarding the instructions and the functionality of the ICAT tests. A total of 2 participants of Study 1 mentioned that there were too many instructions in the ICAT LL task. A participant of Study 1 said that the sorting module in the ICAT CR task was complicated and thus not user friendly, and 2 participants of Study 1 mentioned that this module was problematic. In total, 2 participants of Study 2 mentioned that the ICAT CR task was far easier than the SCIP CR task. A participant of Study 1 suggested replacing some of the textual information in the instructions of the ICAT WAIS LNS task with an example. We did not receive any comment on the ICAT DLL task, perhaps because its functionality was similar to the ICAT LL task. For the ICAT VMT task, a participant of Study 1 mentioned that the time limit of this task was too short. A total of 2 participants of Study 1 mentioned that the practice sets of the ICAT CR, WAIS LNS, and VMT were helpful in understanding the tests.

The results of the correlation analysis between the SCIP-D and ICAT subscores and total scores can be found in Table 3.

The analysis of ASR for the ICAT LL and DLL tasks are reported in Table 4. As can be seen, the insertion (I) rate is 0 for both languages. The number of recalls versus recognition accuracy of each English and Danish word are represented in Figures 11 and 12, respectively. Overall, 332 words were received from 12 English-speaking participants of Study 1 and 887 words were gathered from 28 Danish-speaking subjects (9 from Study 1 and 19 from Study 2). Note that the words which are repeated more than once are included in Figures 11 and 12. Of the English words, *machine*, *milk*, and *coffee* were the most recalled and the least misinterpreted words, whereas *bed* and *hat* were highly misinterpreted and were the least memorized terms. The word *garden* was the most recalled word (45 times) but its accuracy (77.78%) was not as high as the words mentioned earlier. For the Danish word list, *mælk* and *sømand* were correctly recognized for every response received, whereas *seng* and *brev* were misinterpreted frequently.

Table 2. Psychometric factors of poststudy system usability questionnaire for usability evaluation of the internet-based cognitive assessment tool reported for both studies and testing languages.

Factor	Study 1 (N=21), mean (SD)	Study 2 (N=16), mean (SD)	Danish test (N=25), mean (SD)	English test (N=12), mean (SD)
Overall score	4.12 (0.46)	4.36 (0.42)	4.25 (0.45)	4.19 (0.45)
System usage	4.23 (0.53)	4.52 (0.41)	4.39 (0.48)	4.35 (0.45)
Information quality	3.86 (0.55)	4.24 (0.58)	4.11 (0.55)	3.84 (0.64)
Interface quality	4.28 (0.62)	4.25 (0.49)	4.16 (0.57)	4.50 (0.45)

Table 3. Results of correlation analysis applied to the screen for cognitive impairment in psychiatry (Danish version) and internet-based cognitive assessment tool scores.

Cognitive domain	Screen for cognitive impairment in psychiatry–Danish version task	Internet-based cognitive assessment tool task	Pearson correlation coefficient (r)	*P* value
Verbal learning (SCIP-2[a])—using ASR[b] transcripts	VLT[c]-I	LL[d]	0.56	.013
Verbal learning (SCIP-3[e])—using ASR transcripts	VLT-I	LL	0.67	.002
Verbal learning (SCIP-3)—using manual transcripts	VLT-I	LL	0.66	.002
Working memory (SCIP-2)	WMT[f]	CR[g]	−0.12	.63
Working memory (SCIP-3)	WMT	CR	0.11	.65
Executive function (SCIP-3)	Verbal fluency test	Wechsler adult intelligence letter-number sequencing	0.29	.27
Delayed recall (SCIP-3)—using ASR transcripts	VLT-D[h]	DLL[i]	0.34	.15
Delayed recall (SCIP-3)—using manual transcripts	VLT-D	DLL	0.58	.009
Psychomotor speed (SCIP-3)	VMT[j]	VMT	0.71	.001
Total score	Total	Total	0.63	.009

[a]SCIP-2: Screen for Cognitive Impairment in Psychiatry–version 2.

[b]ASR: automatic speech recognition.

[c]VLT-I: verbal learning test-immediate.

[d]LL: list learning.

[e]SCIP-3: Screen for Cognitive Impairment in Psychiatry–version 3.

[f]WMT: working memory test.

[g]CR: Consonant Repetition.

[h]VLT-D: verbal learning test–delayed.

[i]DLL: delayed list learning.

[j]VMT: visuomotor tracking.

Table 4. Performance evaluation of automatic speech recognition in internet-based cognitive assessment tool task 1 (list learning) and task 4 (delayed list learning).

Language	Participants in task 1, n	Participants in task 4, n	Average word error rate	Substitution error ratio, %	Deletion error ratio, %
English	12	11[a]	17.77	77.97	22.03
Danish	28	27[b]	6.31	92.98	7.02

[a]1 English-speaking participant accidentally clicked on the stop button in the internet-based cognitive assessment tool delayed list learning task before repeating the recalled words.

[b]1 Danish participant could not remember any word in the internet-based cognitive assessment tool delayed list learning task.

Figure 11. Total number of recalls versus the recognition accuracy of the English words in task 1 (list learning) and task 4 (delayed list learning).

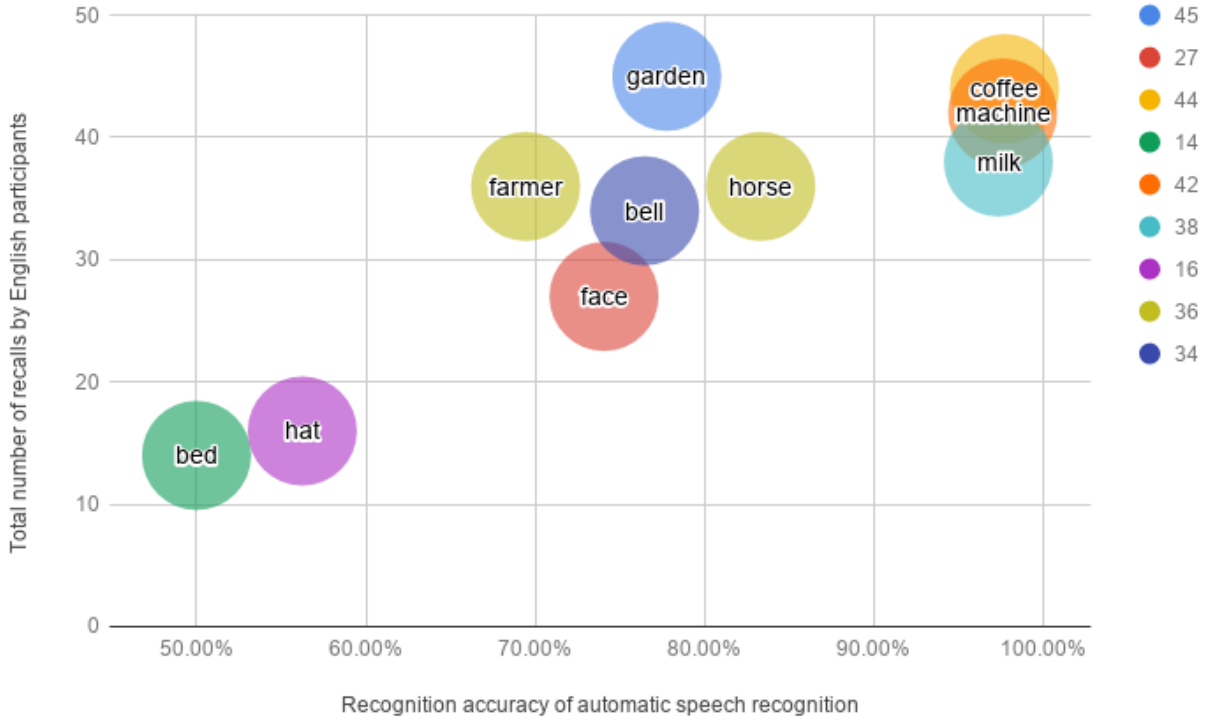
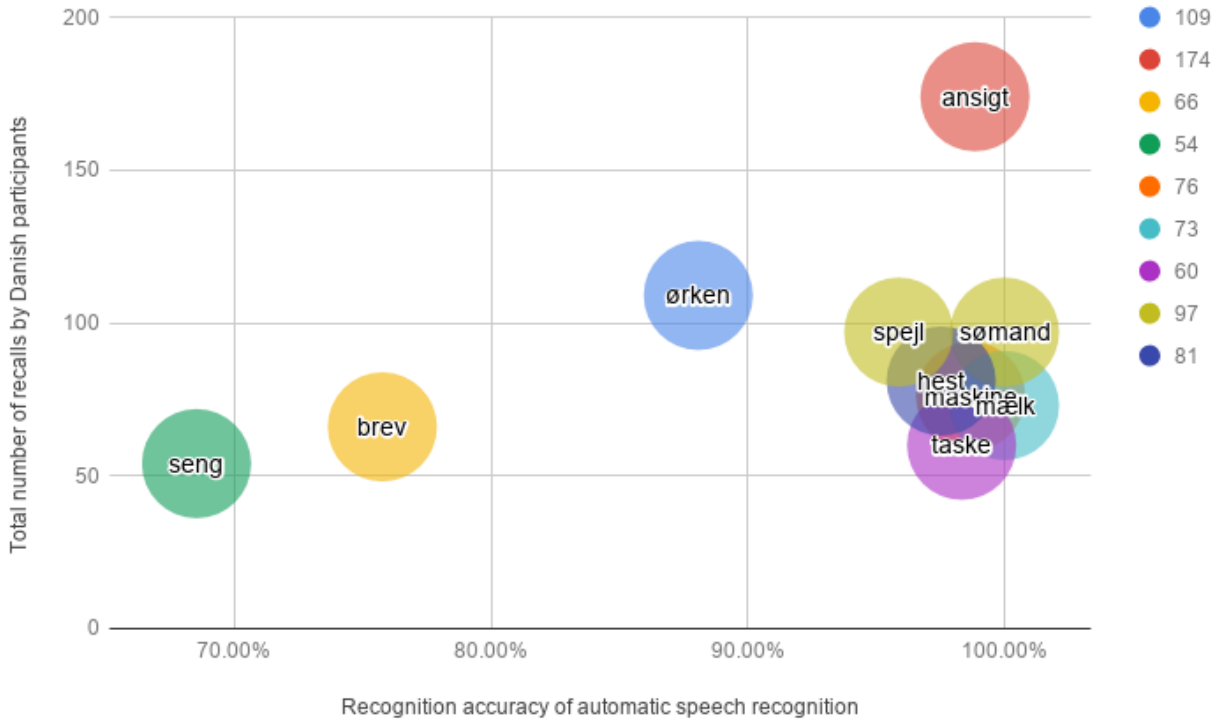


Figure 12. Total number of recalls versus the recognition accuracy of the Danish words in task 1 (list learning) and task 4 (delayed list learning).



Discussion

Principal Findings

The ICAT is the first Web-based cognitive screening tool for affective disorders, designed based on the SCIP as a gold-standard tool, and it uses ASR to assess immediate and delayed verbal recall. The key findings were that the ICAT was easy to use, had promising feasibility outcomes in measuring key cognitive functions, and had acceptable concurrent validity. Specifically, the ICAT and SCIP-3 total scores correlated to a

moderate to strong degree (r=0.63; *P*=.009), and the subtests, namely, LL and VMT, correlated to a moderate (r=0.67; *P*=.002) and strong (r=0.71; *P*=.001) degree, respectively. The usability evaluation of the ICAT system revealed high scores above 4 for system usefulness, interface quality, and overall usage. The information quality was rated lower by the English-speaking participants (3.84), compared with the Danish participants (4.11), which may indicate that the English instructions of the ICAT tests should be revised. The insignificant error rates of ASR, as calculated for the Danish and English responses (6.3% and 17.8%, respectively), indicate a promising future of ASR, particularly for Danish-speaking patients who will be the primary users of the ICAT. According to the results obtained from the recent THINC-it validity study on healthy subjects [10], the 2 cognitive games called Trails (executive function, r=0.74) and Codebreaker (attention, working memory, and executive function, r=0.63) revealed strong to moderate convergent validity, respectively, whereas Symbol Check (working memory, r=0.19) and Spotter (attention, r=0.44) showed low validity. In our study, the ICAT subtest for psychomotor speed also showed moderate concurrent validity, as did the subtest for verbal memory. However, the subtests tapping into working memory and executive skills did not correlate with the original SCIP tasks, which might be because of a suboptimal design of these tests or the small sample size. The ICAT may be an alternative to the THINC-it, which is the most recent cognitive screening tool developed specifically for UD patients. The analysis between the total scores of the SCIP and ICAT showed moderate to strong correlations (r=0.63) in contrast to the moderate concurrent validity (r=0.42) of the THINC-it composite. The higher concurrent validity and the automatic real-time verbal memory assessment via ASR are thus the advantages of the ICAT.

The lack of statistical significance between task 2 of the SCIP and ICAT might be because of the replacement of the oral countdown task with the sorting module because (1) 2 participants in Study 2 mentioned that the ICAT CR subtest was easier compared with the paper-based SCIP CR and (2) participants received high scores in the ICAT CR subtest for both studies (Figure 7), which may indicate a ceiling effect for this task. The insignificant coefficients may indicate that the participants' cognitive load in the ICAT sorting module was less than the countdown task in the SCIP CR subtest. Hence, the ICAT will require additional modifications before conducting a larger validation study of healthy individuals and patients with affective disorders.

The lack of statistical significance in the DLL task was unexpected because the ASR component was the same for both the ICAT LL and DLL subtests. When doing a poststudy analysis of the recorded data, we found that poor recognition was mainly rooted in 2 factors: (1) the subject did very fast recalls of the words and uttered them right after each other, with no or limited pauses in-between each word or (2) the subject spoke very quietly and far from the microphone. Therefore, the lack of a statistically significant correlation between the ICAT and SCIP DLL tasks might be because of the various ways in which the participants repeated the recalled words. It was previously shown that speech recognition did not perform well for non-native speakers [22], which perhaps justified the higher WER of the English responses for the participants of Study 1 (11 non-native English speakers). The analysis of the ASR of the English-speaking subjects would be more robust if we could recruit more English-speaking participants, especially native speakers. The words which received the lowest accuracy (*bed* and *hat* from the English list and *seng* and *brev* from the Danish list) should be replaced with other words provided in the SCIP manual. The lower ratio of deletion error indicated that ASR received most of the verbal responses in the ICAT LL and DLL subtests.

Digitizing validated paper-and-pencil tests requires effort in prototyping, iterative design, implementation, and evaluation. The ICAT is the first Web-based application designed based on the SCIP as a gold-standard cognitive test battery. Moreover, to our knowledge, none of the existing digital cognitive assessment tools provides a real-time assessment of verbal memory. Taking it all together, the ICAT is a novel digital tool for cognitive assessment. The feasibility of the ICAT reported in this study indicates a promising use for out-of-clinical assessment. The ultimate goal of our research is to introduce the ICAT as a brief cognitive assessment tool for remote administration and the assessment of affective disorder patients.

Implications for Future Development

On the basis of our observations, the sorting module in the ICAT CR subtest was difficult to use for most of the participants. In addition to this issue, the analysis did not show significant correlations between the SCIP and ICAT CR subtest. Consequently, the sorting module in the ICAT should be redesigned to resemble the SCIP CR task better, for example, with a speech interface, because changing the type of the interface was perhaps the primary reason for the insignificant correlation coefficient.

To mitigate the speech recognition problems, the ICAT should incorporate detailed instructions and tutorials that teach and train users how to speak loudly, clearly, and close to the microphone. Moreover, the speech recognition should be able to detect when users repeat the words too fast or quietly and then instruct them to slow down or speak more clearly. The goal is to enable the ICAT to be administered by the patient, and hence, a strong emphasis should be placed on providing self-explanatory instructions and tutorials to the users.

Limitations

This is the feasibility study of the ICAT with a limited number of participants. Despite the promising results, there are a set of limitations of the study. First, the evaluation of the ASR for English-speaking participants was limited because of the few number of native English speakers. We did not evaluate the English proficiency of the participants of Study 1 to examine whether or not the ASR recognition error was because of their English proficiency level. Second, the think-aloud method was not practical, especially during the ICAT LL and DLL subtests in which users repeated their recalled words. As cognitive tests demand mental effort, it was hard for the participants to verbalize their thoughts during the test. Hence, an implicit or objective approach for recognizing participants' interaction with

the system throughout the test would be more practical. Third, the nonsignificant coefficients of the executive function and working memory according to Pearson correlation analysis might be because of the modest sample size of Study 2. Fourth, the SCIP VF task and ICAT WAIS LNS task do not translate directly into exactly the same aspect of executive functions. VF performance has been found to correlate with fluid reasoning and shifting aspects of executive function [23], whereas WAIS LNS more specifically measures working memory [24]. It is worth mentioning that currently, Google's ASR converts any arbitrary word to the closest meaningful word. Hence, the rationale for replacing the VF task with the WAIS LNS task in the ICAT was the possibility of misinterpretation caused by using the ASR technology. Finally, this pilot study included only healthy control participants. The ICAT is intended to be used for cognition screening in patients with mood disorders. On the basis of the preliminary findings from this report, our group is, therefore, in the process of validating a slightly revised version of the ICAT in patients with mood disorders.

Conclusions

The ICAT is a patient-administered, Web-based tool to screen for cognitive impairment in patients with affective disorders. The results indicate that the ICAT is a good initial step toward building a digital modified cognitive assessment tool based on the SCIP. The high values of the psychometric factors derived from the PSSUQ scores present the ICAT as a usable and useful tool. The use of real-time ASR during the immediate and delayed recall gave a WER of 17.8% and 6.3% for English and Danish responses, respectively. On the basis of the results and insights derived from this study, future optimization and further validation of the ICAT are now warranted.

Acknowledgments

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Conflicts of Interest

KWM reports having received consultancy fees from Lundbeck, Allergan, and Janssen in the past 3 years. LVK has been a consultant for Lundbeck for the past 3 years. The remaining authors report no conflicts of interest.

Multimedia Appendix 1

User experience design of the (ICAT) internet-based cognitive assessment tool.

[PDF File (Adobe PDF File), 1MB - formative_v3i3e13898_app1.pdf]

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Abbreviations

ASR: automatic speech recognition
BD: bipolar disorder
CACHET: Copenhagen Center for Health Technology
CARP: CACHET Research Platform
CNSVS: central nervous system vital sign
CR: consonant repetition
DLL: delayed list learning
GDPR: general data protection regulation
ICAT: internet-based cognitive assessment tool
ISBD: International Society for Bipolar Disorder
LL: list learning
MCI: mild cognitive impairment
mHealth: mobile health
PSSUQ: poststudy system usability questionnaire
SCIP: screen for cognitive impairment in psychiatry
TEAM: technology enabled mental health

UD: unipolar disorder
UI: user interface
UX: user experience
VF: verbal fluency
VMT: visuomotor tracking
WAIS LNS: Wechsler Adult Intelligence Scale letter-number sequencing
WER: word error rate

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Original Paper

Redesigning a Sentinel Surveillance System for Collecting and Disseminating Near Real-Time Agricultural Injury Reports: System Usability Study

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Abstract

Background: Injury data and reports provide valuable information for both public and private organizations to guide programming, policy, and prevention, but in the increasingly complex and dangerous industry of US agriculture, the injury surveillance needed to produce this data is lacking. To address the gap, AgInjuryNews was established in 2015. The system includes fatal and nonfatal injury cases derived from publicly available reports, including occupational and nonoccupational injuries, occurring in the agricultural, forestry, and fishing (AFF) industry.

Objective: The study aimed to develop a stakeholder-engaged redesign of the interactive, up-to-date, and publicly available dataset of US AFF injury and fatality reports.

Methods: Instructor-led heuristic evaluations within a 15-student undergraduate course, data from 8 student participants of laboratory-based usability testing and 2016 and 2017 AgInjuryNews-registered user surveys, coupled with input from the National Steering Committee informed the development priorities for 2018. An interdisciplinary team employed an agile methodology of 2-week sprints developing in ASP.NET and Structured Query Language to deliver an intuitive frontend and a flexible, yet structured, backend, including a case report input form for capturing more than 50 data points on each injury report.

Results: AgInjuryNews produced 17,714 page views from 43 countries in 2018 captured via Google Analytics, whereas 623 injury reports were coded and loaded, totaling more than 31,000 data points. Newly designed features include customizable email alerts, an interactive map, and expanded search and filter options. User groups such as the Bureau of Labor Statistics and the Agricultural Safety and Health Council of America have endorsed the system within their networks. News media have cited or referenced the system in national outlets such as the New York Times, Politico, and the Washington Post.

Conclusions: The new system's features, functions, and improved data granularity have sparked innovative lines of research and increased collaborative interest domestically and abroad. It is anticipated that this nontraditional sentinel surveillance system and its dataset will continue to serve many purposes for public and private agricultural safety and health stakeholders in the years to come.

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KEYWORDS

agriculture; risk; wounds and injuries; safety; farms; news; newspaper article

Introduction

Background

Although both integral and essential to economic prosperity, agricultural work continues to be among the most dangerous in the United States, with an annual death rate of 24.9 of 100,000 persons compared with 3.5 of 100,000 persons overall [1].On a national level, those employed in the agricultural, forestry, and fishing (AFF) industrial sector are 29 times [2] more likely to be fatally injured while working than workers in other industries [3]. The cost of AFF-related injuries nationally averaged an estimated US $7.6 billion/year (inflation adjusted estimate), which is 30% above the national average of work-related injury costs [4].

Youth employed within this sector also experience more frequent injuries and are nearly 45 times more likely to be fatally injured compared with all other industries combined (28.21 per 100,000 full-time employee (FTE) vs 0.63 per 100,000 FTE) [5]. From 1998 to 2012, the National Institute of Occupational Safety and Health (NIOSH) reported a steady decline in the rate of nonfatal childhood agricultural injuries, but 2014 data show a reversal of this trend (increased injury rates) for 10- to 19-year-old youths [5]. Over the same time period, there has been no measurable decline in the number of childhood agricultural deaths [6], with a child dying in an agriculture-related incident about every 3 days [7-9]. These injuries and fatalities are costly; among children and youth (<18 years), injuries cost the society an estimated US $1 billion per year and fatalities cost US $420 million per year (in 2005 US dollars) [10].

Capturing Injury and Fatality Data

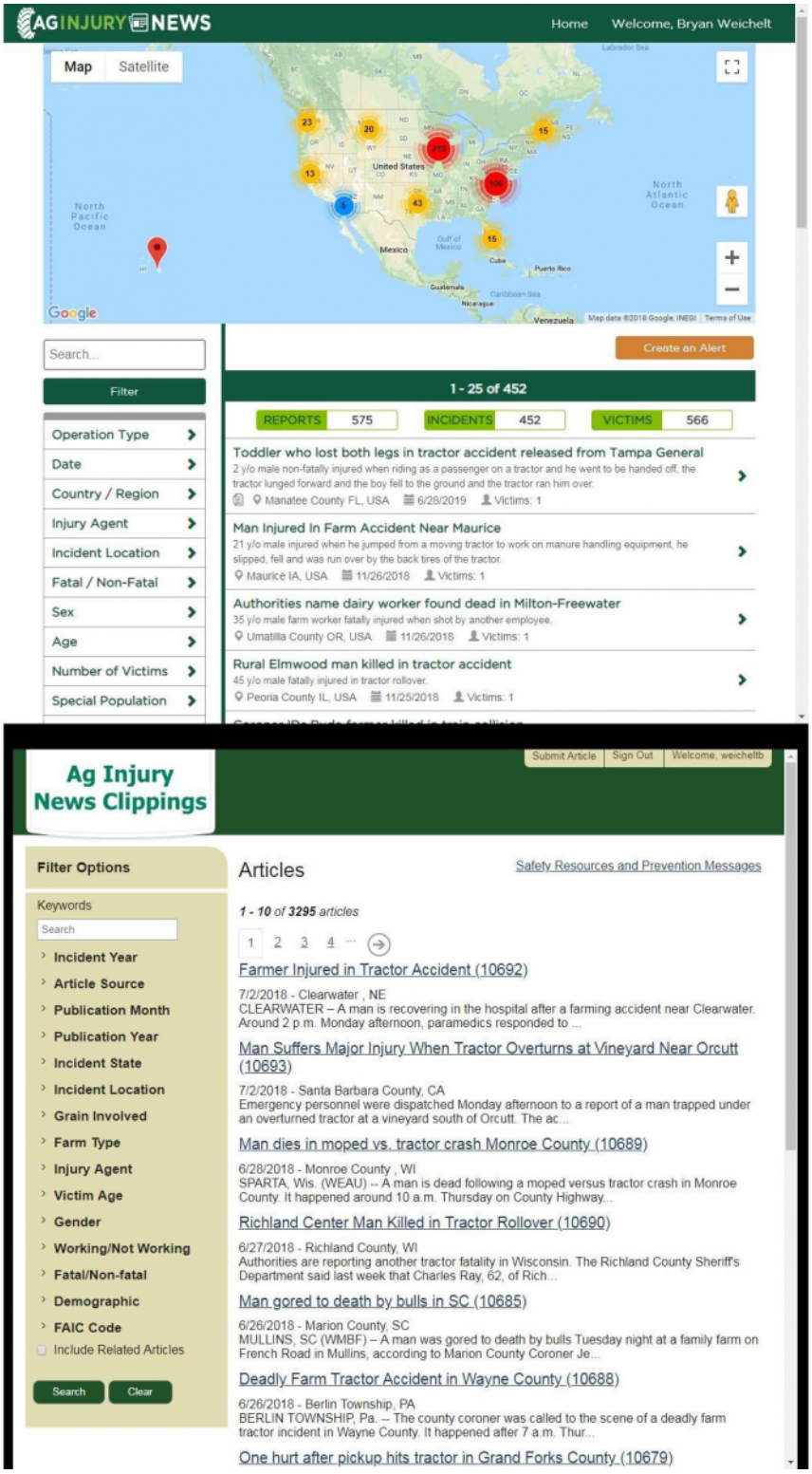
Despite the documented risks, capturing injury and fatality data is increasingly difficult. Several federal and state-funded occupational injury surveillance programs have been eliminated in recent decades, and at present, there is no central database for current US AFF injuries and fatalities [11]. Regional and state-based injury surveillance efforts have had difficulty scaling to the national level, primarily because of the cost to build and sustain a rigorous program. Some state and regional programs, in the United States and abroad, maintain internal databases [10-19]. Many of these also collect and integrate publicly available reports from sources such as news media. These regional programs are further described in a different paper [20]. Researchers have piloted regional injury surveillance efforts, but no recent national efforts have been identified in the literature [21-26].

Capturing data on youth injuries and fatalities is also difficult, as there is no central database on US childhood agricultural injuries and fatalities either [11]. Furthermore, the NIOSH-sponsored Childhood Agricultural Injury Surveillance (CAIS) system that collected and reported childhood agricultural injuries from 1998 to 2014 was discontinued in 2015 [27]. Data provided by CAIS were instrumental in directing injury prevention strategies for youth participating in production agriculture activities.

Origins of AgInjuryNews

Due to the limitations of remaining data sources (eg, police blotters, death certificates, and surveys), the NIOSH-funded National Children's Center for Rural and Agricultural Health and Safety (NCCRAHS) recognized the need for additional injury and fatality data sources. It was identified that social media and news monitoring systems have improved the likelihood that news reports (from multiple sources) can provide a meaningful picture of childhood agricultural trauma, especially the injuries and fatalities severe enough to warrant news reports [28]. NCCRAHS had been collecting injury and fatality news reports for several years, and these reports, along with a subscription service for news clippings, became the content for the first publicly available dataset of its kind on AgInjuryNews, which was launched in early 2015 (see Figure 1) to help fill the gap in childhood agricultural injury information [29]. It was determined from the beginning that as injuries and fatalities frequently occur to nonworking children on agricultural properties, AgInjuryNews (AIN) would include all agricultural-related incidents, regardless of work status (eg, youth bystanders, visitors to agritourism operations, and nonworker victims in public roadway crashes [29]). In 2015, it was decided to expand AIN to include adult incidents and to include forestry and fishing incidents.

Figure 1. AgInjuryNews pre- (lower panel) and postredesign (upper panel) screenshots.



Filling a Gap

Obtaining sufficiently detailed data is a primary challenge when describing injury risk factors and developing appropriate prevention and control measures. The majority of systematically collected data that are available across the industry lack specificity to identify modifiable risk factors. Moreover, collecting injury data in this population through surveys that reach all workers, including self-employed and part-time producers, is wrought with challenges because of the lack of sufficient rosters for recruitment, a predictably low response rate, and all at a very high cost. Analyses of past survey surveillance programs unveiled other major gaps including data quality issues partly due to nonresponse, measurement errors and underreporting, untimeliness, and a lack of flexibility toward intersystem integrations [30].

Since its 2015 launch, the AIN system has become a nationally recognized resource of up-to-date, publicly available injury

data, but does not claim to serve as an official federal dataset. This initiative takes a deliberate approach to identify multiple sources of publicly available data that adequately describe injury risks and incidents. It provides national-level information to guide research, intervention, and public policy in AFF safety and health. The AIN system has been endorsed by the national office of the Bureau of Labor Statistics, which encourages its use among the states' data specialists [29]. The initiative has also been referenced or cited in numerous 2016-2018 state, regional, and national news media articles [31].

As the AIN system continued to grow, both by expanding content with adult, as well as forestry and fishing injury reports, and also by expanding the number and diversity of users, it became evident that upgrades to the system were needed, both to improve data granularity and workflow efficiencies and also to fulfill stakeholder requests and expectations in staying informed of recent traumatic injury events around the nation. In this study, we presented the methods and results of usability testing and development strategies of the new AIN system. We also described multiple future lines of collaborative translational research and several applications of research to practice.

Methods

Institution and Ethics Approval and Informed Consent

Usability testing was exempted from review by the University of Wisconsin–Stevens Point Institutional Review Board (protocol # 16-17.065). No other human subjects were involved in this research and the AgInjuryNews initiative has been exempted for review by the Marshfield Clinic Research Institute's Institutional Review Board.

System Design and Development

Initial design and development of the 2015 version was described in the previous section and in a separate paper [29]. The following subsections will describe the 2018 redesign.

AgInjuryNews User Experience

Intuitively designed products can make tasks easier and impact organizations' bottom line [32]. This emphasis on usability benefits the internal return on investment (ROI) by increasing users' productivity and decreasing errors and the external ROI through savings gained when changes to the product can be made earlier in the design process [33]. When projects go over budget, the causes are often related to usability: frequent requests for changes by end users, overlooked tasks, users' lack of understanding of their own requirements, and insufficient user-analyst communication [34]. Usability methods can also save on development of superfluous features by identifying the end users' needs [35]. Usability metrics are key in calculating the ROI of usability engineering methods and help to reveal patterns that are difficult to see [36].

To evaluate the previous version of the AgInjuryNews system, a 15-student undergraduate usability course at the University of Wisconsin–Stevens Point conducted a thorough, instructor-led (by second author), heuristic evaluation of the AgInjuryNews system in 2016 using usability heuristics proposed by Nielsen [35]. The heuristic evaluation found that the site does not have any catastrophic usability problems and the overall level of usability is good—there are no issues that would prevent users from completing their tasks on the site. A total of 28 unique usability problems were discovered, of which only 2 were considered major (ie, problems that would significantly impact the use of the system). Many of the problems (n=13) were related to the search functionality. The design and implementation did not adequately support intuitive filtering and sorting of the results. In addition, the presentation of the incident details could be improved to make the content easier for users to review. Addressing these issues would result in significantly improved usability of the core feature of the site. The second largest category of problems was related to the layout of nonsearch-related content, particularly the content about the site itself and design of sitewide navigation. Addressing these issues would make the user experience more consistent with users' expectations of information websites.

Usability testing with 8 participants was completed at the University of Wisconsin–Stevens Point in May 2017 by the second author to validate the findings from the heuristic evaluation. The usability testing of AIN also indicated that the overall usability of the site is acceptable according to the System Usability Scale questionnaire (mean 78, SD 22, median 84; n=8) [37] and above average when compared with industry standards [38]. With a few exceptions, participants were able to successfully complete their tasks with the system. Contingent with the heuristic evaluation findings, the main problem areas for participants were related to the search functionality and display of article summary data. One participant was unable to complete a task that required the use of search filters to discover the number of Wisconsin 2016 agricultural fatalities related to all-terrain vehicles (ATVs), and 3 participants were only partially successful in finding the information. Although they were ultimately successful, 2 participants had initial difficulty in finding the link (source URL) to read the original Web-based media article of the injury.

Combining these evaluations with results from 2016 and 2017 AgInjuryNews–registered user feedback surveys, the team prioritized functionality and usability updates that were completed in 2018. The development backlog included items such as basic account registration updates, map integration, and automated and customizable reports delivered via email to users' accounts to provide a near real-time update on media-reported injuries and fatalities in the users' designated region or state.

Project Management

The development of AIN was managed using an agile development methodology with 2-week sprints. The Marshfield Clinic Information Systems development team met with the product owner (first author) and core team members of the AIN project every 2 weeks to review the current development progress and outline the goals and features that were to be developed over the following 2 weeks. Features, tasks, and code were managed within Microsoft Team Foundation Server.

Development Team

The development team comprised a solutions architect, business analyst, programmers, database administrators, systems

administrators, and user experience and design analysts. They worked closely with research scientists with expertise in biomedical and health informatics, information systems, and agricultural health and safety. The team was primarily located within the same health system and primarily housed within the same physical building, except for 2 programmers who worked remotely.

System and Database

AIN was built using ASP.NET and Structured Query Language because these technologies provided the tools and flexibility to build the features and functionality desired for both end users and administers of the AIN site. The development team also had the most experience with these technologies, so using these ensured that the site could be developed and supported by them in an efficient and effective manner.

Database Structure

AIN is a repository of agricultural incidents that resulted in injuries and/or death, which are reported into the system as *Case Report Forms (CRFs)*. The information entered on these CRFs (date/location of incident, victim and injury details, etc; see Table 1) are obtained from news articles, personal interviews, and other *reports* submitted by users and administrators of the AIN system. As multiple sources (eg, a news report and an obituary) often report on the same incident, multiple *reports* can be linked to a single CRF to ensure that each CRF can be updated and reflects the most current information regarding that incident.

Table 1. Incident and victim variables captured.

Incident information category	Input options
Incident date	Month, day, year
Time	Morning (6:00 am-11:59 am)/Afternoon (12:00 pm-5:59 pm)/Evening (6:00 pm-11:59 pm)/Night (12:00 am-5:59 am)/Unknown
Address	Country, state, county, city
Operation type	Agriculture/Fishing/Forestry/Unknown
Occurred during	Work/Leisure/Play/Unknown/Other—please specify
Location of incident	Barn/Field/Forest/Public Roadway, etc
Name	Last, first, middle
Age	Age specified/youth (0-17)/adult (18+)/unknown
Sex	Male/female/unknown/other
Special population	Migrant-seasonal/anabaptist/military veteran
Was the injury fatal	Yes/no/unknown
Date of death reported?	Yes/no
Date of death	Month, day, year
Role in the event	Operator/passenger/bystander/firefighter-EMS[a]/unknown/other
Intentional injury	Not intentional/suicide/homicide/unknown/other
Was this in a confined space?	Yes/no/unknown/NA[b]
Was grain involved?	Yes/no/unknown/NA
Did drowning/suffocation occur?	Yes/no/unknown/NA
Was alcohol or drugs involved?	Yes/no/unknown/NA
Was a seatbelt used?	Yes/no/unknown/NA
Was a helmet used?	Yes/no/unknown/NA
Was rollover protection structure used?	Yes/no/unknown/NA
Was this Agritourism?	Yes/no/unknown/NA
Other personal protective equipment used?	Yes/no/unknown/NA
FAIC[c]	FAIC-1/FAIC-2/FAIC-3/FAIC-4/FAIC-5/FAIC-6/FAIC-7/FAIC-8/FAIC-9/FAIC-10
Injury Agent—Primary source	ATV[d]/building or structure/environment/tractor, etc
Injury Agent—Secondary source	ATV/building or structure/environment/tractor, etc
Occupational Injury and Illness Classification System	Nature of injury, part of body affected, primary source/secondary source/tertiary source, event/exposure

[a]EMS: Emergency Medical Services.

[b]NA: not applicable.

[c]FAIC: Farm and Agricultural Injury Classification.

[d]ATV: all-terrain vehicle.

Stakeholder Engagement—Steering Committee

A total of 15 members were invited to participate on the cross-sector national steering committee in January 2017 and met in person in April 2017. Findings at the meeting informed future direction, including changes to data collection, inclusion criteria, sustainability options, and the database and user interface design. One group teleconference call was held in late 2017 with similar goals as the in-person meeting. Small groups and subcommittees further informed and guided other elements of the redesign through 2018, including the inclusion, design, and integration of multiple coding systems, which is the topic of a separate manuscript [39].

Initial selection of committee members was based on several factors: (1) stake in the success of the project, (2) influence and potential impact, regionally and nationally, and (3) expertise in the members' industry/discipline. Committee members were then targeted, reviewed by an internal team of senior researchers/advisors, and recruited. All 15 members accepted the invitation on the first phone call. They currently represent academics, researchers, safety and health professionals and

trainers, insurers, government data specialists, and industry groups such as the Agricultural Safety and Health Council of America.

Promotion and Dissemination

Promotion of AgInjuryNews has primarily been through the National Farm Medicine Center and NCCRAHS newsletters, websites, academic presentations, and peer-reviewed literature. In addition, unexpected dissemination was through the promotion of AIN via the Bureau of Labor Statistics (BLS) national office to its state's representatives in the field and through media coverage noted earlier in this paper, with AIN typically cited as a data source for news stories related in agricultural injuries (eg, New York Times, Washington Post, and Politico).

Finally, several factors that have been identified by journalists as roadblocks to farm safety coverage—difficulty obtaining statistics, stories, and resources [40]—are addressed by AIN, which also provides a resource for research and translational efforts in the field. For example, the AIN database has been used to promote the use of multiple coding schemes for each agricultural incident to better understand the cause, effect, and prevention of agricultural injury incidents [39].

Results

Overview

As of June 1, 2019, the AgInjuryNews system contained 651 reports regarding 513 unique incidents and 642 victims from 2018 alone. Site visitors tracked via Google Analytics have increased domestically and globally. Current registered users of AIN (n=540) are migrating to the newly launched site at the time of this writing. Registered users have reported their intent to continue using the system and have confirmed its value in their organizations' efforts to inform their research, datasets, interventions, and outreach in surveys conducted in 2016 and 2017. These users and others have begun to leverage the injury reports and dataset for translational research projects and to inform future programs in agricultural health and safety, including a brief report of agricultural injuries published by the Upper Midwest Agricultural Safety and Health center in 2016 [28,41]. Collaborators from around the world have expressed an interest to leverage the system and its dataset for other programs and purposes.

Coding Injuries

Agricultural safety and health researchers have used a variety of classification and coding schemes to identify and categorize injury, illness, and disease associated with agricultural hazards, but coding remains challenging for several key reasons. These challenges include difficulty in distinguishing occupational from nonoccupational injuries; a wide range of locations where agricultural activities occur; many victims have a nonagricultural primary occupation; nonworkers are routinely exposed to work-related hazards; children and seniors are a part of the labor force in production agriculture but are routinely excluded from other hazardous occupations; and other occupational cohorts, such as veterinarians, machinery service technicians, and construction workers, perform work on farms and ranches [39].

Not surprisingly, challenges surfaced during the development of this system. Further complicating the design of the data input form was the need to meaningfully display the data immediately after they had been reviewed and published to the site. The following subsections provide detail into several of those key components.

Customizable Email Alerts

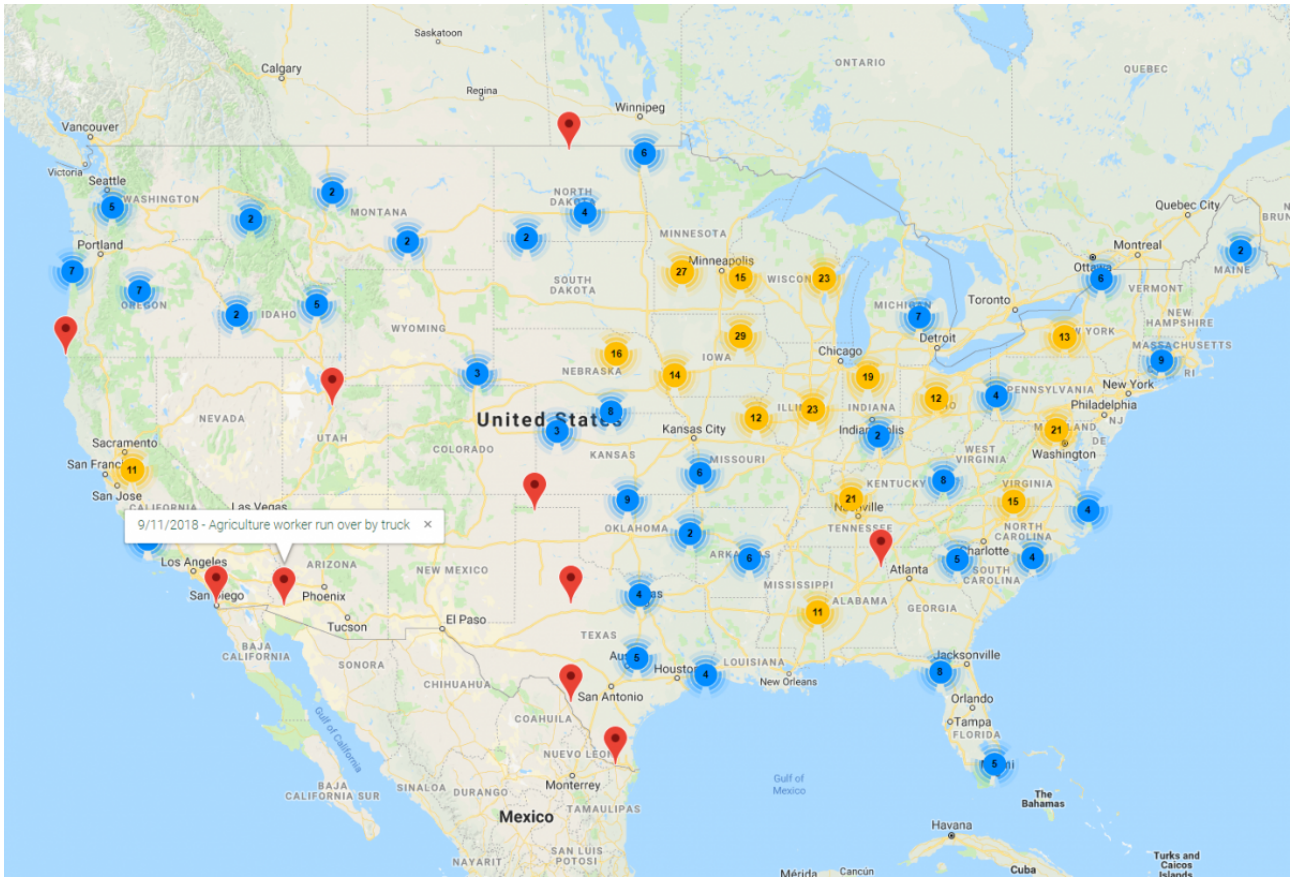
Direct feedback and user survey results indicated a need for a more streamlined notification of injuries occurring within users' sphere of interest. For example, a farm owner and employer may only be interested in learning about injuries occurring in his or her home state. Meanwhile, an ATV safety advocate may want to receive ATV-related injuries occurring in multiple states that involved victims under the age of 12 years. This feature was built to address these needs as well as others not yet identified. We further anticipate that this email alert feature will enhance user adoption and retention across many other stakeholder groups interested in a specific state, region, country, victim age group, injury agent (eg, ATVs or tractors), etc.

Interactive Map

Google Map API (application programming interface)/Marker Clustering API service provides geo-location for addresses. The AIN home page uses this service to pin the locations of incidents on a global map (see Figure 2). Every published incident in the current result set is represented as a pin on the map, and a single incident may have multiple reports linked to it. The location of the pin on the map is determined by the location details of the incident (eg, state, county, or city). As search results are refined, the map is refreshed to zoom in on the locations of the current search results. Full screen viewing is also available, and CRF titles are hyperlinked to the report details page from the map view.

Our team was further presented with a quandary of ethics regarding the pinning of specific addresses on this interactive map. After much discussion and advisement by our external steering committee, the team opted to only display mapped pins at the township/county level as the most granular, rather than specific farm or home addresses.

Figure 2. Map view screenshot.



Search and Filters

One of the biggest values AIN brings to agricultural safety and health stakeholders is the ability to find cases pertinent to what is of interest. AIN accomplishes this by allowing users to filter the site's published CRFs by relevant facets. For example, in a few clicks of the mouse, a researcher can filter the reports to only the ones that involved an ATV and/or incidents that resulted in the death of a youth. In addition to these filter facets, free text search can be used to query for specific terminology used within reports, which is also useful when certain terms are not available as predesignated filter options (eg, pumpkin patch, Christmas tree, drone, or robotic).

Multiple Source Icon

Another feature that was designed and integrated into this latest version was the icon indicating that multiple source types are available for a given CRF. When feasible, the team will collect and enter follow-up reports providing additional relevant information about the case (eg, sale of the farm, specifics of an injury, or criminal charges). If a follow-up report from the same source as the initial report (eg, traditional media, social media, obituary, personal interview, or police report) is entered, no icon appears. If a follow-up report is entered of a different source type, a silver icon appears with hover text *Report has 2 unique sources*. And if another follow-up report is entered from a third source type, a gold icon appears with hover text *Report has 3 unique sources*. This allows users to quickly see which CRFs have multiple source types.

Discussion

Principal Findings

Systems such as AIN are not yet widespread. Similar processes, collection methods, and datasets exist but are often for internal use and may not reach public consumption for a year or more after the original injury dates. The utility of the types of data in this system appears to be most valuable when coded, loaded, and disseminated widely soon after the actual injury event occurred.

The National Academies of Sciences, Engineering, and Medicine (NAS) issued a 2018 report titled *A Smarter National Surveillance System for Occupational Safety and Heath in the 21st Century* [42]. The NAS report clearly defines and describes 5 guiding principles: (1) sustain strong leadership, (2) ensure quality data, (3) protect data, (4) disseminate widely, and (5) support the surveillance workforce. The AIN initiative has been focused on each of these principles with varying degrees of priority, most of which are described in the sections above. Under the advisement of an international steering committee, this stakeholder-engaged initiative has strived to ensure quality data that is well protected, when appropriate, and disseminated widely to support the surveillance workforce and all agricultural safety and health stakeholders.

From the initial conception of this initiative in 2015, the team chose to create a system that not only served our own internal needs but also provided value for external collaborators and agricultural safety and health stakeholders more broadly. With

the initial quiet launch in 2015, the team saw surprising adoption, including the promotion of AIN through the BLS national office to all US state's data specialists. Since that time, the BLS has registered accounts representing more than 25 different US states. We anticipate that with the inclusion of more intuitive and more helpful features, such as the customizable email alerts, this system will prove to be even more valuable to user groups such as the BLS that are interested in specific data (eg, occupational-related fatalities occurring in their US state). Future research in this area will include analyses of these user groups' interests and needs with regard to near real-time injury report data.

Public agencies, such as the BLS, and many private organizations, such as the Agricultural Safety and Health Council of America, John Deere, Breeze Dairy Group, Maple Ridge Dairy (see Figure 3), Rural Mutual Insurance, Zenith Insurance, and M3 Insurance, support using AgInjuryNews to augment existing information and to inform industry-driven occupational safety initiatives. Furthermore, journalists have become an increasingly valuable user group. In 2019, we identified the first case of a journalist finding AIN on her own and crafting a story, unassisted [43]. We envision more journalists using data from AIN to localize a story, either on a tight deadline or as part of an enterprise/investigative piece. AIN may ultimately be a self-sustaining initiative for industry use, while also filling a gap within a more comprehensive federal agricultural injury surveillance program.

Future research can and should include foci on data collection methods, further exploring additional sources of digital injury reports and the semiautomation of their identification and coding. During the 2018 user-/stakeholder-informed system redesign project, the amount of granularity needed for reporting these events increased substantially. Consequently, it is not feasible to automatically fill all 30 or more form fields by text analytic techniques in an accurate and cost-effective manner from unstructured data sources. In other words, human intervention is still needed for the data entry steps; however, it is possible that human intervention will become less necessary over time with the implementation of a new technique that is being specifically developed for news articles known as the Thompson Reuters Intelligence Tagging [44]. If the initiative secures additional funding, we hope to minimize human interaction in processing large amounts of reports to be as efficient and accurate as possible in data collection and abstraction.

Furthermore, we anticipate that future work would include an integration of health informatics techniques with sociocultural analyses. In a future study, we hope to calculate and target the relatedness of articles and further explore options to retrieve news articles that are highly correlated. This step will compile reports that discuss the same event or elements within the event (eg, farm, victim name, or injury agent) over longer periods of time. If successful, these methods could link articles released before a fatality, such as nonfatal injuries that occurred to the same person or on the same farm. This information could indicate important trends leading to the fatality. Articles released after the same fatality may report long-term results of the incident such as the tribulations of raising an injured child, legal actions taken, or the larger economic impacts of injuries and fatalities (ie, the fatality resulted in having to sell the farm). The related news reports, once identified through their linkages, could become a longitudinal account, albeit intermittent, that may be harnessed as a powerful intervention for change. Before developing algorithms, this correlation can be built out of sets of articles known to be linked over time and explored through textual analysis.

Text analysis is a common methodology in anthropology and seeks to test or validate coding schemes to highlight important patterns [45-50]. This process can be achieved with software such as ATLAS.ti, but it is anticipated that these patterns would be initially validated and analyzed manually. If successful, more contextual accounts that explicate the patterns of injuries, near misses, fatalities, and the long-term effects of these events could be a more potent behavioral intervention than statistical facts [51-54].

Finally, experiential reports from initial users and data entry specialists of AgInjuryNews are supported by research on fear appeal effectiveness, suggesting that reading detailed news accounts of actual childhood agricultural trauma events could have a modifying effect on perspectives about children's (<16 years) roles in agricultural settings. Research should explore if and how this Web-based tool and the data within could become a novel approach for influencing farm parents and employers to modify their behavioral intentions regarding agricultural work assignments for youth.

Figure 3. Farm owner and manager searching AgInjuryNews for local injury reports.

Limitations

Limitations with news reports data are evident in publications and our own preliminary findings [20,55]. Perhaps most notably, media reports do not always collect enough detail, do not cover all AFF fatalities, and cover even fewer stories relating to AFF nonfatal injuries. There are also some gaps in collection efforts, and there is room for improvement in interagency collaborations, a topic of future research [56]. In addition, previous studies have identified a discrepancy in the number of drowning fatalities among youth as being poorly captured by news media [25]. However, it is also possible that news media reports may be increasingly the best source of data we have when it comes to current, up-to-date information and could serve as a content pipeline for a readily available digital dataset that contains circumstantial data surrounding an incident, follow-up interviews, legal actions, community reactions, fate of the farm, and other details.

With respect to the usability testing of the preredesign version, the sample of 8 undergraduate student participants is too low to draw meaningful inferences regarding the prevalence of usability problems among the key demographics of AIN. However, given the diagnostic nature of the assessment, a small number of participants is enough to capture insights to improve the product and increasing the number of participants does not necessarily yield better ROI because of diminishing returns [57].

Conclusions and Implications for the Future

The innovation of this initiative is the combination of capturing, coding, and disseminating publicly available data on agricultural injuries and fatalities, primarily mined from news media reports and coupled with relevant prevention materials. The collection of this type of data has historically been limited to individualistic approaches, single-state or regionally focused, and is project specific to satisfy the needs of a funder or to inform a state or regional effort for use with targeted interventions, communications, and the like. AIN, with a national focus, has expanded an informatics-based, stakeholder-engaged approach to collect and disseminate valuable information and injury data to anyone with internet access.

Several significant implications may emanate from this initiative: (1) the system was constructed with an industry-agnostic application in mind and could be easily adopted by other industries beyond AFF; (2) with the guidance and support of the steering committee, we will continue to explore self-sufficient system sustainability options and plan to pilot at least one option by the end of 2020; (3) the initiative engages new partners as agricultural safety advocates and will likely open additional opportunities for collaboration with industry partners on other regional-, national-, or international-level initiatives; (4) we expect this line of research to influence recommendations in the updated National Occupational Research Agenda for AFF in terms of injury

prevention and public-private partnerships, including increased capacity to secure private-sector funds for interventions [58].

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Authors' Contributions

All authors contributed to the conception or design of the work; BW led the project; JV led the developer/technology team; BW, TH, SG, ER, JV, KP, and DJM collaborated on the acquisition, analysis, or interpretation of data for the work; BW and DJM drafted the manuscript; all authors reviewed it critically for important intellectual content; TH, SG, KP, CB, MS, ES, KN, MAP, RR, and DJM contributed throughout the development project, advising on aspects and system features within their areas of expertise. All authors approved the final version to be submitted/published; and all authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

None declared.

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Abbreviations

AFF: agricultural, forestry, and fishing
AIN: AgInjuryNews
API: application programming interface
ATV: all-terrain vehicle
BLS: Bureau of Labor Statistics
CAIS: Childhood Agricultural Injury Surveillance

CRF: Case Report Form
FTE: full-time employee
NAS: National Academies of Sciences, Engineering, and Medicine
NCCRAHS: National Children's Center for Rural and Agricultural Health and Safety
NIOSH: National Institute of Occupational Safety and Health
ROI: return on investment

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Original Paper

Use of Short Messaging Service to Improve Follow-Up for Abnormal Pap Test Results in Minority and Medically Underserved Women in North Carolina: Questionnaire on Attitudes and Acceptability

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Abstract

Background: An estimated one in eight cervical cancer cases are due to a lack of follow-up care for abnormal Pap test results. Low rates of completion of follow-up care particularly affect low-income minority women. The burden of cervical cancer could be reduced through interventions that improve timely colposcopy follow-up and treatment of abnormal screening results. Mobile communications via text messaging present a low-cost opportunity to increase rates of clinic return among women referred to follow-up after obtaining abnormal screening results.

Objective: Our aims were to determine the acceptability and feasibility of using text messaging to increase completion of follow-up care following abnormal cervical cancer screening (Pap test) results and to examine factors that may affect the acceptability and use of text messaging to increase communications between health care providers (HCP) and low-income minority women.

Methods: The study participants were 15 low-income women who had undergone a Pap test within the preceding 12 months. Semistructured interviews, including open- and closed-ended questions from a validated questionnaire, were conducted by phone or in person. Responses to closed-ended survey items were tabulated, and descriptive statistics were generated using Microsoft Excel. Responses to the open-ended questions were coded and analyzed using NVivo 11 qualitative analysis software.

Results: Nearly all participants (14/15, 93%) were comfortable receiving a text message from an HCP stating that their Pap test results were available (<40 years: 100%; ≥40 years: 86%). Over half (8/15; 53%) of the participants were comfortable receiving a text message stating that their Pap test results were abnormal, although many preferred to receive such information via a phone call (6/15; 40%). Most participants (9/15; 60%) believed that receiving a text reminder would make them more likely to attend their appointment. The preferred method for receiving a reminder appeared to vary by age, with older women preferring telephone reminders over text messaging reminders. Analysis of open-ended questions suggested that text messaging appeals to some women due to its wide use and convenience for communicating with HCPs. However, women cited concerns about the confidentiality of messages and barriers to understanding the messages, including the physical capacity to read and accurately interpret the content of the messaging.

Conclusions: Most participants indicated a willingness to receive text messages from their HCPs about cervical cancer screening results and believed that text messages were the best way to remind them of appointments for follow-up care. Potential concerns

could be addressed by excluding explicit references to the nature of the appointment in the text message in order to avoid disclosure of sensitive health information to unauthorized individuals. Although text messaging seems promising to improve adherence to timely follow-up, personal preferences should be considered by allowing patients to opt-out of text communications.

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KEYWORDS

cervical cancer; Pap tests; abnormal results; text messaging; appointment reminders

Introduction

Cervical cancer mortality rates are significantly higher in African American/black women than any other racial or ethnic group in the United States [1,2]. This health disparity persists, especially in the South [3], despite evidence that black non-Hispanic woman participate in primary cervical cancer screening activities at approximately the same rates as white non-Hispanic women [4]. Regular cotesting with Pap tests (cytology) and oncogenic types of human papillomavirus (HPV), the virus that causes cervical cancer, is the primary screening method recommended to detect the presence of abnormal precancerous lesions [5].

In the United States, recommended follow-up for abnormal Pap results is completion of colposcopy with biopsy to confirm the presence of a high-grade lesion requiring treatment (cervical intraepithelial neoplasia, grade 2 or more severe, CIN2+), followed by treatment of CIN2+ through outpatient procedures such as loop electrosurgical excision procedure or cold cone biopsy [6]. Progression to invasive cervical cancer (ICC) can be prevented with the early detection of high-grade lesions and adherence to follow-up recommendations for further diagnostics and treatment [6]. Thus, the burden of cervical cancer could be significantly reduced through interventions that promote timely follow-up and treatment of women with abnormal Pap results [7].

Standard clinical protocols require that patients are notified of abnormal Pap results and referred to appropriate follow-up colposcopy and treatment procedures. However, multiple and complex factors may contribute to patient nonadherence to recommended follow-up once patients are informed of their abnormal screening results. These factors include patients' lack of the following factors: knowledge about HPV infection and cervical cancer [8], understanding about the seriousness of an abnormal Pap diagnosis [9], trust in health care providers (HCPs), health insurance, and family and social support [10,7]. Another important challenge is the inability to inform the patient of an abnormal result in a timely fashion due to a disconnected or changed phone number or an incorrect address to send or forward screening results [11]. Any one of these factors may lead a woman to miss or delay her follow-up care, increasing her chances of a poor clinical outcome.

Racial and ethnic differences have been observed in follow-up rates after an abnormal Pap test [12-15], in which African American and Hispanic women were less likely to schedule follow-up visits and receive follow-up care. In contrast, other studies have shown differences in follow-up rates between races to be negligible or even nonexistent [16]. It is imperative that women at the greatest risk of cervical cancer receive follow-up care after an abnormal Pap test or high-risk HPV test result to reduce cancer disparities. This can be achieved by increasing follow-up visits in this higher risk population [5].

The rapid expansion of mobile communications may present a low-cost opportunity to improve follow-up rates. Following an abnormal Pap test result, patients who receive a reminder via text message or short messaging service (SMS) may be more likely to attend a follow-up visit. SMS interventions have been shown to improve the rate of attendance at health care appointments for surveyed populations [17] and may have a similar impact as phone call and postal reminders [18-20]. With respect to cervical cancer, a prior study reported on the use of an SMS intervention to increase knowledge and encourage Pap test screening in Korean American [21] and African American women [22]. However, the feasibility of an SMS intervention to improve follow-up rates for in-clinic colposcopy attendance after an abnormal Pap test result has not been previously explored. For such an intervention to be successful among low-income and minority women, research is needed to understand appropriate SMS-based content, messaging, and context [23] and to determine the likelihood that such an approach would be acceptable to this population of patients.

Therefore, the objective of this study was to explore factors that may play a role in the use of text messaging as a mode to increase communications between HCPs among low-income and minority women who have undergone Pap tests as well as the need to return to the clinic to prevent potential advanced cancers.

Methods

Study Design

Participants were recruited from two clinics serving low-income and minority populations—a free community-based clinic and a university-based clinic—both of which are located in Durham, North Carolina. Women were eligible to participate in the study if they were between the ages of 21 and 60 years and had undergone a Pap test in the preceding 12 months. Participants were recruited by collaborating HCPs who provided eligible patients written information about the study and flyers with contact information at the time of their clinic appointment. Interested women signed forms giving permission for the research team to contact them and were contacted by phone for study enrollment. Due to challenges in successfully enrolling women through this process (eg, wrong telephone numbers, failure of participants to reply to messages, and difficulty scheduling appointments), the recruitment strategy was shifted to screen, enroll, and interview patients before or immediately

after examination by the HCP, unless patients preferred to be contacted at a later time. The clinic provided a room where interviews could be conducted confidentially. This approach greatly reduced the loss between referral from the HCP and successful study completion within the allotted study period.

Interviews

After the participants completed an informed consent, semistructured interviews were conducted over the phone or in person, depending on the preference of the participant. The 58-item interview guide included items from a review of the literature of SMS interventions and a validated questionnaire exploring attitudes and knowledge about HPV and cervical cancer. The combination of open- and closed-ended items included topics on overall attitudes of patients about text messaging practices, relationship with HCPs, preferences about clinic and appointment reminders, and knowledge about cervical cancer and HPV. Interviews were audio recorded and transcribed.

Data Analyses

Responses to closed-ended survey items were tabulated, and descriptive statistics were generated using Excel to report the demographic data, texting practices, and preferences variables. Responses to the open-ended questions were examined by two experienced qualitative researchers during four stages of analysis. As part of the first stage, transcripts were entered into NVivo (version 11; NVivo qualitative data analysis software; QSR International Pty Ltd), a qualitative software analysis package, and organized to allow each reader to efficiently access the same data while allowing for separate sets of analyses. Second, each reader independently read the original transcripts line by line to identify general themes or codes that emerged from the data using the memo functions and other tools of the software. Third, the readers compared their interpretations and refined themes that could be confirmed and systematically evidenced by the data. Fourth, the coders agreed on a final set of themes that appeared to be the most relevant to the study participants based on the frequency of appearance and richness of the evidence.

Results

Participants

The median age of the 15 participants was 34 years (range: 21-58 years). Most women were of African American race (n=13, 87%), had at least some college education (n=10, 57%), and were unemployed (n=9, 60%). In addition, a majority had health insurance (n=10, 67%), most through Medicaid, and nearly all owned a cell phone (n=14, 93%).

Cell Phone Use

Of the 14 women who own a cell phone, 13 (93%) used text messaging, with some differences seen in the frequency of use according to age. All 10 women who had at least some college education (100%) and most women with a high school degree or less education (4/5, 75%) used their cell phone to send text messages (Table 1).

Table 1. Sociodemographic characteristics and cell phone utilization.

Characteristic	Overall (N=15)	Age <40 years (N=8)	Age ≥40 years (N=7)	Fisher exact *P* value
Age (years), median (range)	34 (21-58)	24 (21-34)	50 (46-58)	N/A[a]
Race, n (%)				>.99
African American	13 (87)	7 (88)	6 (86)	
White	2 (13)	1 (13)	1 (14)	
Education, n (%)				>.99
Less than or high school degree	5 (33)	3 (38)	2 (29)	
Some college/college degree	10 (57)	5 (63)	5 (71)	
Employed, n (%)	6 (40)	4 (50)	2 (29)	.61
Has health insurance, n (%)	10 (67)	5 (63)	5 (71)	>.99
Owns a cell phone, n (%)	14 (93)	7 (88)	7 (100)	>.99
Cell phone use per day, n (%)[b]				.001
≤10	6 (43)	0	6 (86)	
>10	8 (57)	7 (100)	1 (14)	
Text messages received per day, n (%)[b]				.20
<25	11 (79)	4 (57)	7 (100)	
≥25	3 (21)	3 (43)	0	
Text messages sent per day, n (%)[c]				.46
<25	11 (85)	5 (71)	6 (100)	
≥25	2 (15)	2 (29)	0 (0)	
Reported phone uses, n (%)[b,d]				
Send text messages	13 (93)	7 (100)	6 (86)	>.99
Find directions	10 (71)	6 (86)	4 (57)	.56
Take photos	13 (93)	7 (100)	6 (86)	>.99
Check Facebook or Twitter	10 (71)	7 (100)	3 (43)	.07

[a]N/A: not applicable.

[b]N=14 women who owned a cell phone (n=7 for women aged <40 years and n=7 for women aged ≥40 years).

[c]N=13, missing one response (n=7 for women aged <40 years and n=6 for women aged ≥40 years).

[d]More than one choice could be selected.

Communication Preferences

Most women (n=14, 93%) indicated that they were comfortable receiving text messages from their HCPs following primary screening visits. Nearly all women in the study (n=14, 93%) were comfortable receiving a text message from an HCP, stating that their Pap test results are available. However, 75% (6/8) of women aged <40 years and only 29% (2/7) of women aged ≥40 years were comfortable receiving a text message stating that their Pap test results were abnormal (Table 2).

When offered a list of preferences for receiving information about their abnormal Pap test results (including via phone, text, letter, or some other way), 6 (43%) of the 14 participants who owned cell phones preferred to receive this information by phone, 2 (14%) preferred text, and 6 (43%) stated no preference.

Nearly half (7/15, 47%) of all participating women were comfortable receiving a reminder via phone to come back to the clinic for follow-up care after an abnormal Pap test, and 33% were comfortable receiving a reminder by text message. Most participants (13/15, 87%) indicated that if they received a text message from the clinic, they would be willing to respond to indicate that they had received the message (Table 2).

Table 2. Women's communication preferences for test results overall and stratified by age. No significant relationships were found (using the Fisher exact test).

Preference	Overall (N=15), n (%)	Age <40 years (n=8), n (%)	Age ≥40 years (n=7), n (%)	Fisher exact *P* value
Comfortable receiving information that lab test results are available through:				
Phone message	15 (100)	8 (100)	7 (100)	>.99
Text message	13 (87)	8 (100)	5 (83)	.20
Comfortable receiving a text message from a health care provider stating that Pap test results are:				
Available	14 (93)	8 (100)	6 (86)	.47
Abnormal	8 (53)	6 (75)	2 (29)	.13
Willing to respond to indicate that you had received a text message from the clinic	13 (87)	8 (100)	5 (71)	.20

Attitudes About Communication Preferences

Analysis of open-ended questions provided useful details on the benefits and barriers to using text messaging for communicating with HCPs, receiving test results, and receiving follow-up visit reminders (Table 3). Cited advantages of text messaging included ease of use and convenience, especially to receive notifications. For some women, texting was no different than the current common practice of providing appointment reminders by phone. However, several participants (particularly older participants) reported barriers to text messaging, including inconvenience (it is easier to call), lack of texting proficiency (not comfortable with texting, texting too slowly, or technologically challenged), difficulty in texting (diminished physical ability), and a lack of confidence in their ability to correctly understand and interpret the content of the text message (often due to low literacy). Some participants felt that the text message would be useless because they generally ignore unsolicited text messages from a source unknown to them.

Most participants also reported concerns over privacy and confidentiality of health information communicated by text, such as receiving a notification for a positive Pap test or for a follow-up visit after a positive Pap test. Most participants were concerned that family members, friends, coworkers, or strangers could gain access to personal health information if the phone was lost or left unattended or was used by others (eg, some participants share their phone with family members). Some participants were also concerned about the potential of hackers accessing their private health information. When probed to explore what might allay their privacy concerns, participants seemed open to discussing strategies such as encryption or passwords, although some still expressed skepticism about the ability of the clinic to safeguard the information.

Table 3. Emergent themes: attitudes about receiving text message reminders to return to the clinic to follow-up on abnormal cervical cancer test results.

Theme	Response
Benefits	
Convenience	"Text just makes it easier to check and see, and then it would be helpful if the text contained a number to call back." [P[a]14]
Notification	"It's impersonal, but just to text me to inform me to come in or your results is back, that's notification." [P7]
Barriers	
Capacity to text (knowledge, comfort, and ability)	"It's a lot of text messages on here, but I don't know how to pull it up on my phone. I just don't know how to do it." [P9]
	"I'm not a text person myself. To me – texting is for the younger generation. It takes more time to text than to just call." [P3]
Physical limitations	"My hand get tired and I have carpal tunnel so I don't mess with it...And then I have arthritis in my hands too, so can't do that..." [P3]
Trust	"I have seen some messages about different things but like I said, if it was unsolicited, I didn't pay it any attention." [P10]
Confidentiality and privacy	"Let's say for example, I leave my phone sitting right here and I go to the bathroom, then all of a sudden, they decided to text me and the text is gonna show up on my phone." [P10]
	"Some people don't have a lock on their phone like I don't have a lock on my phone." [P12]
	"It's hackers out there and...they go into you medical history and they can pull it up and see everything right there on the phone." [P8]

[a]P: participant.

Discussion

In this study, we determined the feasibility and acceptability of using text messaging to improve abnormal Pap test follow-up in minority and medically underserved women in North Carolina. Overall, most respondents seemed receptive to text messaging reminders from their health care providers. Most participants were open to receiving text message notifications that their tests results were available as well as text message reminders about the need to come back to the clinic for follow-up appointments. More respondents preferred receiving abnormal Pap test results by phone rather than by text, although a large proportion reported no preference.

Although most participants reported finding text messaging easy to use and convenient, some participants reported barriers to using text messages (such as comfort, knowledge, and literacy) and concerns about the confidentiality of their private health information. To address issues of confidentiality, clinics could minimize details in the message about the nature of the test results or appointment. Personal preferences should be considered in the use of this technology by allowing patients to opt-out of text communications. Incorrect contact information is a challenge for health care institutions to ensure adequate follow-up, which might be addressed by verbal communication or text message confirmation of the correct number while the patient is still at the clinic for her screening appointment.

A strength of this study lies in the use of open-ended and closed-ended items, which allowed the researchers to both determine the proportion of particular attitudes and collect more detailed information on the benefits of using text messaging to increase compliance with HCP instructions and guidelines as well as the challenges and barriers that may need to be overcome to maximize the use of this technology in this population. Many cognitive and personal factors are associated with failure to comply with recommended follow-up on abnormal results [9-11], which represent broader contextual issues for consideration. For example, one limitation of this study is that we did not systematically collect data on previous experience with abnormal Pap results to assess how these experiences might affect current attitudes.

This study has other limitations. First, due to the small sample size and the nature of the population enrolled (majority of minority and medically underserved women in North Carolina), participants' opinions collected in this study may not reflect those of a broader population. Second, although the focus of the study was to determine the acceptability of text messaging among women who had already undergone primary screening, the importance attributed to the use of all mobile phone apps, including social media platforms (ie, Facebook) particularly for younger women who are more accustomed to these technologies, was not examined. Third, further research is needed to study the effects of such apps on secondary and tertiary prevention activities.

Successful follow-up care and treatment of women with abnormal Pap test results are important for preventing ICC. Reminders are useful tools, which have shown to improve regular screening practices and may allow health care providers to improve adherence to follow-up recommendations. Mobile phones are ubiquitous and provide a convenient and low-cost approach to improve adherence rates. Further research in an actual intervention study is needed to assess the feasibility and effectiveness of SMS approaches to improve adherence to follow-up care among high-risk women with abnormal cervical cancer screening results. A trial is in development to evaluate the effect of a text message intervention on increasing follow-up completion.

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Conflicts of Interest

None declared.

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Abbreviations

HCP: health care providers
HPV: human papillomavirus
ICC: invasive cervical cancer
SMS: short messaging service

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Original Paper

A Health Education Website Developed to Meet Young People's Information Needs About Web-Based Pornography and Sharing of Sexually Explicit Imagery (SCOPE): Usability Study

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Abstract

Background: Although we know that many young people watch online pornography and engage in *sexting*, there is limited literature examining their needs in relation to information on these highly sensitive and complex issues. Online resources exist; however, we can find no evidence of any of them having been formally tested for usability within the target population.

Objective: This study aimed to test the usability of a resource about online pornography and sexting among young people.

Methods: Semistructured interviews were conducted with 17 participants aged 15 to 29 years.

Results: We found that the *SCOPE* resource was perceived as trustworthy and credible because of its evidence-based content, nonjudgmental tone, and balanced perspectives. Multimedia and video content enhanced the layout and usability of the resource; however, content relevance could be improved by targeting age and developmental stages. Participants identified resource sections such as *Real Stories* from young people as relevant and engaging. However, they raised issues with the translation of formative research findings relating to these stories into their final presentation.

Conclusions: Our findings suggest that young people prefer online resources about complex issues, such as online pornography and sexting, if they are balanced in content and tone. Most importantly, in the context of responding to complex and sensitive issues such as these, co-design methods can ensure that young people are central to the development of resources and avoid gaps in translating research into practice. In the context of limited literature focusing on the usability of online resources about these topics, this paper provides important insights for public health practitioners working in this emerging space.

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KEYWORDS

adolescent; pornography; health promotion; internet; sex education

Introduction

Background

Researchers and communities have raised concerns about the high prevalence of exposure to online pornography among young people [1] as well as the relatively high incidence of sharing of personal sexually explicit imagery (sending nudes or sexting) [2]. Although public health research in this area is increasing [1,2], evidence about the effects of engagement with new sexual media remains mixed [3]. Studies have shown that young people are frequently exposed to sexual risk behaviors, gender stereotypes, and inequality when they view pornography [4]. Viewing pornography has been shown to be associated with early age of first sex, condomless sex, sexist attitudes, and aggression [3]. For example, a large (n=4564) survey of young people aged 14 to 17 years found that boys who regularly watch

online pornography were significantly more likely to express negative gender attitudes [5]. Studies are yet to describe the direction or strength of these associations to be able to identify a causal relationship between pornography and harm [6,7].

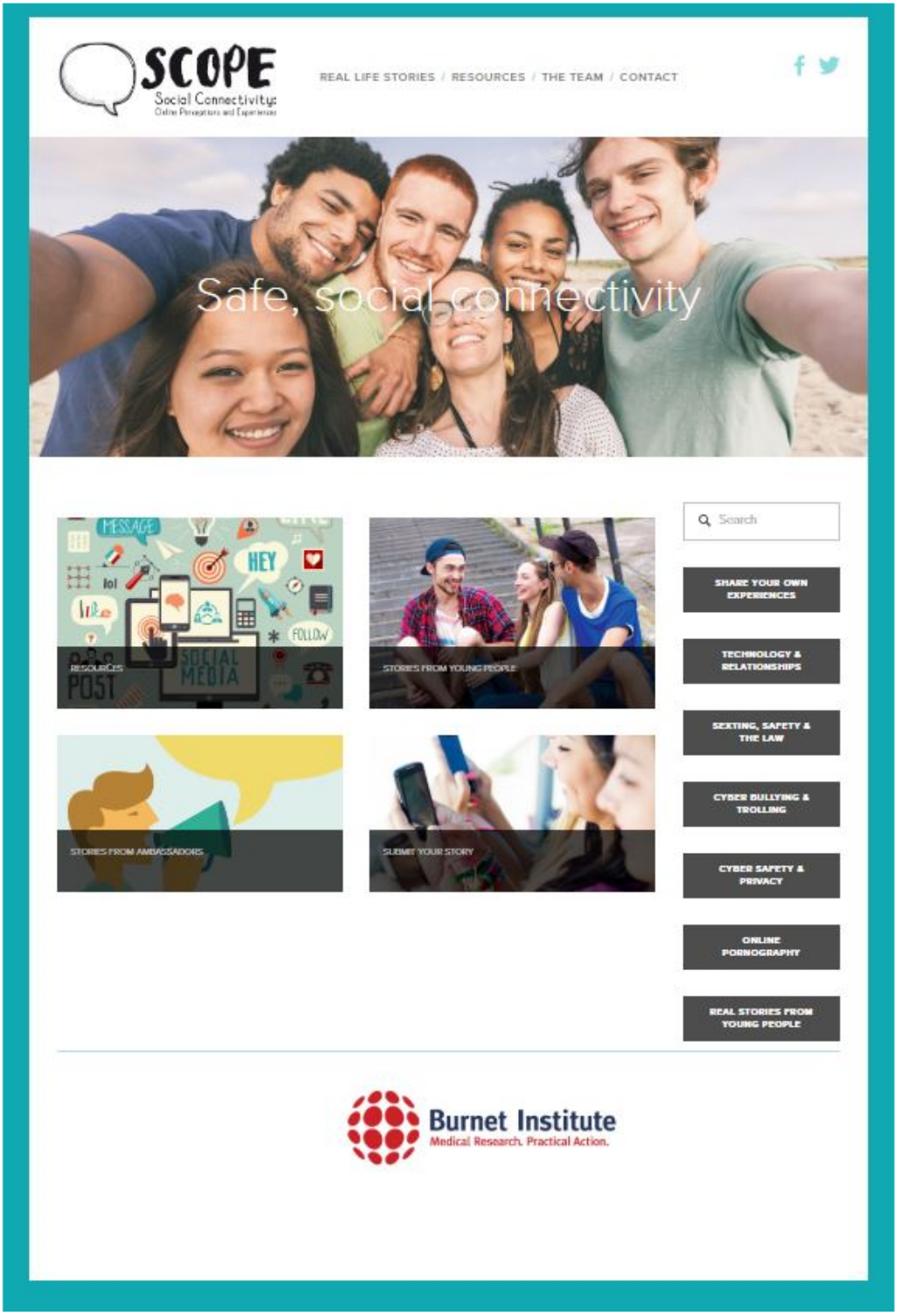
Some literature even suggests that young people may experience pornography as an important source of education and exploration in the context of limited alternative education about sex [8,9]. Similarly, while sharing sexually explicit images, sometimes referred to as *sexting* or *sending nudes*, has been shown to be common among young people [10,11] and nonconsensual sharing or technology-facilitated violence has been shown to have damaging health consequences [12], some studies suggest that young people may see consensual sharing of images as a normal and even positive part of their sexual lives rather than as inherently risky behavior [2,13]. Pornography and sexting are complex and sensitive topics with limited consensus on the best practice for researching and responding to the issues [6,14]. Although the effects are still being investigated, experts and young people have expressed a need for specific online health resources to address unmet education needs around these topics [15].

Extensive literature has shown that online health promotion approaches are most successful if they are tailored, nonjudgmental, and responsive to young people's information needs [16]. Engaging with target users in the development and testing of resources can enhance the relevance of the resource [16,17]. In terms of usability, studies also suggest that young people prefer interactive content, opportunities to engage with other young people, and easy-to-navigate resources without too much text [18]. Although a large body of evaluative studies of sexual health websites exists [19], few studies have specifically evaluated the relevance and usability of health websites addressing pornography and the sharing of sexually explicit media images for young people. This is an important step in the development process for evidence-based resources.

SCOPE Website Development

In late 2015, the Burnet Institute received a small grant from a philanthropic foundation to develop an online resource focused on technology and relationships. Consistent with the best practice health promotion theory, we conducted formative research with a target audience of young people aged 15 to 29 years from Australia [14]. The findings of the research led us to develop a website, predominantly focused on the issues of managing personal sexually explicit imagery, pornography use, and general online issues, including cyberbullying (Figure 1). The website included 3 sections: an information page on each of the topics listed above, a resources section with links to services and other sites, and a real stories page with user-generated content about the issues. On the basis of participant feedback, we used sex-positive, nonjudgmental language and integrated user-generated stories from young people relevant to the key topics to enhance the credibility and relevance of the information. We also provided information about the services and laws relevant to the topics (ie, laws related to distributing personal sexually explicit imagery in Australia) [14]. The website was developed as a minimum viable product with which to conduct usability and content testing with the target audience before further implementation and evaluation. After the website was developed, we planned a small formative evaluation to test the website's usability, relevance, and acceptability before any scale up.

Figure 1. SCOPE Online Resource home page.



This Study

This study investigated the relevance, usability, and acceptability of the SCOPE website among its target audience. Insights are intended to inform development of future online health promotion interventions, with particular application to websites and resources about sexually explicit media and young people.

Methods

Participants

The eligible participants were aged 15 to 29 years and living in Australia.

Recruitment

Convenience sampling methods guided our recruitment of participants using paid advertisements on Facebook and a post

from the Burnet Institute Facebook account. Potential participants were invited to contact the research team via an online contact form or email if interested. Participants were told that the interview involved exploring a website and talking to researchers about their opinions and feedback as they explored the content. They were advised that the interviewers were not involved in the website development. The Monash University Human Research Ethics Committee approved the research, and participants consented to the publication of anonymized data.

Procedure

Following consent, participants were sent a unique link to access a private, secure chat room where they *met* the researcher at a prearranged time for the interview. Participants were invited to take part in one-on-one, semistructured interviews through Atlassian HipChat, an online text-based chatroom tool. Interviews involved the researcher guiding the participant through predefined sections of the website and asking semistructured interview questions about each aspect of the website usability, including layout, language, platform, and content relevance. The participants were specifically directed to access the home page, real stories page, online pornography page, and *sexting* pages of the website. They were asked to explore and read the content and alert the interviewer when they were ready to discuss each section. Interviews ranged from 45 to 60 min, and the participants were reimbursed with a Aus $20 gift voucher.

The rationale for using online interview methods included that we wanted to engage with participants in real time as they explored the resource to capture their thoughts and opinions. We also wanted to guide them through specific content on the website and ask relevant questions immediately after they had engaged with the section and to reduce social desirability bias. Using a traditional postexposure survey would not have enabled this type of engagement. Furthermore, we were concerned that an in-person guided exposure and face-to-face interview may not allow participants to be open and honest about these sensitive issues or offer their opinions. Young people are digital natives who communicate frequently via online platforms. In this context, conducting qualitative interviews in private chatrooms has previously been shown to be an acceptable and convenient method of eliciting meaningful data on sensitive topics from young people, with some limitations [20-24]. For example, conducting online interviews with young people can increase their likelihood of signing up; however, building a rapport can be more difficult, and participants can withdraw from the interview simply by not answering. [20]. Despite these limitations, the method is particularly effective for testing website content because participants have a level of anonymity and separation from researchers, allowing them to explore the website in an organic setting (their own device and at their own pace) and to be open and honest about sensitive topics such as pornography.

Data Analysis

Deidentified transcripts were analyzed thematically using QSR International NVivo software. Framework analysis methodology guided a deductive thematic analysis, and additional themes were inductively coded as they emerged [25]. Framework analysis has been identified as an ideal qualitative method for interpreting data specific to public health policy or practice [25]. The analytical framework for this study was refined by AD based on the process of familiarization, which involves a preliminary review of the entire dataset in relation to answering the key research question: *How does the target audience perceive the usability of the online resource?* The framework included 3 key nodes: relevance, usability, and acceptability. Each included 2 subnodes: barriers and enablers. Researcher AD deductively coded the entire dataset. Subthemes were inductively identified as they emerged across each of the nodes. Researcher CW cross coded a sample of transcripts. Discrepancies in interpretation or coding were discussed and resolved before finalization of analysis.

Results

Participant Characteristics

A total of 17 young people participated in the interviews. Participants' age range was 15 to 27 years with an average age of 21 years. Overall, 15 participants identified as female and 2 identified as male. All participants were living in the greater Melbourne region. In total, 3 participants were still attending secondary school, 10 were university undergraduate students, and 4 had completed a bachelor's degree or postgraduate degree.

Resource Usability

The 3 themes identified across the data relating to the resources usability are reported below and include *responding to sensitive health issues*, *translating formative findings into acceptable content*, and *who are young people?—creating acceptable and accessible content*.

Responding to Sensitive Issues: Balance, Tone, and Credibility

Creating content and a tone that is responsive to the sensitive and complex nature of these issues was perceived as the most important aspect of the SCOPE website's acceptability. For instance, information about pornography and sharing of sexually explicit imagery was identified as *balanced* and nonjudgmental. This was perceived to be in contrast to fear-based or values-based resources on issues such as pornography and sharing of sexually explicit images. As participants stated:

> *Some [websites] are very obviously politically motivated or have some sort of agenda, and provide either false facts or twisted facts to suit their message. Some websites can present things in an "objective" way but obscure the context to fit their politics—it can take more skill and digging to figure this out. I think being aware of a website's agenda is something useful when gathering info.* [P11]

As the responses demonstrate, participants were critical of other resources perceived to be judgmental or motivated by social or political agendas. There was a sense of relief that SCOPE acknowledged that many people use pornography and that this was not negatively framed:

> *The fact that they mention that porn isn't a bad thing is a breath of fresh air since growing up porn has*

> *been viewed as a bad thing...it doesn't sound cheesy or lecture-y.* [P14]

On the basis of their concerns about biased or values-based information, several participants mentioned the importance of credibility. One feature of the SCOPE website that participants noted made it appear *trustworthy* was the use of linked citations to substantiate information and the provision of secondary research related to the topics. However, research links were not provided for every piece of information across the sections. In the context of sensitive and politicized issues, providing direct access to research across all content would improve acceptability as this participant stated:

> *The first thing I wanted to read is the research it mentions—it'd be good to have a link to that (sorry I'm so obsessed with credibility!!).* [P3]

The website was perceived to be visually responsive to the sensitive nature of the issues. For instance, images were suggestive of the topic but displayed a level of subtlety. For example, as shown in Figure 2 below, the Online Pornography page images show a person on a phone in bed and a water hose. These are suggestive—without showing explicit images. This enabled participants with various experiences and backgrounds to engage without feeling uncomfortable. As this participant commented:

> *I like the top photo, it's not too revealing, even the wording is subtle which is good for reading in public* [P14]

Participants appeared conscious of their positioning as *young people* in relation to the tone and language of the resource. According to the participants, the language used throughout the website was clear and accessible without being *childish* or *patronizing*. This is explained here by a participant who said:

> *It's very suited to young people. It's easy to understand, but a step up from language you would use with a child.* [P4]

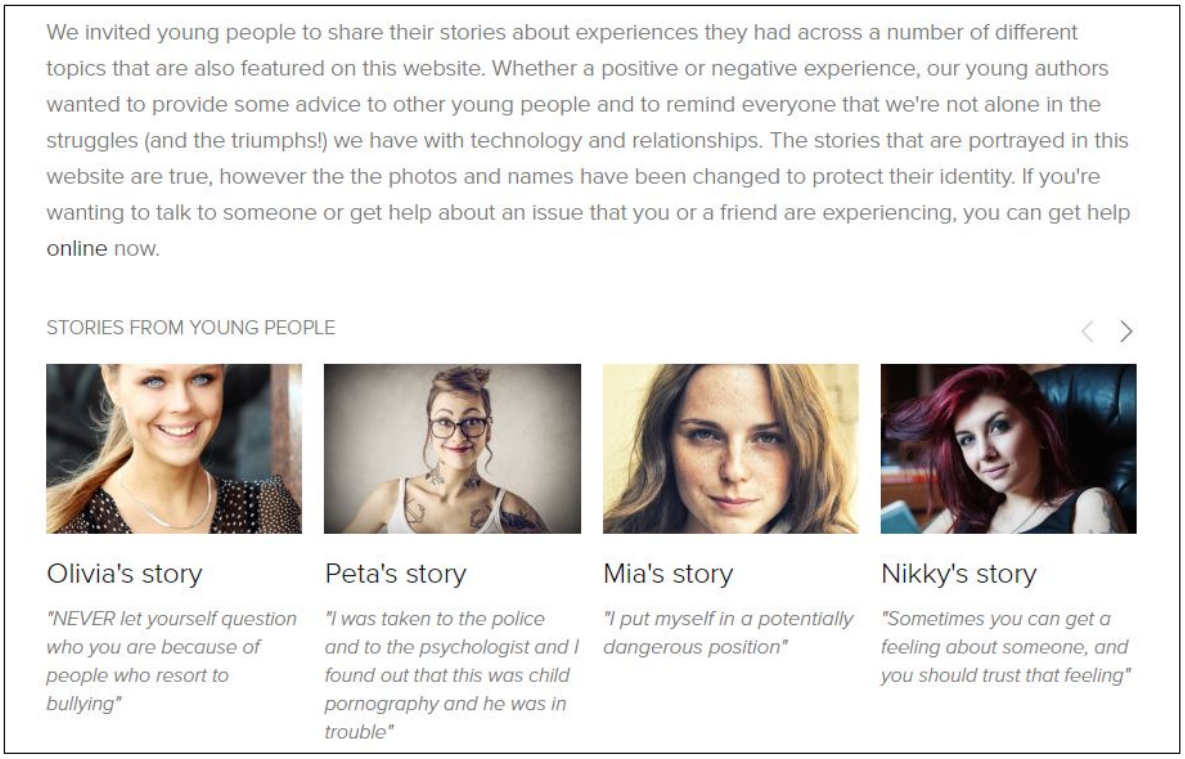
Figure 2. SCOPE Online Resource–Online Pornography page.

Translating Formative Findings Into Acceptable Content

On the basis of findings from formative research, the Real Stories page illustrated in Figure 3 was marketed as user-generated content about young people's experiences with technology. Young people were invited to send in their stories via the website or social media. The aim of the content was to reduce shame about negative experiences and encourage awareness among other young people. In this study, we wanted to understand if the Real Stories section was usable and acceptable. Our participants reported that including real stories from other young people helped to acknowledge the complexity of the issues. Participants appreciated that the stories did not attempt to simplify the issues by acknowledging the complexity of young people's online experiences. The stories raised issues as part of a broader discussion of harm reduction rather than as warning or moralistic messages. Their comments also reflected a sense of frustration around advice they had encountered elsewhere to restrict online use by *logging off as* a response to these concerns. As this participant suggested:

> *The story was good because it wasn't just black and white, like it's a hard decision to make and it's not that easy just logging off.* [P14]

Figure 3. SCOPE Online Resource–Real Stories page.



Although the website presented stories from young people that were real, stock images were used in place of an actual biographical profile picture to protect the anonymity of young people who shared their stories. A number of participants also raised concerns about the page because they felt it was unclear if the stories and people were real, which reduced their trust in the content overall. Participants' critical media literacy reduced their acceptance of the Real Stories page, which was a key aspect of the website. As this participant stated:

> *I just clicked through to one though and it was like a cautionary tale of sharing photos on the internet with people you haven't met. It uses a stock image photo next to the story, so I'm not sure if it is real? Young people are very aware of reverse-image searching on Google. All of them use Shutterstock photos, which shows like Catfish teach young people how to discern pretty quickly (sic). And also the site links to Catfish itself, so it seems a bit of a contradiction...So any story about a young person that purports to be real, alongside a photo that's a stock image, may not be successful...I am skeptical of the website being helpful for info if the stories are not genuine.* [P1]

Despite their concerns about the presentation of Real Stories, most considered including *real stories* from young people as enhancing the acceptability and relevance of the resource. However, many identified barriers to actually sharing their own stories on platforms such as this. These included, being retraumatized by telling their story and experiencing embarrassment—regardless of the website's commitment to anonymity. Participants reported that they would also be unlikely to share the content on social media between friends because of the sensitive nature of the topics. As these participants reflected:

> *I think it can be very embarrassing and I would always have the fear that someone could identify me through the story. It can also be a very sensitive topic and people might not be confident/ready to share with the world.* [P2]

> *I suppose anonymity and embarrassment! I don't think any young person wants everyone at school or community to know their embarrassing story. That's why so many of these stories are told in hindsight, which is a shame cause teenagers could probably benefit from knowing they're not alone from their own peers rather than adults. That said, I wouldn't feel comfortable submitting my story because I'm naturally shy, and I also generally worry about safety and so on.* [P11]

Participant responses to the section highlight potential challenges to translating users' needs and wants into relevant and acceptable content. Participants' concerns about the disingenuous nature of the real stories content because of the use of stock images and their own reservations around sharing personal stories highlight potential impacts on audience engagement when an idea developed in formative research stages does not fully translate into acceptable content.

Who Are Young People? Creating Acceptable and Accessible Content

To understand the acceptability of the website, we asked participants who they thought it was aimed at and who would use it. Although some participants saw the website as personally

relevant, many identified people *younger* than them as the intended audience. They perceived groups of *preteen* young people, as more naive, less experienced, and in need of this type of information, as is illustrated in the exchange below. Others said that the website looked like something "my mother would send to me" (P7), which suggested that adults might be more concerned about these issues than young people themselves:

> *Do you think that this information would be relevant for young people?* [Interviewer]
>
> *Yeah young people, probably pre-teen like year 7-10 (sic).* [P14]
>
> *Ok, why that age group?* [Interviewer]
>
> *because we're already aware of these issues, some of use face them on a daily basis, or at least hear about them. Like personally it's common-sense—some of these issues you should know what you should and shouldn't do (sic).* [P14]

As savvy users of online content, our users were highly critical of accessibility of the website. Although the home page layout supported easy navigation, the online pornography and sexting pages could be improved through interactivity, links, and videos at the top of the page and by reducing the amount of text. As participants explained:

> *I'm sceptical that young people would read that much text so maybe the images/buttons/videos could be moved to break it up into smaller bits.* [P1]
>
> *I think the paragraphs need to be broken up using maybe subtitles? (sic) Just to make specific information easy to access.* [P2]
>
> *It still seems like a bit of a lecture—maybe make it interactive and fun, that is, competitions/videos/etc the personal stories would probably be the best though—more relatable.* [P14]

Discussion

Principal Findings

The overall results of our interviews suggest that the resource was perceived as trustworthy and credible because of its evidence-based content, nonjudgmental tone, and balanced perspectives. The resource was also perceived as relevant overall; however, there was a perception that the topics included were more relevant to younger participants and that the Real Stories section was disingenuous. The usability of the resource could be improved by targeting content by age and developmental stages, reduced text, headlines to communicate key points, and increased audiovisual assets. Although the conceptual framework underpinning the resource was perceived as usable, results suggest that issues in the final design of the resource could be improved to enhance overall efficacy.

Respondents were aware of the polarized nature of pornography and sexting and were skeptical of information provided without evidence or balanced narratives. This is consistent with research that suggests that young people have an interest in sexuality and respond best to environments that encourage trust and openness and rely on evidence rather than moralistic undertones [26]. However, relying solely on evidence is challenging when dealing with emerging public health issues such as online pornography, where evidence is still being developed [7]. Our results suggest that this may be overcome by providing young people with the best available information, including on why there is lack a of consensus in evidence, and providing opposing views and discussion points to help them make their own informed decisions.

Potentially overexposing young people to information is often perceived as a barrier to providing sexual health education [27]. This has been shown to be of particular concern in relation to online pornography, as adults fear conversations or information that may encourage their child to seek out the content [28]. Using informative headlines with expandable information sections (*progressive disclosure*) could mitigate this risk, while engaging audiences with various developmental stages and information needs. Presenting information in this way would simultaneously meet the needs of young audiences by decluttering and simplifying information for quick and easy access.

Importantly, the findings remind us that although young people share commonalities, they are not a homogenous group, and this should be considered in the development of health education resources. Furthermore, although the target audience for the SCOPE resource was Australians aged 15 to 29 years, respondents often referred to the importance of this type of resource for younger ages. This could be explained by the literature that suggests that young people typically underestimate the impact of pornography on themselves compared with other people [29]. However, it could also be the case that as respondents pointed out, younger children (10-14 years) are engaging in these behaviors or exposed to the content with little support. This explanation supports the need for research to consider how to develop resources that sensitively meet the information needs of younger children on these topics.

Interestingly, our results demonstrated gaps in translating findings from the participatory development research into the resource. For example, a key finding from the development research was that young people wanted to engage with *real stories* to learn from other young people's experience [14]. However, in practice, the translation of these findings into a *Real Stories* section resulted in concerns about credibility. Furthermore, our participants identified a range of barriers to submitting their own stories. Responses indicated practical guidance for how to improve credibility, such as not using stock images of young people to illustrate anonymous stories. Participants' skepticism highlights broader issues with traditional research methods for intervention design, including phased research that involves audiences in formative design and content testing rather than as co-designers of the materials throughout the process. Our findings support the move toward iterative co-design methodologies that engage audiences as experts or *co-designers* to ensure the conceptualization of issues, ideation of approaches to address them, and design of resources that align with their needs and wants [30]. These methods are particularly relevant to developing interventions on topics which are sensitive, complex, and still emerging such as online pornography and sharing of sexually explicit images.

Limitations

Our study has several limitations. Our recruitment strategy utilized social media advertising, meaning that we attracted those with social media experience and potentially those interested in the topic; it is possible that these perspectives vary from those who do not use social media but who are still at risk of other technology-related harms. Our sample was heavily skewed toward female participants. This is consistent with sexual health research more broadly, where engagement with male respondents has been challenging [4,31,32]. Interviews were conducted online rather than in person, excluding the opportunity to observe participants' body language and tone. Despite these limitations, the data collection method appeared to provide opportunities for participants to engage with the topics and the content in an anonymous forum. The insights provided suggest that the methods are useful for conducting usability testing of health education resources, particularly those aiming to reach young people, and thus provides important insights relevant to an emerging area of health promotion research and practice.

Conclusions

A range of service providers and organizations are developing resources to respond to growing concerns of the impacts of new sexual media—such as pornography and sharing of sexually explicit images among young people. However, within resource-constrained environments, content testing for usability, relevance, and acceptability are not frequently conducted. Small-scale studies testing websites before scale-up activities can inform future research and development. Our study illustrates the importance of providing balanced and nonjudgmental perspectives when engaging with young people on these issues. However, it also shows limitations to formative research translation and creating content aimed at all young people rather than diverse groups. Most importantly, in the context of responding to emerging, complex, and sensitive issues, co-design methods can ensure that young people are central to the development of resources to meet their needs and avoid gaps in the context of emerging evidence and practice.

Conflicts of Interest

None declared.

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Original Paper

Validity of the Polar M430 Activity Monitor in Free-Living Conditions: Validation Study

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Abstract

Background: Accelerometers, often in conjunction with heart rate sensors, are extensively used to track physical activity (PA) in research. Research-grade instruments are often expensive and have limited battery capacity, limited storage, and high participant burden. Consumer-based activity trackers are equipped with similar technology and designed for long-term wear, and can therefore potentially be used in research.

Objective: We aimed to assess the criterion validity of the Polar M430 sport watch, compared with 2 research-grade instruments (ActiGraph and Actiheart), worn on 4 different locations using 1- and 3-axis accelerometers.

Methods: A total of 50 participants wore 2 ActiGraphs (wrist and hip), 2 Actihearts (upper and lower chest position), and 1 Polar M430 sport watch for 1 full day. We compared reported time (minutes) spent in sedentary behavior and in light, moderate, vigorous, and moderate to vigorous PA, step counts, activity energy expenditure, and total energy expenditure between devices. We used Pearson correlations, intraclass correlations, mean absolute percentage errors (MAPEs), and Bland-Altman plots to assess criterion validity.

Results: Pearson correlations between the Polar M430 and all research-grade instruments were moderate or stronger for vigorous PA (*r* range .59-.76), moderate to vigorous PA (*r* range .51-.75), steps (*r* range .85-.87), total energy expenditure (*r* range .88-.94), and activity energy expenditure (*r* range .74-.79). Bland-Altman plots showed higher agreement for higher intensities of PA. MAPE was high for most outcomes. Only total energy expenditure measured by the hip-worn ActiGraph and both Actiheart positions had acceptable or close to acceptable errors with MAPEs of 6.94% (ActiGraph, 3 axes), 8.26% (ActiGraph, 1 axis), 14.54% (Actiheart, upper position), and 14.37% (Actiheart, lower position). The wrist-worn ActiGraph had a MAPE of 15.94% for measuring steps. All other outcomes had a MAPE of 22% or higher. For most outcomes, the Polar M430 was most strongly correlated with the hip-worn triaxial ActiGraph, with a moderate or strong Pearson correlation for sedentary behavior (*r*=.52) and for light (*r*=.7), moderate (*r*=.57), vigorous (*r*=.76), and moderate to vigorous (*r*=.75) PA. In addition, correlations were strong or very strong for activity energy expenditure (*r*=.75), steps (*r*=.85), and total energy expenditure (*r*=.91).

Conclusions: The Polar M430 can potentially be used as an addition to established research-grade instruments to collect some PA variables over a prolonged period. However, due to the high MAPE of most outcomes, only total energy expenditure can be trusted to provide close to valid results. Depending on the variable, the Polar M430 over- or underreported most metrics, and may therefore be better suited to report changes in PA over time for some outcomes, rather than as an accurate instrument for PA status in a population.

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KEYWORDS

actigraphy; fitness trackers; motor activity; validation studies

Introduction

Background

Lack of physical activity (PA) is the fourth-leading risk factor for global mortality, and the World Health Organization recommends at least 150 minutes weekly of moderate-intensity PA (eg, 30 minutes of moderate PA, 5 times per week) or 75 minutes weekly of vigorous-intensity PA for adults, and 60 minutes weekly of moderate to vigorous PA (MVPA) for children and adolescents [1]. However, worldwide, these recommendations are not reached by 80% of adolescents and 31% of adults (ranging from 17% in Southeast Asia to 43% in the eastern Mediterranean and the Americas) [2]. Two national reports from the Norwegian Directorate of Health show that, in the Norwegian population, these recommendation were reached by only 20% in 2009 [3] and 32% in 2015 [4].

Accelerometers and combined sensing (ie, accelerometers and heart rate) are used to track PA. Research-grade instruments are often expensive and have limited battery capacity, limited storage, and high participant burden. Consumer-based activity trackers, on the other hand, are designed for long-term wear, equipped with similar technologies, generally cheaper, and less intrusive, and can potentially track PA for research purposes.

Consumer-based activity trackers are increasingly being evaluated for use in research. Recent examples includes Lawrie et al [5] and Beukenhorst et al [6], who included smart watches in their research protocols. The major limitation of these devices is the limited knowledge of device validity. Due to the rapid growth of new devices, high-quality validation studies of emerging models are needed [7]. Specifically, to our knowledge, no validation study on the Polar M430 has been conducted to date. Most previous validation studies have compared multiple consumer devices with 1- or 2-criterion instruments (eg, [8,9]). In this study, we compared 1 consumer device with multiple criteria, placed on multiple locations, and analyzing 1 and 3 axes of the accelerometer.

Objective

The aim of this study was to assess the criterion validity of time (in minutes) spent in various PA intensity zones, step counts, and energy expenditure (EE) between the Polar M430 and 2 extensively used research-grade instruments (ActiGraph and Actiheart) worn on 4 different locations using uniaxial and triaxial measurements in free-living conditions. We used multiple criteria because we wanted to show how the choice of criterion and placement affects outcomes. The ActiGraph can be considered a reference standard for PA intensity in free-living people, but because the Actiheart also has a heart rate sensor, it can be an attractive alternative in many cases.

Methods

Sample

We recruited 50 participants, who were eligible for inclusion if they were 18 years of age or older with normal physical function. We used convenience sampling to maximize ranges for weight, height, body mass index, age, and sex.

Instruments

The Polar M430 (Polar Electro Oy, Kempele, Finland), released in 2017, is a sport watch with a 6–light-emitting diode wrist-based optical heart rate sensor and a 50-Hz triaxial accelerometer for tracking PA. It weighs 51 g, with 20 days of battery life.

ActiGraph wGT3X-BT (ActiGraph LLC, Pensacola, FL, USA) is a 19-g triaxial accelerometer with a 30- to 100-Hz sampling rate, to be worn on the wrist, hip, ankle, or thigh, with 25 days of battery life. ActiGraph has been previously validated for sedentary behavior [10-12], PA intensity for both uniaxial [12] and triaxial [13] acceleration, step counting [14], and EE [15].

The Actiheart (CamNtech Ltd, Cambridge, UK) is a 10-g uniaxial accelerometer with 32-Hz sampling rate and additional electrocardiography with 128-Hz sampling rate, to be worn on the chest, with 21 days of battery life. The Actiheart is extensively used to measure EE, and has been shown by Brage et al to produce valid estimations for EE both in laboratory settings [16] and under free-living conditions [17].

Procedure

We used self-reported information on height, weight, age, sex, and dominant hand to initialize the devices. The Polar M430 and an ActiGraph (attached with an elastic band) were placed on the wrist of the nondominant hand. One ActiGraph was placed on the right hip (attached with an elastic band). One Actiheart was placed approximately at the level of the second intercostal space at the sternum (medial part) and to the left (lateral part). The second Actiheart was placed approximately at the level of the fifth intercostal space at the sternum (medial part) and to the left (lateral part). The Actihearts were attached with 2 Red Dot 2238 electrodes (3M, St Paul, MN, USA) each. Table 1 [18] gives the setup used for all instruments and Figure 1 shows the placement of each instrument.

Devices were attached by 1 of 2 researchers after agreement of method in accordance with manufacturer recommendations. Participants were instructed to wear all instruments at all times except for temporarily removing the ActiGraph for showering and water activities. Participants wore all instruments for 1 full day (24 hours). We collected data in May 2018. Participants received written and oral instructions on how to wear the devices. All participants signed an informed consent form.

Table 1. Device setup and output variables.

Variables	Instrument		
	ActiGraph	Actiheart	Polar M430
Hardware and setup			
Epoch length (lowest available)	10 s	15 s	24 h
Accelerometer sample rate	100 Hz	32 Hz	50 Hz
Wear location	Nondominant wrist, right hip	Chest (V_2), chest (V_5)	Nondominant wrist
Parameters	Height, weight, sex, age, wear location	Height, weight, sex, age	Height, weight, sex, age, wear location
Software for setup and download	ActiLife 6.13.3	Actiheart 4.0.122	Polar Flow [18]
Software for analysis	QCAT[a]/ActiLife	QCAT/Actiheart	Polar Flow
Device model	wGT3X-BT	4	2P
Device firmware version	1.9.2	H90.65	1.1.34
Output variables			
Sitting or sedentary behavior	Yes	Yes	Yes
Light physical activity	Yes	Yes	Yes
Moderate physical activity	Yes	Yes	Yes
Vigorous physical activity	Yes	Yes	Yes
Activity energy expenditure	Yes	Yes	No
Total energy expenditure	No	Yes	Yes
Steps	Yes	No	Yes

[a]QCAT: Quality Control and Analysis Tool.

Figure 1. Instrument placement and Polar M430 illustrations.

Variable Creation

Using the proprietary software of ActiGraph and the Actiheart, we exported activity counts into comma-separated values files, using the lowest possible epoch setting, that is, 10- (ActiGraph) and 15- (Actiheart) second epochs. From the ActiGraph, triaxial (vertical, horizontal, lateral) counts and steps per epoch were exported. From the Actiheart, uniaxial (vertical) counts were exported. We extracted precalculated variables from the Polar M430 from Polar Flow directly. Table 1 details the software and epochs.

Due to no agreed-upon cut points for calculating PA intensity from the wrist-worn ActiGraph in adults, we applied a conversion function provided by ActiLife version 6.13.3 (after ActiLife export; ActiGraph) to the wrist-worn ActiGraph data before further analysis (Multimedia Appendix 1).

Exported comma-separated values files with epoch data were imported into the custom-made Quality Control and Analysis Tool (QCAT) developed at UiT The Arctic University of Norway and Technical University of Munich. We converted activity counts into 60-second epochs before doing further analysis. We used counts per minute (CPM) to calculate minutes in the various PA intensity zones, using several algorithms. By

using QCAT, data from ActiGraph and Actiheart were analyzed by the same program and comparable variables were created. We included only valid days, a priori defined as all instruments worn at least 10 hours per day [19], in the analysis. We identified nonwear time using the triaxial wear-time algorithm of Hecht et al [20]. Multimedia Appendix 2 shows correlations between QCAT and ActiLife.

For the ActiGraph data (wrist and hip), we calculated 5 PA intensity zones using cut points defined by Freedson et al [12] and Matthews et al [21], using only the vertical axis. In addition, we used a combination of the methods of Sasaki et al [13], Kozey-Keadle et al [10], and Peterson et al [11] to generate the same PA intensity zones using all 3 axes, or vector magnitude (VM). To our knowledge, there are no agreed-upon cut points for chest-based PA counts in adults using an Actiheart. However, we used cut points identified in a study by Schrack et al [22]. We combined minutes spent in vigorous and very vigorous intensity into 1 variable. Table 2 gives an overview of each cut point set.

As QCAT does not support EE calculation, we calculated this variable from the proprietary software tools ActiLife and Actiheart. We calculated EE from ActiLife using the Freedson combination 1998 formula (Freedson et al [12] plus Williams work-energy equation) for uniaxial calculation and the Freedson VM3 combination 2011 formula (Sasaki et al [13] plus Williams work-energy equation) for triaxial calculation. We analyzed nonwear time using the default Troiano [23] settings. Actiheart uses a branched model where recorded activity and heart rate from the electrocardiogram are used together to improve EE calculations [24].

While the Actiheart reports resting EE (REE), activity EE (AEE), diet-induced thermogenesis, and total EE (TEE), the ActiGraph reports only AEE, and the Polar M430 reports only TEE. Since Actiheart used the Schofield equation [25] when calculating REE, we used the same equation to convert between AEE and TEE for the Polar M430 and the Actiheart. Furthermore, we subtracted or added, respectively, 10% of TEE to account for diet-induced thermogenesis.

The Polar M430 exports data for TEE, steps, and 5 PA intensity zones: minutes in (1) rest, (2) sitting, (3) low-intensity PA, (4) medium-intensity PA, and (5) high-intensity PA. We did not know the algorithm used by Polar to assign PA in 1 of these 5 categories, but we used the following conversion between the Polar M430 and other instruments: sitting = sedentary, low = light, medium = moderate, and high = vigorous + very vigorous PA. We did not use “minutes in rest” from the Polar M430. We compared steps only between the Polar M430 and the 2 ActiGraph locations, as this variable is not available in the exported Actiheart data. We did not compare heart rate outcomes in this analysis, as our aim was to investigate PA measures. We will address heart rate measures in a separate analysis.

Table 2. Alternative cut-point sets for physical activity intensity zones.

Intensity zone	ActiGraph uniaxial CPM[a]	ActiGraph triaxial CPM vector magnitude	Actiheart CPM
Sedentary	≤99	≤149	≤10
Light	100-1951	150-2689	11-95
Moderate	1952-5724	2690-6166	96-234
Vigorous	5725-9498	6167-9642	≥235
Very vigorous	≥9499	≥9643	N/A[b]

[a]CPM: counts per minute.

[b]N/A: not applicable.

Statistical Analysis

We investigated Polar M430 validity for the following variables: sedentary behavior minutes per day, light PA minutes per day, moderate PA minutes per day, vigorous PA minutes per day, MVPA minutes per day, steps per day, AEE per day, and TEE per day. We used the Shapiro-Wilk test to test normality. We calculated and compared Pearson and Spearman correlations, with and without bootstrapping. Finally, we used the Pearson correlation coefficient, with bootstrapping, to assess the association between all instrument outcomes.

We used correlation cutoffs suggested by Evans [26]: very weak, less than .2; weak, .2-.4; moderate, .4-.6; strong, .6-.8; and very strong, greater than .8. We also calculated the intraclass correlation coefficient (ICC) to test agreement between instruments (absolute agreement, 2-way random, and single measures), which is not indicated by Pearson. We used the 95% confidence intervals of the ICC estimate to indicate poor (<.5), moderate (.5-.75), good (.75-.9), and excellent (>.9) agreement [27]. Mean absolute percentage error (MAPE) was used to calculate measurement error between devices for each outcome. There is no agreed-upon cutoff for MAPE, but previous validation studies have used a MAPE of less than 5% [9] or 10% [28,29] to indicate low error.

We also used Bland-Altman plots to assess the agreement between instrument outcomes [30]. Bland-Altman limits of agreement (LoA) indicate the mean difference between 2 instruments, when comparing the mean for each outcome. A positive mean value indicates an overreporting from the Polar M430. The width of the upper and lower LoA indicates the agreement between instruments, where a narrower range indicates a higher agreement.

For each variable, we present (as a figure or multimedia appendix) a scatterplot and a Bland-Altman plot for each criterion. In the scatterplot, the blue straight line shows the fit line for the Pearson correlations. The black dashed line shows

how a perfect correlation and agreement would appear, and can be used, together with the ICC, to see how much the Polar M430 over- or underreported the variables. In the Bland-Altman plot, the blue line indicates the mean difference between the Polar M430 and each criterion. Red lines show the upper and lower LoA.

Finally, we performed sensitivity and specificity tests to evaluate the ability of the Polar M430 to identify a target of 10,000 steps/day [31]. We did not report sensitivity and specificity for the recommended 30 minutes of MVPA per day, because the Polar M430 recorded at least 30 minutes of MVPA for all participants. All statistical analysis were performed using R version 3.5.3 (R Foundation).

Ethics Approval and Consent to Participate

The Norwegian regional committees for medical and health research ethics reviewed the study (2019/557/REK nord). All participants gave informed and written consent. This study was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments.

Results

Participant Demographics and Wear Time

Table 3 presents participants' height, weight, body mass index, age, and sex.

All ActiGraphs had a wear time of at least 10 hours and were included in the analysis. Recording on 1 Actiheart in the upper position failed, and we excluded it from the analysis. Two Actihearts were incorrectly initialized and were excluded from the TEE and AEE analyses. Although 7 Actihearts in the upper position and 5 Actihearts in the lower position had less than 10 hours of wear time, we did not exclude these because the participants informed us that they did not remove the device and manual review of the activity data indicated misclassification of nonwear and sleep.

Polar M430 Validity and Agreement

Multimedia Appendix 3 shows all outcomes for all criteria. Table 4 gives an overview of group data for all variables from the Polar M430. The tables in Multimedia Appendix 4 present all outcomes and group variables for each variable and all criteria.

Table 3. Participant characteristics (N=50).

Variable	Value	Range
Height (cm), mean (SD)	173.7 (10.1)	152-193
Weight (kg), mean (SD)	75.3 (16.4)	49-125
Body mass index (kg/m^2), mean (SD)	24.7 (3.6)	19.0-33.6
Age (years), mean (SD)	45.1 (15.5)	19-74
Females, n (%)	24 (48)	N/A[a]

[a]N/A: not applicable.

Table 4. Data of exported variables from the Polar M430 (N=50).

Variable	Value
Sedentary behavior (minutes), mean (SD)	500.61 (110.78)
Light physical activity (minutes), mean (SD)	308.45 (96.40)
Moderate physical activity (minutes), mean (SD)	98.10 (48.71)
Vigorous physical activity (minutes), mean (SD)	25.55 (37.27)
Moderate to vigorous physical activity (minutes), mean (SD)	123.65 (67.50)
Total energy expenditure (kcal), mean (SD)	2591.5 (619.1)
Activity energy expenditure (kcal), mean (SD)	N/A[a]
Steps, n (%)	13,426 (4775)

[a]N/A: not applicable.

Sedentary Behavior

Only the hip-worn ActiGraph VM gave a moderate Pearson correlation with the Polar M430. The remaining criteria gave a weak or very weak correlation. All ICC agreements were poor. The Bland-Altman LoA indicated underreporting of sedentary behavior by the Polar M430 compared with the hip-worn ActiGraph, and overreporting of the remaining criteria. All MAPEs were high. Table A in Multimedia Appendix 4 provides details of all criteria. Multimedia Appendix 5 gives correlations and Bland-Altman plots for the Polar M430 against each criterion.

Light Physical Activity

The hip-worn ActiGraph and both Actihearts gave a strong Pearson correlation with the Polar M430. The highest ICC

agreement was shown for the hip-worn ActiGraph CPM, with a poor to moderate ICC. The Bland-Altman LoA indicated an overreporting of light PA by the Polar M430 compared with the hip-worn ActiGraph CPM and both Actihearts, and an underreporting for the remaining criteria. All MAPEs were high. Table B in Multimedia Appendix 4 provides details of all criteria. Multimedia Appendix 6 gives correlations and Bland-Altman plots for the Polar M430 against each criterion.

Moderate Physical Activity

All criteria except the Actiheart in the upper position gave a moderate Pearson correlation with the Polar M430. The highest ICC agreement was shown for the Actiheart in the lower position, with a poor to moderate ICC. The Bland-Altman LoA indicated an overreporting of moderate PA by the Polar M430 compared with the hip-worn ActiGraph CPM and both Actihearts, and an underreporting for the remaining criteria. All MAPEs were high. Table C in Multimedia Appendix 4 provides details of all criteria. Multimedia Appendix 7 gives correlations and Bland-Altman plots for the Polar M430 against each criterion.

Vigorous Physical Activity

The hip-worn ActiGraph gave a strong Pearson correlation with the Polar M430. The wrist-worn ActiGraph reported 0 minutes in vigorous PA and were therefore excluded from analysis. The Actiheart in the upper and lower position gave a strong and moderate correlation, respectively. The highest ICC agreement was shown for the hip-worn ActiGraph VM, with a poor to good ICC. The Bland-Altman LoA indicated an overreporting of vigorous PA by the Polar M430 compared with the hip-worn ActiGraph, and an underreporting for both Actihearts. All MAPEs were high. Table D in Multimedia Appendix 4 provides details of all criteria. Multimedia Appendix 8 gives correlations and Bland-Altman plots for the Polar M430 against each criterion.

Moderate to Vigorous Physical Activity

All criteria, regardless of cut points and number of axes considered, gave a moderately or strongly significant Pearson correlation when comparing MVPA for the Polar M430. The hip-worn ActiGraph VM had the strongest correlation. The highest ICC agreement was shown for the Actiheart in the lower position, with a poor to good ICC. The Bland-Altman LoA indicated an overreporting of MVPA by the Polar M430 compared with the hip-worn ActiGraph, a minor underreporting for the Actiheart in the upper position, and an underreporting for the wrist-worn ActiGraph and the Actiheart in the lower position. All MAPEs were high. Table E in Multimedia Appendix 4 provides details of all criteria. Figures 2 and 3 show correlations and Bland-Altman plots, respectively, for the Polar M430 against each criterion.

Figure 2. Correlation between the Polar M430 and all criterion measures for moderate to vigorous physical activity (MVPA). CPM: counts per minute; ICC: intraclass correlation coefficient; VM: vector magnitude.

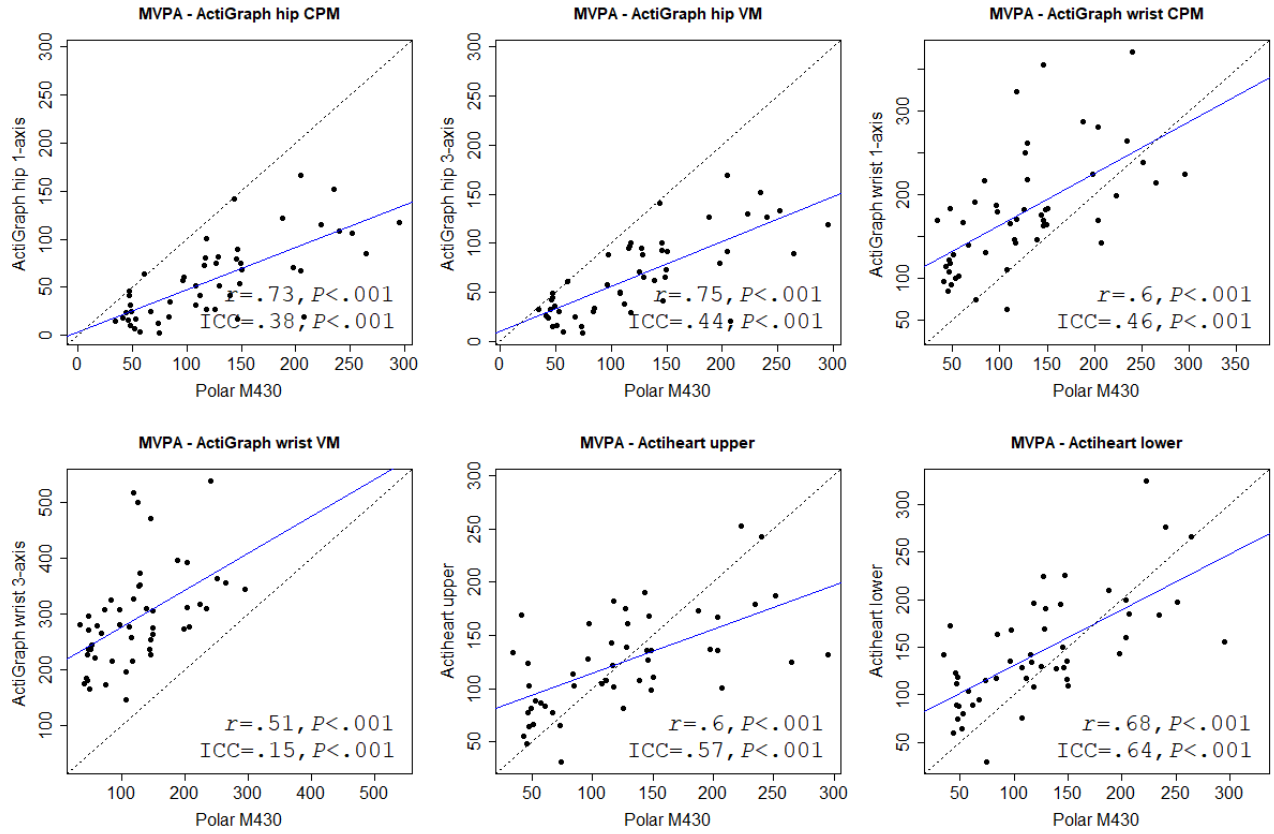
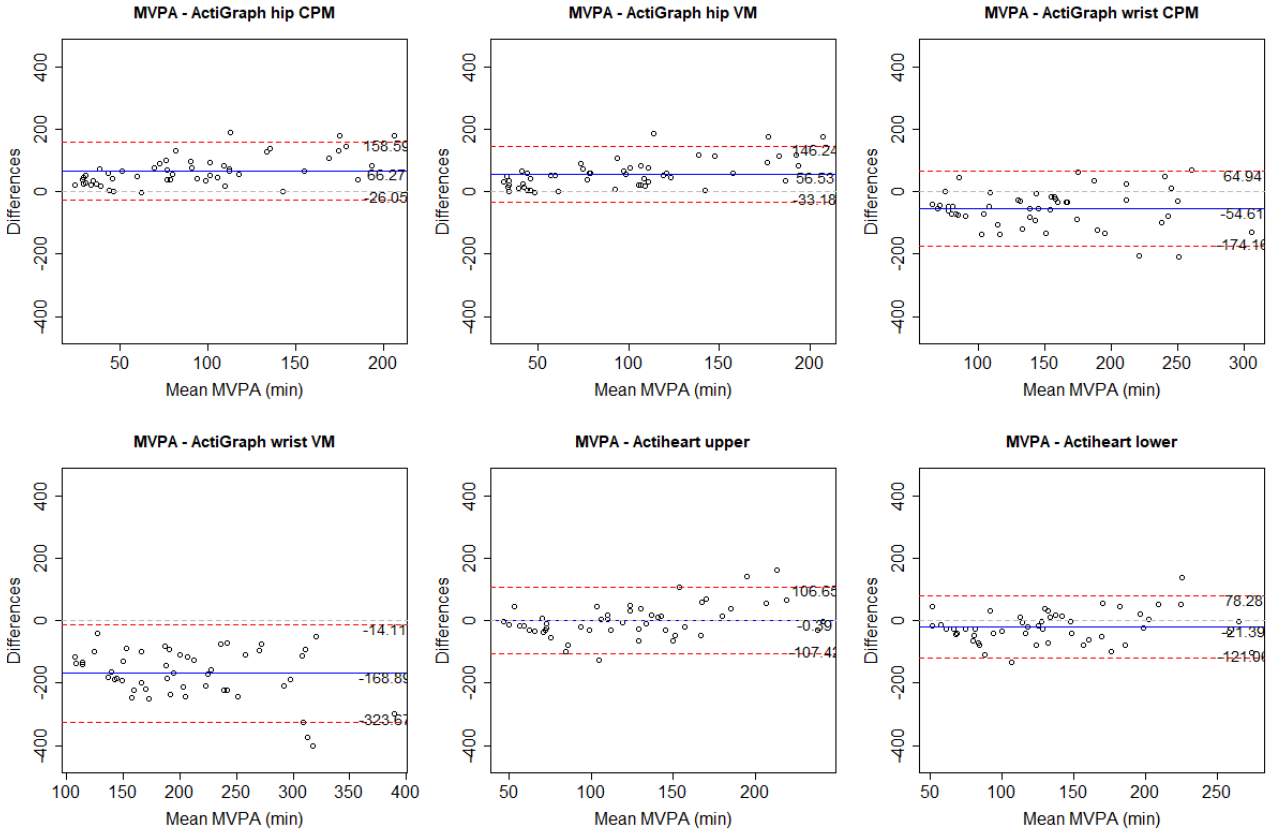


Figure 3. Bland-Altman plots for the Polar M430 and each criterion measure for moderate to vigorous physical activity (MVPA). Numbers are mean difference and upper and lower limits of agreement (95% CI). CPM: counts per minute; VM: vector magnitude.



Activity Energy Expenditure

All criteria showed a strong and significant Pearson correlation for AEE, where the wrist-worn ActiGraph VM was marginally stronger than the other criteria. ICC agreement was highest for the hip-worn ActiGraph VM with a moderate to good agreement. The Bland-Altman LoA showed an overreporting of AEE by the Polar M430 compared with the hip-worn ActiGraph and an underreporting for the wrist-worn ActiGraph and both Actihearts. All MAPEs were high. Table F in Multimedia Appendix 4 provides details of all criteria. Multimedia Appendix 9 gives correlations and Bland-Altman plots for the Polar M430 against each criterion. Multimedia Appendix 10 gives a combined plot for AEE and TEE.

Total Energy Expenditure

All criteria showed a very strong and significant Pearson correlation for TEE. The correlation for wrist-worn ActiGraph CPM was marginally stronger than other ActiGraphs. ICC agreement was highest for the hip-worn ActiGraph VM, with good to excellent agreement. The Bland-Altman LoA showed an overreporting of TEE by the Polar M430 compared with the hip-worn ActiGraph, and an underreporting for remaining criteria. The hip-worn ActiGraph had an acceptable MAPE of 6.94% (VM) and 8.26% (CPM). the remaining criteria had a high MAPE. Table G in Multimedia Appendix 4 provides details of all criteria. ActiGraph does not report TEE, and group data are therefore not available. Figures 4 and 5 show correlations and Bland-Altman plots, respectively, for the Polar M430 against each criterion.

Figure 4. Correlation between the Polar M430 and each criterion measure for total energy expenditure (TEE). CPM: counts per minute; ICC: intraclass correlation coefficient; VM: vector magnitude.

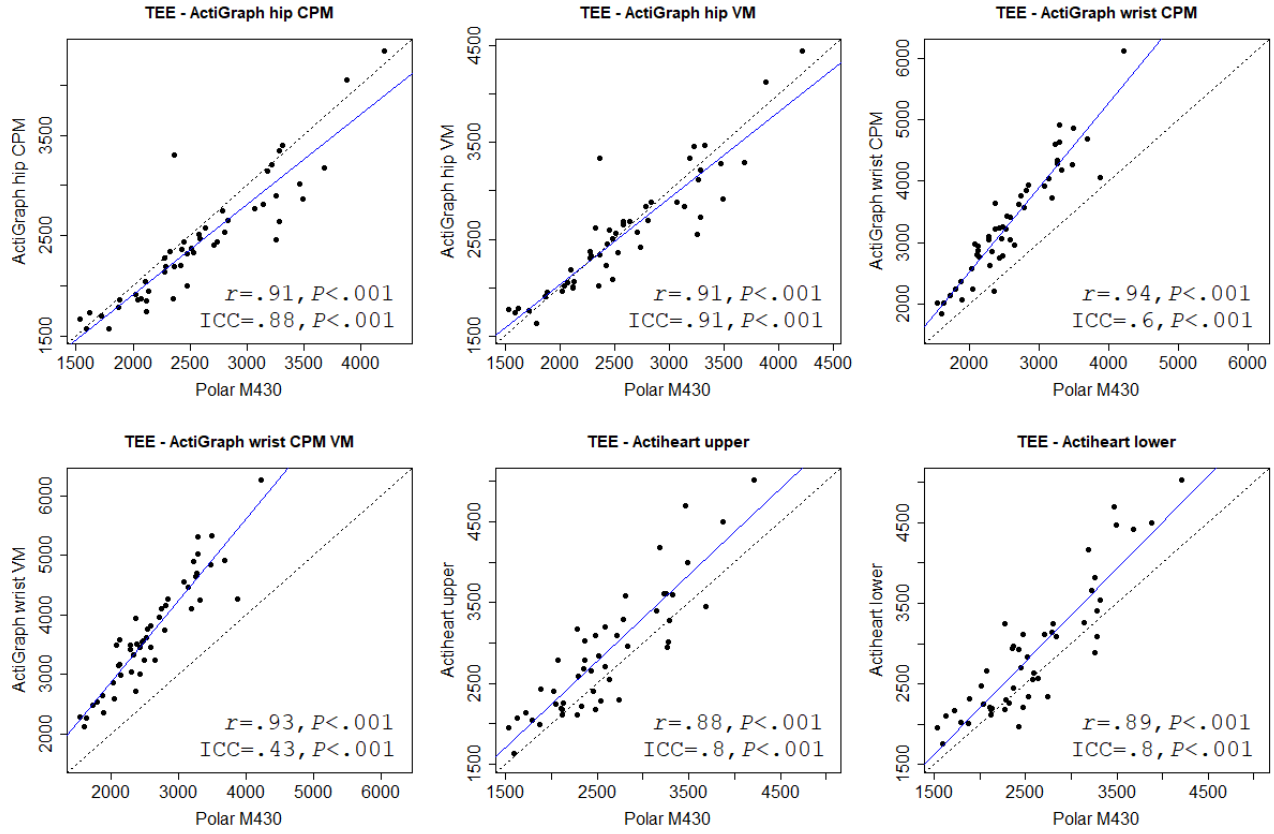
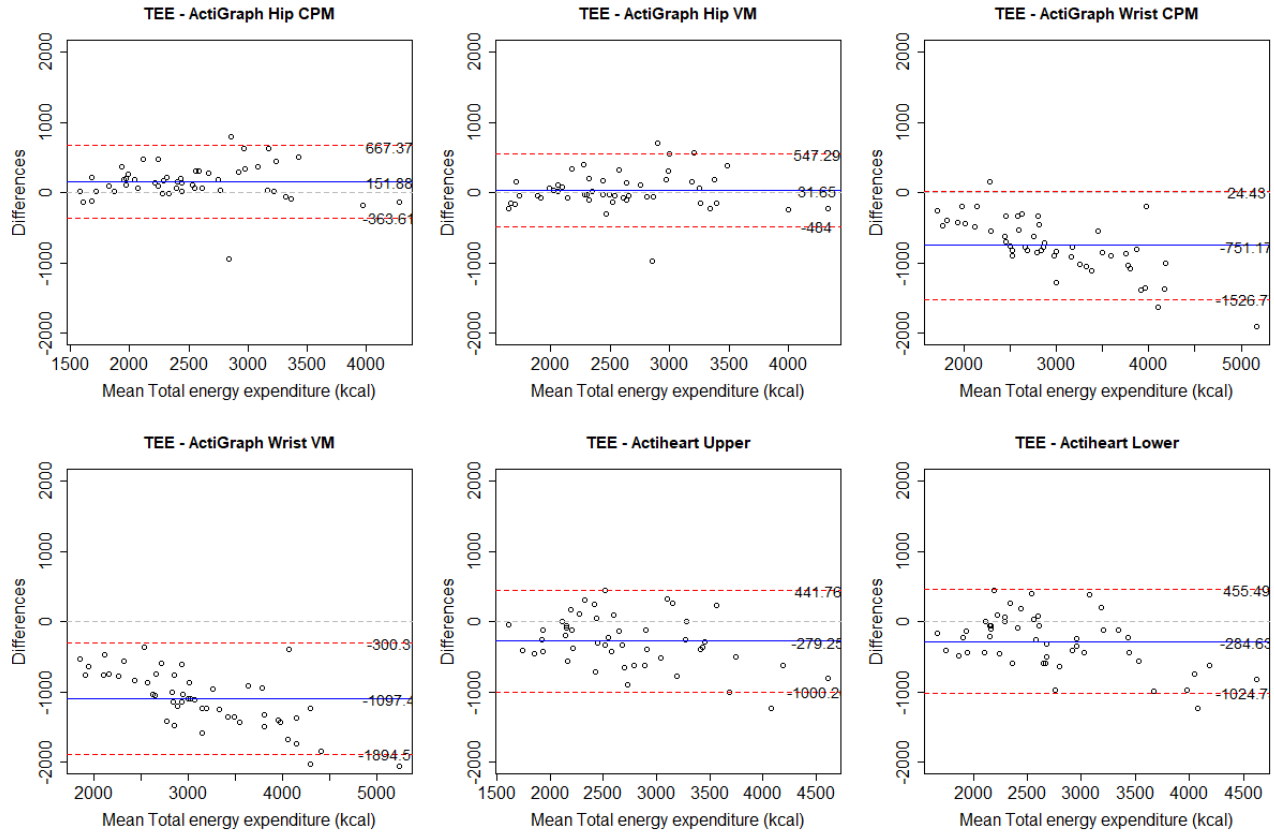


Figure 5. Bland-Altman plots for the Polar M430 and each criterion measure for total energy expenditure (TEE). Numbers are mean difference and upper and lower limits of agreement (95% CI). CPM: counts per minute; VM: vector magnitude.

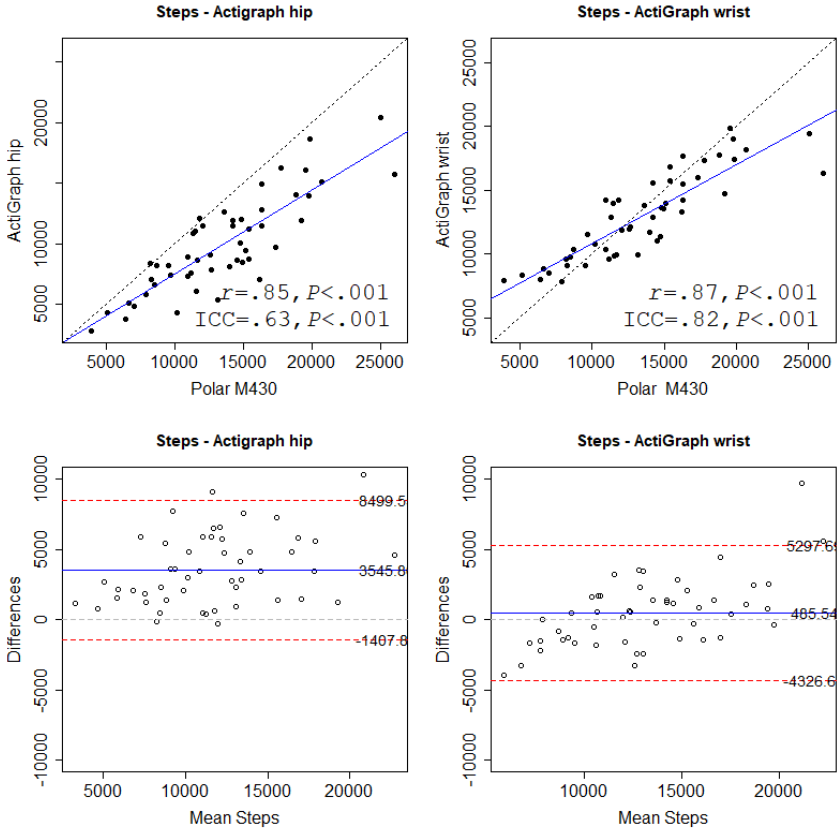


Steps

There was a very strong significant, and approximately equal, correlation between the Polar M430 and both the wrist-worn and hip-worn ActiGraph when measuring steps. ICC agreement was moderate to good for both locations. The Bland-Altman plot showed that the Polar M430 overreported steps for both placements of the ActiGraph, but at a higher rate on the hip-worn ActiGraph. Both MAPEs were high, but the hip-worn ActiGraph had the lowest MAPE. Table H in Multimedia Appendix 4 provides details of all criteria. Figure 6 shows correlations and Bland-Altman plots for the Polar M430 against both criteria.

Sensitivity (true-positive) analysis showed that the Polar M430, compared with the hip-worn ActiGraph, identified all cases in which a participant achieved 10,000 steps/day. For the wrist-worn ActiGraph, sensitivity was .94. Specificity, the ability of the Polar M430 to correctly identify those not achieving the 10,000 step/day target was .43 for the hip-worn ActiGraph and .71 for the wrist-worn ActiGraph.

Figure 6. Correlations and Bland-Altman plots for the Polar M430 and the wrist-worn and hip-worn ActiGraph for steps. Numbers in the Bland-Altman plots are mean difference and upper and lower limits of agreement (95% CI). ICC: intraclass correlation coefficient.



Discussion

Principal Findings

We have shown how the available variables correlate and agree between the Polar M430 and 6 different combinations of device, placement, and number of accelerometer axes. For most outcomes, the Polar M430 showed the strongest correlation with the hip-worn triaxial ActiGraph (VM). Similarly, agreement was most often highest (or almost as high) when we compared the Polar M430 with this criterion. Exceptions are MVPA and moderate PA, where the Actiheart in the lower position showed a somewhat higher agreement.

A previous study by Tudor-Locke et al [32] showed that the hip-worn ActiGraph had a higher accuracy for step counting than the wrist-worn ActiGraph in laboratory settings. Under free-living conditions, the same study showed that the ActiGraph detected more steps when placed on the wrist. It is therefore possible to conclude that, although our study showed that the wrist-worn ActiGraph had a higher correlation, higher agreement, and lower MAPE, the true step counts may be closer to the numbers reported by the hip-worn ActiGraph. Similarly, studies comparing how wear location affected PA intensity [33] and EE [34,35] outcomes showed that the hip-worn ActiGraph is more accurate than the wrist-worn ActiGraph.

When compared with the hip-worn ActiGraph VM, the Polar M430 had a very strong correlation for TEE and steps, a strong correlation for AEE, MVPA, light PA, and vigorous PA, and a moderate correlation for sedentary behavior and moderate PA. Bland-Altman plots showed that the mean agreement was higher for higher intensities of PA, with underreporting by the Polar M430 for sedentary behavior and light PA, and overreporting for the remaining variables. Sensitivity analysis also indicated that the Polar M430 overreported the number of steps. However, MAPE was high for most variables, and only TEE had an acceptable MAPE of 6.9%. Multimedia Appendix 11 and Multimedia Appendix 12 give correlations and Bland-Altman

plots, respectively, for the Polar M430 and the hip-worn ActiGraph VM for all variables.

MVPA was strongly correlated for all criteria except 1 (ie, wrist-worn ActiGraph VM), and all criteria gave a strong correlation for AEE and a very strong correlation for TEE and steps. For the hip-worn ActiGraph, most outcomes showed a stronger correlation when using the triaxial variable than the uniaxial variable. For all criteria, all correlations for TEE were stronger and all MAPEs were smaller than for AEE. This is expected, as REE constitutes between 60% and 75% of TEE [36]. Except for sedentary behavior and moderate PA, outcomes were similar for the upper and lower position of the Actiheart. This is in accordance with a previous study by Brage et al [37], in which position did not affect outcome significantly.

Comparison With Previous Studies

We identified 12 previous studies that compared wrist-worn Polar devices with an objective criterion measure for measuring steps, PA intensity, and EE. These studies tested 5 different Polar models: the Polar Loop (released in 2013), Polar V800 (released in 2014), Polar A300 (released in 2015), Polar A360 (released in 2015), and Polar M600 (released in 2016). We found no studies on the Polar M430 (released in 2017). The validity of EE, steps, and PA intensity levels for the Polar devices in these studies varied, and correlations ranged from weak to strong, depending on the study setting (laboratory vs free-living), device, and criterion measure.

We found 3 previous Polar validation studies on EE in laboratory settings showed a very weak to weak Pearson correlation for the Polar Loop (r range .02-.3) [38] and Polar A360 (r=.28) [39], and a very strong correlation for the Polar V800 (r range .63-.85) [28]. In free-living study participants, the Polar Loop [40], Polar A300 [41], and Polar V800 [42], showed a very strong (r=.9), strong (r=.83), and weak to moderate (r range .34-.69) correlation, respectively, for EE.

We found 3 studies on PA intensity levels in free-living populations showed poor agreement for the Polar A300 (ICC=.36) [41], strong to very strong Pearson correlation for the Polar V800 (r range .84-.93) [42], and moderate Spearman correlation and poor agreement for MVPA on the Polar M600 (ρ=.53, ICC=.38) [43]. We found no studies comparing PA intensity levels conducted in laboratory settings.

A total of 5 studies compared steps in laboratory settings. The Polar Loop was tested in 4 studies, where Wahl et al (r range .06-.83) [38], Wang et al (correlation not given) [44], and Fokkema et al (r range .08-.26) [9], showed low validity for steps, with a higher validity for higher walking speeds in 1 study (Wahl et al [38]). An et al [45], on the other hand, found higher validity for this device (r range .4-.7). Bunn et al [46] tested the Polar A360 and also found it to have low validity (r range –.24 to .49). In addition, 4 studies compared steps in free-living populations. The Polar Loop showed a strong to very strong Pearson correlation (r range .7-.89) [47], the Polar A300 showed a very strong correlation (r=.99) [41], the Polar V800 showed a very strong correlation (r range .89-.92) [42]), and the Polar M600 showed good agreement (ICC=.7) and a strong Spearman correlation (ρ=.85) [43].

The results from previous studies showed that the validity of Polar devices, ranging from the Polar Loop, released in 2013, to the Polar M600, released in 2016, was highly dependent on the study setting. Studies conducted in free-living populations seem to agree that EE was reasonably valid, but not always. Our study also showed a strong correlation for AEE and a very strong correlation for TEE, for some criteria. The correlations for MVPA were stronger in our study than in all other studies. Results from previous research on step counting in free-living populations showed similar strong correlations to those found in our study.

With the exception of the Polar Loop, there are a limited number of studies for each device. For all other devices, only 1 or 2 studies were available for a given device, and at most 1 per device in free-living populations. In addition, previous studies used a range of criteria, and as we found in our study, correlations between the Polar M430 and each criterion can be very different depending on which criterion is used for comparison. It is therefore difficult to compare our results with previous validation studies. However, because all of the previous validation studies were conducted on older devices, it is reasonable that our results showed stronger correlations and higher agreements, as modern devices are likely to be more accurate than older devices.

Other studies on non-Polar consumer-based activity trackers generally agreed that the validity of step was high, but validity for EE was lower. In a 2015 systematic review, Evenson et al [48] concluded that, for consumer-based activity trackers such as Jawbone and Fitbit, validity of steps was high, but validity for EE was lower. Similarly, Feehan et al [49] systematically reviewed Fitbit devices and found that validity for EE was low, but validity for measuring steps was higher. Bunn et al [50] systematically reviewed validation studies testing devices by Fitbit, Garmin, Apple, Misfit, Samsung Gear, TomTom, and Lumo, and found a tendency for devices to underestimate EE and steps, but step validity was higher at higher intensities. This is partly in contrast to our study. Compared with step counting, TEE showed higher correlations for all ActiGraph outcomes. For AEE, on the other hand, step counting was more strongly correlated.

Strengths and Limitations

The strengths of this study include the large sample size, with a wide range for participant weight, height, body mass index, and age. We compared the Polar M430 against multiple criterion measures, showing that the outcomes were highly dependent on instrument type and placement. Furthermore, we used 1 tool (QCAT) to convert all activity counts into PA intensity variables, thereby limiting the number of unknowns introduced when using multiple software packages.

Limitations are mainly related to uncertainties in cutoffs and conversions. We compared TEE and AEE between instruments because the Polar M430 did not report AEE and the ActiGraph did not report TEE. We used the same algorithm for adding and removing REE, but since we did not know how Polar calculates REE, we did not know the conversion's accuracy. No agreed-upon cut points for PA intensity exist for the Actiheart or the wrist-worn ActiGraph, so the accuracy of related

outcomes was also somewhat uncertain. We did not individually calibrate Actiheart devices, which could have given a more accurate EE measure. Finally, the Hecht 2009 nonwear time algorithm was not created for uniaxial accelerometer CPM. This likely caused misclassification between nonwear time and sedentary behavior, and lower correlation for this outcome.

Conclusion

This first validation study of the Polar M430 indicated higher validity for MVPA, steps, and EE than with previous Polar devices. The Polar M430 can potentially be used as an addition to established research-grade instruments to collect some PA variables over a prolonged period. Depending on the variable, the Polar M430 over- or underreported most metrics and may therefore be better suited to report changes in PA over time for some outcomes, rather than as an accurate instrument for PA status in a population. Due to the high MAPE of most outcomes, only TEE or activity tracking in large samples can be trusted to provide close to valid results. Before using any consumer activity tracker or smart watch in research, we suggest piloting the selected device in the population under study. In a future study, we will attempt to create a function for converting Polar M430 reported steps, MVPA, and EE into the ActiGraph hip-worn VM equivalent, in order to determine whether such an approach can be used to better track PA status in a population over time.

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Authors' Contributions

A Henriksen, SG, LH, and GH conceived the study. All authors contributed to the planning of the study. A Henriksen and LH collected the data. A Henriksen, LH, SG, and A Horsch analyzed the data. A Henriksen wrote the manuscript with input from all authors. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
ActiGraph wrist-to-hip activity-count conversion table.
[DOCX File, 12KB - formative_v3i3e14438_app1.docx]

Multimedia Appendix 2
Correlations between ActiLife and the Quality Control and Analysis Tool.
[DOCX File, 12KB - formative_v3i3e14438_app2.docx]

Multimedia Appendix 3
Group data and outcomes for all variables.
[XLSX File (Microsoft Excel File), 23KB - formative_v3i3e14438_app3.xlsx]

Multimedia Appendix 4
Tables (A to H) of group data for each criterion compared with the Polar M430 for all outcomes.
[DOCX File, 26KB - formative_v3i3e14438_app4.docx]

Multimedia Appendix 5
Correlations and Bland-Altman plots for the Polar M430 and each criterion measure for sedentary behavior. Numbers in the Bland-Altman plots are mean difference and upper and lower limits of agreement (95% CI).
[PNG File, 56KB - formative_v3i3e14438_app5.png]

Multimedia Appendix 6
Correlations and Bland-Altman plots for the Polar M430 and each criterion measure for light physical activity. Numbers in the Bland-Altman plots are mean difference and upper and lower limits of agreement (95% CI).
[PNG File, 57KB - formative_v3i3e14438_app6.png]

Multimedia Appendix 7

Correlations and Bland-Altman plots for the Polar M430 and each criterion measure for moderate physical activity. Numbers in the Bland-Altman plots are mean difference and upper and lower limits of agreement (95% CI).
[PNG File, 56KB - formative_v3i3e14438_app7.png]

Multimedia Appendix 8
Correlations and Bland-Altman plots for the Polar M430 and each criterion measure for vigorous physical activity. Numbers in the Bland-Altman plots are mean difference and upper and lower limits of agreement (95% CI).
[PNG File, 38KB - formative_v3i3e14438_app8.png]

Multimedia Appendix 9
Correlations and Bland-Altman plots for the Polar M430 and each criterion measure for activity energy expenditure. Numbers in the Bland-Altman plots are mean difference and upper and lower limits of agreement (95% CI).
[PNG File, 56KB - formative_v3i3e14438_app9.png]

Multimedia Appendix 10
Combined scatterplots for energy expenditure with Pearson correlations and intraclass correlations for activity energy expenditure and total energy expenditure.
[PNG File, 46KB - formative_v3i3e14438_app10.png]

Multimedia Appendix 11
Correlations for the Polar M430 and hip-worn triaxial ActiGraph for all variables.
[PNG File, 35KB - formative_v3i3e14438_app11.png]

Multimedia Appendix 12
Bland-Altman plots for the Polar M430 and hip-worn triaxial ActiGraph, for all variables. Numbers are mean difference and upper and lower limits of agreement (95% CI).
[PNG File, 31KB - formative_v3i3e14438_app12.png]

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Abbreviations

AEE: activity energy expenditure
CPM: counts per minute
EE: energy expenditure
ICC: intraclass correlation coefficient
LoA: limits of agreement
MAPE: mean absolute percentage error
MVPA: moderate to vigorous physical activity
PA: physical activity
QCAT: Quality Control and Analysis Tool
REE: resting energy expenditure
TEE: total energy expenditure
VM: vector magnitude

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Original Paper

An E-Learning Program for Increasing Physical Activity Associated Behaviors Among People with Spinal Cord Injury: Usability Study

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Abstract

Background: The majority of people with spinal cord injury (SCI) in the United States are not meeting the recommended guidelines for regular physical activity. Behavior change techniques (eg, goal setting and action planning) that are framed within the principles of the social cognitive theory (self-efficacy and self-regulation) have the potential to enhance physical activity behavior.

Objective: The aim of the study was to develop and test the usability of an electronic learning (e-learning) program for improving social cognitive factors related to physical activity behavior among people with SCI.

Methods: The program was created through an iterative process of development and refinement, using a modification of a similar methodology used to develop evidence-informed guidelines in health promotion for people with disabilities (Guidelines, Recommendations, and Adaptations Including Disability; GRAIDs framework). The study included 4 phases: (1) initial product creation, (2) national survey, (3) expert review, and (4) usability testing. Usability testing included both quantitative and qualitative data collection and analyses.

Results: The review of the program by an expert panel (n=5) and the results from a national survey (n=142) led to several refinements. Usability testing demonstrated that the program could be completed in a timely manner (<30 min). Participants reported 5 themes: (1) the program improves social cognitions related to physical activity participation; (2) reflection of physical activity behavior; (3) positive perceptions of the quality of the program; (4) positive perceptions of the program operation and effectiveness; and (5) recommendations for improvement. Each item was incorporated into a revised program version 1.0.

Conclusions: This study incorporated an evidence-based framework for developing a brief 30-min e-learning program for increasing the physical activity behavior among people with SCI. The Exercise Strategies Through Optimized Relevant Interactive E-learning Storytelling (e-STORIES) program could be completed in a timely manner and was reported by participants as valuable and useful for enhancing intent-to-perform physical activity in individuals with SCI. The program has the potential to be applied in a variety of settings, but feasibility testing is required before implementing in a larger trial.

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KEYWORDS

physical activity; mhealth; ehealth; people with disabilities; spinal cord injuries

Introduction

Background

Regular physical activity participation is a core component of the postrehabilitative care among people with spinal cord injury (SCI). Over 30 years of research has indicated that people with SCI can increase one or more aspects of their physical and mental health through participation in physical activity [1,2]. Physical activity participation can further reduce the risk of chronic disease [3] and other secondary medical conditions [4]. Nevertheless, reports have indicated that the majority of people with SCI do not participate in sufficient amount of leisure-time physical activity (LTPA) to achieve health benefits [5-7].

Individuals with SCI are often overwhelmed by a multitude of barriers [8] that prevent them from participating in LTPA (ie, scheduled activity done in their free time, such as exercise or sport). These barriers can include the lack of transportation, time, and knowledge and the psychological factors such as lack of intrinsic motivation and negative attitudes or beliefs [8]. Negative perceptions can include the belief that the society does not perceive people with SCI as capable of participating in LTPA, that engaging in exercise can cause pain or injury, or that preinjury physical activities are no longer available. These challenges support the need to develop convenient educational programs that can effectively increase the LTPA behavior among individuals with SCI.

Interventions aimed at increasing LTPA in people with neurological disabilities have been found to be more effective when framed within a theory of behavior change [9]. In particular, the social cognitive theory (SCT) is an established and commonly applied theory for promoting physical activity among people with disabilities [2,10]. A strength of SCT over other models of health behavior is that it specifies predictors and principles that can be used for informing, enabling, guiding, and motivating individuals to independently modify (ie, self-regulate) their health behaviors [11]. Specific SCT-based techniques that can be utilized by LTPA promotion programs for persons with SCI include coping with barriers, monitoring behavior, setting goals, and action planning [9,12-14].

One method that may be effective for communicating physical activity information is through story-based communications [15-18]. Perrier et al [16] have suggested that aspects of narrative inquiry may explain LTPA behavior among people with SCI, in addition to the theory-based determinants. Story-based communications capitalize on the narrative tradition, whereby people are recognized as story-telling beings who make sense of their life events and lives by hearing and sharing stories [19,20]. Although a story is characterized by personal communication (ie, what is actually being told by a person), narrative differs insofar as it is characterized by the properties, such as themes or structures, that comprise the stories [20].

Preliminary data suggest that storytelling might be an effective strategy for conveying physical activity information to people with SCI [18,21]. Furthermore, qualitative inquiry suggests that storytelling may be more effective when it is tailored to the individual's *narrative style* [16]. Within the context of SCI and physical activity, narrative style refers to how a person with SCI perceives LTPA impacting their personal life story. Using narratives first developed by Arthur Frank [20], 3 key narrative styles have been identified and adapted to the narrative inquiry with regard to SCI and LTPA [16,17]: (1) chaos narrative (lack of future and focus on preinjury LTPA), (2) restitution or cure narrative (LTPA as a means to restore former self), and (3) quest narrative (LTPA as an opportunity for social involvement, health benefits, and enjoyment postinjury). The goal of incorporating these narrative styles into a storied communication about LTPA is to connect with individuals with SCI who identify with a particular narrative, and to thereby promote examination of their own thoughts concerning their LTPA behavior [16]. However, these narratives have not yet been embedded and tested within a story-based, electronic learning (e-learning) program developed for people with SCI.

E-learning technologies, combined with health behavior theory and narrative style, have the potential to provide educational opportunities to teach people how to overcome barriers to LTPA. E-learning authoring software (eg, Articulate 360) can be used to deliver easily accessible, interactive, and personalized educational programs. With the guidance of a narrative, individuals can be the narrators of their own e-learning storyline that adapts to their responses from programmed questions and queries. E-learning narratives can be combined with behavior change activities and engaging, visually attractive content (eg, text, pictures, audio, animation, and video) to modify SCT determinants, enhancing the likelihood of an individual engaging in LTPA. Although there are long-term behavioral coaching programs that can increase engagement in LTPA [2], there are limited educational programs that are short in duration and can be implemented in time-sensitive settings (eg, clinic waiting rooms) or disseminated on a national level.

Objective

The aim of this study was to develop and test the usability of a brief e-learning program that embedded SCI narratives in a story-based approach, with the goal of improving SCT constructs that are related to LTPA. Program development included immersive involvement by people with SCI and input from an expert panel of researchers. This paper describes the development and usability of the program e-STORIES (Exercise Strategies Through Optimized Relevant Interactive E-learning Storytelling).

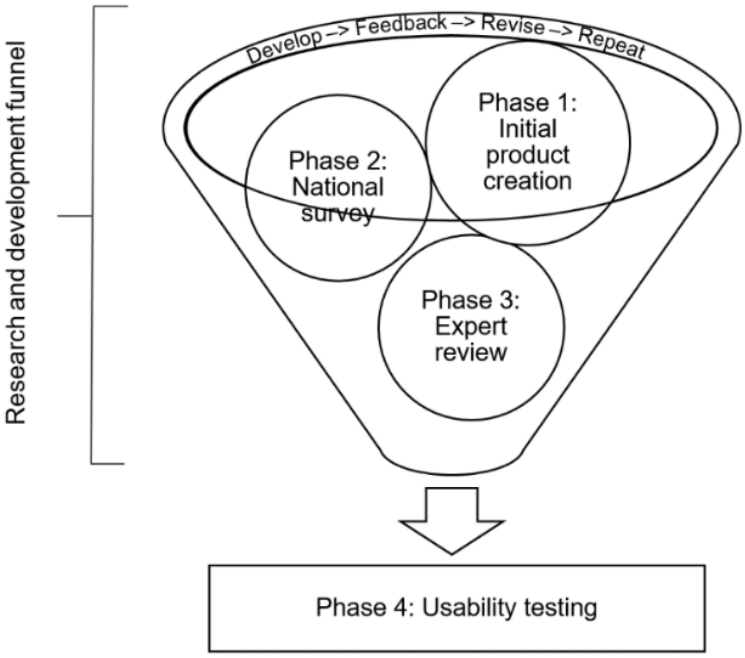
Methods

Overview

The e-STORIES development process was adapted from the Guidelines, Recommendations, and Adaptations Including Disability (GRAIDs) framework [22]. GRAIDs was chosen as a guiding framework as it is a systematic series of steps for developing or modifying health promotion programs or guidelines for people with disabilities and has been used to develop at least 11 programs thus far [22]. Following this framework, the e-STORIES program was developed through 4 phases: (1) a review of the literature to inform initial development, (2) a national survey of people with SCI, (3) an expert panel that reviewed and vetted the content material, and

(4) usability tests among a sample of people with SCI. These phases went through an iterative research and development process of *develop, feedback, revise, and repeat* (see Figure 1).

Figure 1. Research and development process for spinal cord injury Exercise Strategies Through Optimized Relevant Interactive E-learning Storytelling program.



Phase 1: Initial Product Creation

Initial development of the computer-based program involved 4 elements: literature review, storyboard creation, theory and intervention alignment, and creation of the infrastructure for the program.

Literature Review

A systematic review of peer-reviewed publications was conducted using the search terms: “spinal cord injury” AND “physical activity” AND “behavior change” AND “self-management.” The study inclusion criteria included studies that were (1) peer-reviewed, (2) conducted within the past 2 years (2016-2018), (3) classified as a review paper, and (4) indexed in PubMed, Cumulative Index to Nursing and Allied Health Literature, or Scopus. The search for review papers returned a total of 10 articles and no duplicates. After screening these articles for eligibility criteria there was only 1 article remaining. Other articles were removed owing to not being a systematic review or not targeting SCI population.

The single systematic review of physical activity self-management interventions for people with SCI was used to identify behavioral LTPA interventions and strategies to aid in content development for the e-STORIES program [23]. This report identified 31 unique studies published from 1980 to 2015. On the basis of the review of these studies and the consideration of the SCT constructs, the project team incorporated into the e-STORIES program, the behavior change techniques [12] of goal setting, problem solving, and action planning. After the completion of the storyboard and the basic infrastructure for the e-learning product, the behavior change techniques and narratives were incorporated to generate program version 0.1.

Storyboard Creation

The first stage of development was to create a storyboard that outlined the flow of the program, content suggestions, and scripts, as well as naming the project and designing a logo. The storyboard displayed the flow of the e-learning intervention and whether the information would be delivered by audio, text, pictures, animation, video, or some combinations of these media. The storyboard also helped with the construction of the pathways for tailored survey responses (ie, the flow of the program would adapt, based on a participant’s responses, to items related with confidence and self-regulatory strategies such as goal setting or planning).

Theory and Intervention Alignment

SCT is based on the interplay between the behavioral factors, personal factors, and environmental factors [24]. The intervention was framed within SCT such that the intervention content was designed to target, and improve, the SCT constructs of self-efficacy, self-regulation, and outcome expectations. This was achieved by providing the participants with activities that taught them how to set Specific Measurable, Achievable, Relevant, Time goals, action plan, problem-solving barriers (targets self-regulation constructs of SCT), identify true and false outcomes of LTPA (targets outcome expectations), and view video content of others with SCI performing LTPA (targets vicarious experience).

Program Infrastructure

Storyline 360, developed by Articulate Global Inc, is an e-learning authoring tool that was used to create the e-STORIES program. This software allowed the program to be interactive and instructional through multimedia that included digital movies, pictures, sound files, animation, graphics, and other

electronic files. After a story board was created, the basic outline of the program was developed in Articulate's Storyline 360. The outline included (1) program introduction, (2) assessment of theory constructs, (3) LTPA behavior change activities, and (4) printed copy of the participant's results.

Phase 2: National Survey

The second phase of the study included a survey of individuals with SCI that was delivered on the Web using Qualtrics. The survey aimed to collect descriptive information on the physical activity readiness and identification with SCI narratives related to LTPA, to inform and revise the program. Participants were asked to indicate which of the following best described their current level of physical activity: (a) Yes, I have been doing LTPA regularly for more than 6 months; (b) Yes, I have been doing LTPA regularly for less than 6 months; (c) No, but I intend to start doing LTPA regularly in the next 30 days; (d) No, but I intend to start doing LTPA regularly in the next 6 months; or (e) No, and I do NOT intend to start doing LTPA regularly in the next 6 months [6].

A description of each of the three SCI LTPA narrative styles was developed from the literature [16,20]: (1) LTPA is not important to me and it reminds me of how I am not able to do things like before my SCI (chaos); (2) LTPA helps to improve function and maintain my physical health for a potential cure (cure); or (3) LTPA helps me through life and helps me connect with others similar to me (quest). The survey ended with 2 open-ended questions that asked participants for desired features and messages: (1) What do you think should be included in an educational program that aims to increase physical activity among people with SCI? and (2) What would you tell another person with an SCI if you were trying to help them become more physically active?

Participants

People with SCI were recruited through one of 12 SCI-related support groups or organization pages on a social media platform. The eligibility criteria included participants who (1) were aged 18 years or above, (2) had a diagnosis of SCI, (3) had the ability to use hands and arms to exercise, and (4) had the ability to converse in English and complete the survey forms.

Analyses

Using a measure of physical activity readiness, participants were categorized as physical activity nonintenders, intenders, or actors [25], to assess the differences of physical activity readiness among the SCI narratives [6,25]. This hypothesis was based on previous literature [17,21], and if true, one programming strategy could involve grouping the physical activity readiness with SCI narratives. Fisher exact test was used to assess the differences in categorical variables (sex, injury level, and physical activity readiness) by narrative groups. Owing to the nonnormal distribution of the numerical variables (age and years since injury), Kruskal-Wallis test was used to examine the differences in age and years since injury by narrative groups. SAS version 9.4 was used for statistical analysis and statistical significance was set a priori at $P<.05$.

Phase 3: Expert Panel Review

An expert panel reviewed each component of the e-learning program for quality and accuracy using Articulate's 360 Review, which allowed them to review the program online and add comments. The panel included an exercise psychologist, an exercise physiologist, a rehabilitation scientist, an information specialist, and a clinician who had several decades of experience in exercise research in SCI. After completing the review, each expert provided a summary of suggested revisions. This feedback led to several revisions, including textual, audio, and video changes and adding features to better guide participants. This phase included program *versions 0.2 and 0.3*.

Phase 4: Usability Testing

Study Design

The usability testing incorporated a nested mixed-methods design (quantitative+qualitative), where the qualitative component was embedded within a primarily quantitative study design. In other words, the usability study included a qualitative interview within a design that emphasized the core fundamentals of usability testing. Quantitative and qualitative aspects were treated with equal value. On the basis of the best practice recommendations for usability testing [26], a mixed-methods design was chosen to provide a comprehensive evaluation of usability in 4 core areas: effectiveness, efficiency, satisfaction, and usefulness.

Belief systems in the mixed-methods studies are critical as they influence all aspects of a study, including the design, analyses, and even the presentation of the results [27]. Separate belief systems (ie, philosophical assumptions) guided each method of this study until data were interpreted within the discussion, which allowed the research team to adhere fully to the quality and rigor demanded by both methods. This approach was aligned with the paradigm of dialectical pluralism [28]. Dialectical pluralism is a metaparadigm that calls for the use of separate belief systems for both the quantitative and qualitative aspects of a mixed-methods study, particularly when the study aims to give equal emphasis to both methods. The quantitative study components aligned with the positivist perspective: reality and knowledge are singular and, thus, every event within the world can be scientifically quantified. For example, statistically significant results inform us of an event that has occurred. The qualitative study component was underpinned by an interpretivist philosophical approach: reality is multiple and subjective (ie, ontological relativism) and knowledge is socially constructed (epistemological subjectivism) [29]. For example, the research team acknowledged that the qualitative results would be created through the interaction of the interviewer and interviewee. Therefore, the interviewer did not ask questions as a blind observer. Instead, the interviewer understood that the participants' responses could be probed with additional follow-up questions to create a richer dataset (based upon the insight of the interviewer).

Recruitment

This study aimed to enroll 12 inactive people with SCI to satisfy the best practice recommendations for usability testing [26]. People were eligible if they were (1) aged 18 years or above,

(2) diagnosed with an SCI, (3) achieving less than 60 min of moderate or vigorous intensity exercise per week, (4) able to speak and understand English, and (5) able to operate a computer. This project was approved by the Institutional Review Board of the university. Before the enrollment, written consent was obtained from each participant.

Procedure

Participants were briefed about the study and provided the written consent forms. After obtaining the consent, participants' demographics and clinical characteristics were recorded. Participants were then instructed to complete 16 usability tasks which involved navigating through and completing the entirety of the program and responding to the interactive questions. A research assistant took written notes while observing the participants perform the usability tasks and recorded the time taken by the participants to complete the entire e-learning program (all tasks). This was followed by a one-on-one interview conducted in a private and comfortable setting within the research laboratory. Examples of the interview questions included: "Describe to me some positive experiences of the program," "Describe to me some negative experiences or issues you experienced with the program," and "Tell me your overall thoughts about the program." The interview was recorded by an audio device, which was later transcribed for qualitative analysis.

Measures

Usability was defined in terms of effectiveness (ie, the ease at which individuals can use the product), efficiency (ie, the speed at which an individual can accurately complete a task), usefulness (ie, the extent a product can enable the users to achieve their goals and the willingness to use the product), and satisfaction (ie, the users' perceptions and opinions of the product). Usefulness and satisfaction were explored through qualitative means, whereas effectiveness and efficiency were examined through quantitative metrics.

Effectiveness

Effectiveness was measured as the number of slides on which participants experienced an issue or problem, divided by the total slides that were completed without issues, which resulted in a single percentage value. The research team set an a priori benchmark of acceptable effectiveness at 90% [26].

Relative Efficiency

Relative efficiency was measured by the time required to complete the entire module, which included the 16 tasks. The research team established a benchmark of acceptable efficiency at 30 min, which was 8 min longer than it took the lead researcher to complete the module. The program was developed to be brief so that it could be used during clinic visits (eg, waiting periods) or at a baseline visit for someone starting an exercise intervention.

Usefulness and Satisfaction

Researchers assessed the usefulness and satisfaction through participants' qualitative feedback from the face-to-face interviews. Each interview included open-ended questions that sought to gain insight into the participants' overall perceptions of the module, their likes and dislikes regarding module features and content, whether they would use the module if it was provided to them in the clinic, and whether they perceived the information as valuable. One member of the research team conducted the interviews. The interviewer had 2 years of experience with qualitative research that involved usability testing of exercise technology.

Analysis

Participant characteristics and quantitative usability data were descriptively reported. Qualitative data were analyzed using latent deductive thematic analysis (ie, a thematic analysis process was used in which data were analyzed with the intent of developing a surface level description of the 4 core areas of usability) [30]. Thematic analysis was conducted by 2 researchers who were guided by the 6 steps proposed by Braun and Clarke [31]. First, the analysts independently read through the transcribed interviews and listened to the verbal recordings when the meaning of the written text was ambiguous (familiarization). Second, the analysts generated initial codes from segments of the transcribed interviews. Third, the analysts refined these codes into fewer subthemes and repeated this process for each transcription. Fourth, the analysts then met to review their subthemes, which they then integrated and refined into a single set of themes. Fifth, the analysts then defined and named each of these themes. Sixth, the resultant themes were reported. To enhance the quality of these data, the analysts functioned together as critical friends [32,33] and conducted the analysis within the aforementioned interpretivist philosophical approach. Both analysts had training and experience in the mixed-methods research and exercise training for people with SCI. One analyst was the principal investigator who was a physically active person living with SCI and believed in the value of LTPA. The other analyst had a background in adapted physical activity.

Results

A total of 154 people with SCI contributed to the development of the program. The national survey was completed by 142 participants, and 12 people enrolled in and completed the usability testing.

National Survey

Participant characteristics for the national survey are shown in Table 1. Data for age and years since injury were comparable with national estimates, but there was a slightly higher representation of females than that which has been reported nationally [34]. There were 61.3% (87/142) participants that identified with the cure narrative, 30.2% with quest narrative, and 8.5% with the chaos narrative. The finding that the majority of the sample identified with a cure narrative is in line with previous research [17]. Fisher exact test indicated no significant differences (P=.18) in physical activity readiness across the narrative groups. The open-ended questions were compiled into a list and redundancies removed to provide a list of suggestions to include in the program. Overall, the analysis of the national survey data resulted in the addition of video content of active people with SCI who shared their stories, videos of adapted

exercises and sports, and emphasis of health benefits associated with LTPA.

Table 1. Results of national survey (N=142).

Characteristics	Values
Age (years), mean (SD)	42 (14)
Years since injury (years), mean (SD)	12 (12)
Gender[a], n	
Male	71
Female	55
Level of injury, n	
Paraplegia	91
Tetraplegia	51
Narratives, n	
Cure	87
Quest	43
Chaos	12
Physical Activity readiness, n	
Actor	115
Intender	22
Nonintender	5

[a]Data from 16 participants are unreported.

Expert Panel

The following summarizes the revisions completed after the expert review: a statement about pain and exercising as a person with SCI was changed; some videos were re-recorded to improve quality; volume was increased on several audio clips; minor text edits were made; option was added in narratives for participants to use their own words or phrase; and examples of goals and next steps were provided.

Usability Study

Usability testing of program *version 0.4* led to several minor revisions that were incorporated within the final program *version 1.0*. In total, participants experienced 29 usability issues. The issues were related to (1) operating action prompts during a task (24/29, 83% of issues), (2) operation errors (a broken navigation button that linked to the previous page; 2/29, 7% of issues), (3) verbal clarity (2/29, 7% of issues), and (4) video resolution (1/29, 3% of issues). Table 2 provides demographics for participants in the usability study.

Table 2. Participant demographics of usability study (N=12).

Characteristics	Values
Age (years), mean (SD)	53 (11)
Years since injury (years), mean (SD)	23 (13)
Gender, n	
Male	8
Female	4
Level of injury, n	
Paraplegia	12
Tetraplegia	0

Effectiveness

The mean effectiveness score was 86% (SD 10%; 95% CI 80%-91%). This value was slightly lower than our a priori benchmark of 90%, indicating that minor changes were required to reduce operation issues.

Efficiency

The mean time to complete the program was 28 min 20 seconds (SD 6 min 45 seconds; 95% CI 25 mins 43 seconds to 33 min 3 seconds), which was lower than our a priori benchmark of 30 min.

Usefulness and Satisfaction

The analysts identified 5 themes regarding the usability of the program: (1) the program promoted reflection/introspection of physical activity behavior; (2) the program improved social cognitions related to physical activity participation; (3) the participants had positive perceptions of the quality of the program; (4) the participants had positive perceptions of program operation and effectiveness; and (5) participant recommendations for improvement. These themes and their subthemes and supporting quotes are shown in Table 3.

Participants reported that the program promoted valuable thoughts of self-reflection regarding physical activity behavior. The program provided relevant and encouraging information to establish reasonable outcome expectations of LTPA and to progress from a focus on the injury to resuming normal daily activities as reported by participant 1: “It definitely gets you from being focused on the actual injury to getting back into life, getting that groove back into life.”

Participants reported that the program improves social cognitions related to physical activity participation such as self-regulation. The program increased the participants’ confidence to plan and schedule PA through behavior change techniques that included goal setting, demonstration of the behavior, and how to plan physical activity around barriers that prevent participation. Participants further noted that the content provided meaningful and relevant information, with an uplifting and motivating tone:

> *It gets you to thinking. It gets you out of the doom and gloom process, and into the hopefulness, the looking forward to...And that's why I see it as being a major help in that area.* [Participant 2]

Participants reported high levels of satisfaction with the program design, including the animations and general flow of the slides. Participants further described the program as self-explanatory, intuitive, easy to operate, and engaging. However, the participants also had recommendations for improving the usability of the program. Participants noted that minor changes in the form of visual cues or instructional prompts and a back button could assist navigation and clarity in areas of the program that caused confusion.

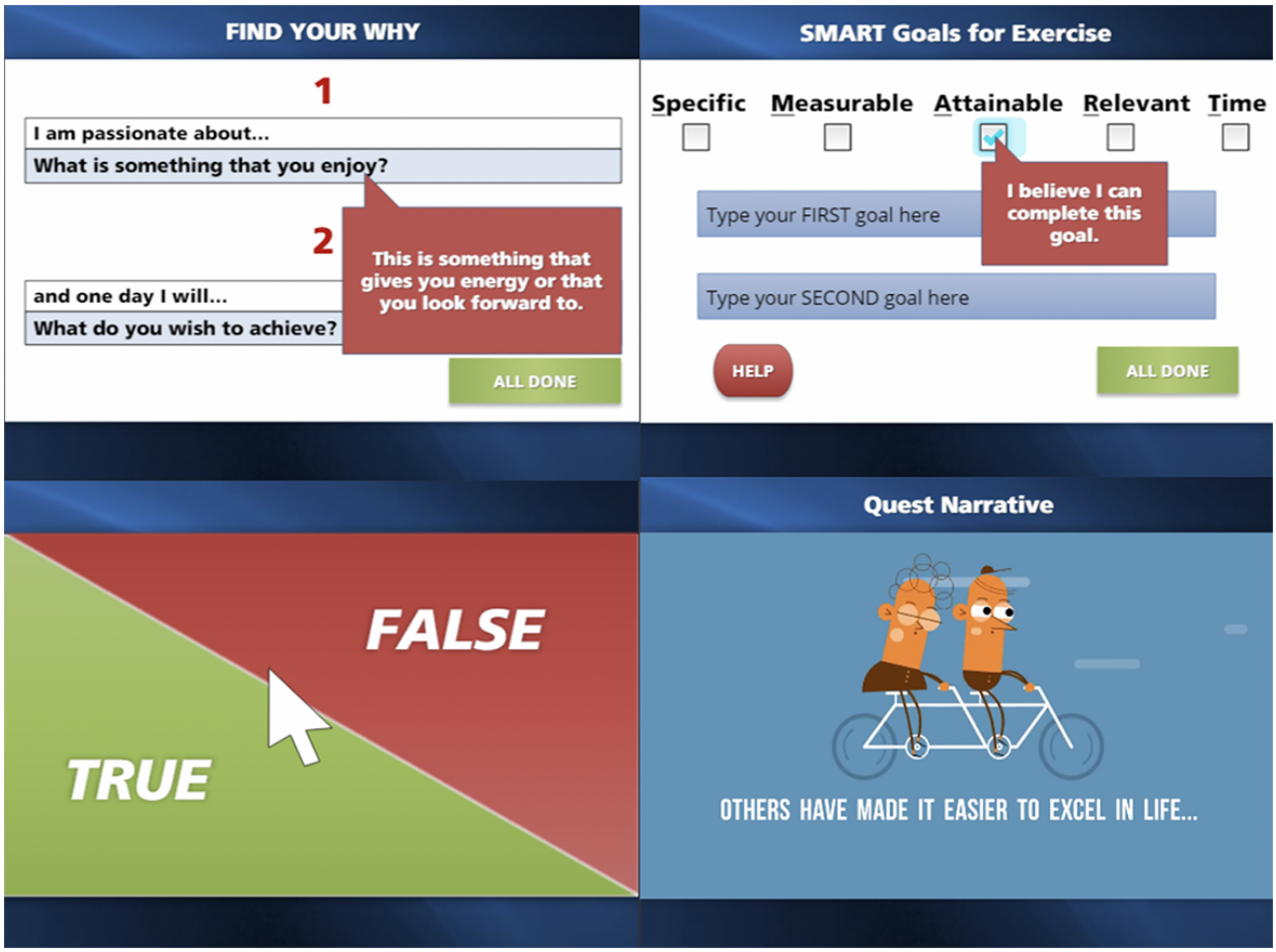
Table 3. Qualitative results of usability study.

Themes and subthemes	Supporting quotes
The program promoted reflection/introspection of physical activity behavior	
The program provided relevant and encouraging information that fostered thoughts of hope	"It gets you to thinking. It gets you out of the doom and gloom process, and into the hopefulness, the looking forward to...And that's why I see it as being a major help in that area."[Participant 002]
The program provided valuable suggestions to progress from a focus on the injury to resuming normal daily activities	“It definitely gets you from being focused on the actual injury to getting back into life, getting that groove back into life.” [Participant 001]
The program improves social cognitions related to physical activity participation	
The program enhanced participants’ intentions to plan and schedule physical activity.	“It was very valuable because, like I said, I'm going to apply this to my everyday life from now on, and I'm going to start setting more planned goals and put them into motion.” [Participant 009]
Goal setting and vicarious experiences were memorable techniques that were learned from the program	“I think the positive is kinda relaying how you would go about obtaining a goal, like the time aspect of it. Set it 10 minutes per day, 30 days. And, the stories about the spinal cord injuries. Just seeing somebody else overcome the journey you've already been on.” [Participant 005]
Positive perceptions of the quality of the program	
The content provided information that was meaningful and relevant to the individual	“It's really a new day about spinal cord injury, and it show a lot about peer support when you're a spinal cord injury. It shows a lot about activities, it shows about people who've had trauma in their life and who have overcome the trauma, and they're living a very high functional life.” [Participant 002]
Participants were satisfied with the program design	“That was awesome and I liked the way he told his story about what happened to him. Some of the drawings and the way they did, I thought that was pretty good. The animation, the way they did that. I thought that was good.” [Participant 013]
Perceived as a valuable tool to enhance physical activity behavior for people with acute spinal cord injury	“Just that, I think, it would be beneficial for anyone with a spinal cord injury to participate in it or see it, especially somebody newly injured.” [Participant 008]
The content had a tone that was uplifting and motivating	“Very uplifting. I loved the manner in which the information was presented. It was very positive. It was motivating.” [Participant 008]
Positive perceptions of program operation and effectiveness	
The program was self-explanatory and intuitive	“It kind of explained what it wanted you to do. You just clicked on it and it told you.” [Participant 011]
The program was easy to operate	“I guess with the mouse, with the clicking...The mouse helped me navigate through it easier and stuff, instead of using the pad.” [Participant 001]
The program was engaging	“It's quite interactive, and well thought out I will say. It's easy to navigate and keeps you into it. So, it's very much needed for a lot of people to get back into feeling the need for this type of program.” [Participant 009]
Recommendations for improvement	
Improve visual cues/prompts to assist navigation	“The navigation was not bad, but it’s just...do I click on the box or do I move it? So that was a little confusing.” [Participant 001]
Enhance the definition of the different types of exercise intensities and the action prompts	“The only negative I had was the calculation of the mild to moderate when it changed it from. I entered 30 and it went to 90. It's just a little confusing...Yeah. A different color on the words mild, moderate, heavy. Maybe put them in bold. A different font. Just something to make it stand out so that it's emphasized...Potentially lead with: “You're going to be asked about three different levels of exercise,“ so that you know ahead of time that you'll be asked the same thing three times just differentiating mild, moderate, and heavy.” [Participant 008]
Provide the ability to go back to a previous screen	“Well not being able to go back to the previous screen if I messed up. I even tried to click next one time and it didn't work either. So that was a negative.” [Participant 006]

Description of Exercise Strategies Through Optimized Relevant Interactive E-learning Storytelling Version 1.0

The final program version included a total of *41* slides (examples shown in Figure 2). The program further contained *16 interactive tasks*, *12 videos*, and *a summary print-out* (see video of full program in Multimedia Appendix 1). The program begins with an introduction, which includes animated videos and a description of acquiring an SCI, discussion of why exercise and planning is important, introduction of program coach, and information about how to maximize the program. Next section of the program includes some questions concerning LTPA behavior, LTPA self-efficacy, and self-regulatory efficacy. Once completed, the program guides the participants through several activities, including selecting a narrative, debunking myths about exercise and SCI, identifying an intrinsic motivation for LTPA, setting a goal for LTPA with a plan for the next step, and matching common barriers to exercise with solutions. The participant then views a video that includes people with SCI sharing their stories and exercising at a recreational facility. Finally, a print-out summarized each participant's learning module, which included their physical activity goals with a next step, primary motivation for exercise, LTPA narrative, and reported moderate-to-vigorous LTPA minutes.

Figure 2. Screenshots of spinal cord Exercise Strategies Through Optimized Relevant Interactive E-learning Storytelling injury program.



Discussion

Principal Findings

This project incorporated an evidence-based framework for developing and testing a storied e-learning program to increase physical activity among people with SCI. Usability testing demonstrated that people could independently complete the program in a timely manner and that the program was perceived as valuable and useful for improving confidence to engage in physical activity and associated self-regulating behaviors among people with SCI. Usability testing identified minor operation issues that were rectified in the final version of the e-STORIES program.

A strength of this project was the high value placed on stakeholder feedback. Development of the program included input from over 150 participants with SCI. Such feedback informed critical development decisions, including the decision to not tailor the presentation of the SCI narratives based on the participant's physical activity readiness and to halt further usability testing. Given that usability testing can be defined in several ways, the determination of an endpoint for usability testing is often a difficult task [35]. In this study, the research team found that a synthesis of both the quantitative and qualitative findings was useful in deciding to halt usability testing. Although several usability issues were identified from the quantitative data (particularly the engagement tasks), participants reported favorable perceptions of the program.

Furthermore, participants reported that the issues they experienced could be remedied by minor visual enhancements to facilitate navigation, versus changes in program content or information.

Statistical analysis of the results from the national survey (phase 2) did not support tailoring the presentation of SCI narratives based on the participant's physical activity readiness. Findings demonstrated no significant differences among the SCI narratives and the physical activity readiness. However, only 8.3% (12/142) of the people identified with the chaos narrative, which likely affected the analyses. This finding is consistent with previous research which reported that less people with SCI identified with the chaos narrative when compared with the cure and quest narratives in LTPA studies [16,17]. Nevertheless, the qualitative results indicated that people with SCI found the content relatable and viewing narratives seemed to encourage introspection, or self-examination of thoughts, of LTPA.

Although usability results suggested that the e-STORIES program could potentially improve self-efficacy and self-regulatory skills to perform physical activity, further research is required to explore whether the program can be successfully implemented in pragmatic, real-world settings. One such setting is within the waiting area of a rehabilitation hospital for SCI patients, where the patient could discuss the e-STORIES results with their physician, as people with SCI perceive doctors as a trusted and credible source of PA information [36]. In addition, several of the participants who completed the usability study indicated that the program was ideal for individuals with newly acquired SCI, so another potential setting could be inpatient clinics for people with SCI. Given that all but one participant of the usability study had SCI for 11 or more years since the time of injury, it would be beneficial to test the program among people with recently acquired SCI. A strength of the e-learning program is its potential to reach a broader sample of people with SCI, as e-STORIES could be disseminated globally through internet-distribution channels such as the National Center on Health, Physical Activity and Disability. Finally, the e-learning program could be utilized as a supplementary behavior change tool in an exercise training regime.

Limitations

This project had a few limitations. Although the sample size for usability testing met 1 minimum recommendation, the sample limited our understanding of usability within various subgroups of people with SCI. Only people with paraplegia enrolled in the study, and these individuals were, on average, middle-aged. This limitation supports the need to test the program with larger heterogeneous samples of people with SCI, particularly individuals who are in the acute or subacute stage postinjury, a period when the program could be highly valuable as noted by several study participants. Another limitation was the low number of individuals in the chaos narrative, reducing the power to detect differences in readiness among the narratives. Finally, although only 3 narratives were presented in the program (cure, quest, and chaos), it is important to note that there have been several other narratives concerning LTPA among people with SCI in the literature [37], such as *exercise is medicine* and *exercise is progressive redemption*, which were not presented in this study.

Conclusions

e-STORIES is a brief, online program developed through an iterative process that was informed by the life experiences of more than 150 people with SCI, including the creator of the program (JW). The usability study demonstrated that people with SCI perceived the e-STORIES program as valuable, useful, effective, and of high quality. However, feasibility testing is required before the implementation of the program in a larger trial.

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Authors' Contributions

JW, BL, JR, and KMG contributed to the design of the study and the development of the program. JH completed all recruitment and data collection for the usability study. JW, BL, and HW analyzed the study results. JW led the program development and the manuscript development. KMG and JR oversaw the implementation of the project. All authors contributed to the formulation of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Video of Exercise Strategies Through Optimized Relevant Interactive E-learning Storytelling program.

[MP4 File (MP4 Video), 79MB - formative_v3i3e14788_app1.mp4]

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Abbreviations

e-learning: electronic learning
e-STORIES: Exercise Strategies Through Optimized Relevant Interactive E-learning Storytelling
GRAIDs: Guidelines, Recommendations, Adaptations Including Disability
LTPA: leisure-time physical activity
SCI: spinal cord injury
SCT: social cognitive theory

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Original Paper

An Interactive Website for Whiplash Management (My Whiplash Navigator): Process Evaluation of Design and Implementation

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Abstract

Background: Whiplash is a health and economic burden worldwide. Contributing to this burden is poor guideline adherence and variable management by health care professionals (HCPs). Web-based tools that facilitate clinical pathways of care are an innovative solution to improve management.

Objective: The study aimed to develop, implement, and evaluate a Web-based tool to support whiplash management following a robust process.

Methods: This study followed the first 3 processes of a research translation framework (idea generation, feasibility, and efficacy) to inform the development, implementation, and evaluation of a website that supports HCPs in whiplash management. Development followed the idea generation and feasibility processes to inform the content, design, features, and functionality of the website. This involved stakeholder (eg, industry partners, website developers, and HCPs) consultations through face-to-face meetings, surveys, and focus group discussions. Implementation followed the feasibility process to determine the practicality of the website for clinical use and the most effective strategy to promote wider uptake. Implementation strategies included classroom education, educational meetings, educational outreach, reminders, and direct phone contact. The analysis of website use and practicality of implementation involved collection of website metrics. Evaluation followed the feasibility and efficacy processes to investigate the acceptability and extent to which the website assisted HCPs in gaining knowledge about whiplash management. Surveys were conducted among student, primary, and specialist HCPs to explore ease of access, use, and satisfaction with the website, as well as self-rated improvements in knowledge of risk assessment, management, and communication between HCPs. Website logs of specialist management decisions (eg, shared care, specialist care, and referred care) were also obtained to determine actual practice.

Results: The development process delivered an interactive, user-friendly, and acceptable website, *My Whiplash Navigator*, tailored to the needs of HCPs. A total of 260 registrations were recorded from June 2016 to March 2018, including 175 student, 65 primary, and 20 specialist HCPs. The most effective implementation strategies were classroom education for students (81%

uptake, 175/215) and educational meetings for primary HCPs (43% uptake, 47/110). Popular pages visited included *advice and exercises* and *risk assessment*. Most HCPs agreed that their knowledge about risk management (79/97, 81%) and exercises (85/97, 88%) improved. The specialists' most common management decision was *shared care*, an improvement from a previous cohort. Areas to improve were navigation and access to outcome measures.

Conclusions: A robust process resulted in an innovative, interactive, user-friendly, and acceptable website, the *My Whiplash Navigator*. Implementation with HCPs was best achieved through classroom education and educational meetings. Evaluation of the website showed improved knowledge and practice to be more consistent with a risk-based clinical care pathway for whiplash. The positive results provide sufficient evidence to scale implementation nationally and involve other target markets such as people with whiplash, insurers, and insurance regulators.

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KEYWORDS

primary health care; whiplash injuries; clinical decision support; clinical pathways; rehabilitation

Introduction

Background

Whiplash-associated disorders (WAD) remain a huge health and economic burden internationally [1-3], with 50% of people experiencing persistent pain and disability [4-6]. One possible contributor to this burden is that WAD guidelines are inconsistently applied by health care professionals (HCPs) [7,8]. Inconsistent and costly practices include high rates of imaging, excessive use of passive treatments, and delayed and poorly directed specialist referral [8-13]. These practices persist despite extensive and strategic guideline implementation [14-16], highlighting the need for adopting other strategies to promote guideline-based care.

Clinical pathways of care are a promising strategy to improve HCP practice by incorporating guideline recommendations into health care processes [17]. A clinical pathway of care for WAD was developed that uses risk assessment [18,19] and guideline-based treatments matched to the risk of nonrecovery [20]. People at low risk require less intensive treatment and are provided with existing guideline-based resources [21,22]. People at medium and high risk of nonrecovery are referred early to HCPs who specialize in WAD (specialist HCPs), as recommended by WAD guidelines [21]. The specialist HCP more thoroughly assesses the physical and psychological factors associated with nonrecovery. This model of care has been successfully implemented in people with low back pain [23] but is yet to be tested and implemented in people with WAD.

Web-based tools such as computerized decision support systems are one of the most effective strategies to support the implementation of clinical pathways and guidelines, thereby improving HCP practice [24-26]. In musculoskeletal health, these tools are used to provide clinical information, guide triage, and match patients to appropriate resources and treatments [27]. These tools are shown to be effective in improving HCP practice in the management of conditions such as hypertension, diabetes, and osteoarthritis [28,29]. The positive results in other conditions suggest that a Web-based tool might also be an effective strategy to support the WAD clinical pathway of care.

To be effective, Web-based tools need to be developed and implemented using a robust process that ensures maximum uptake by users. Research translation frameworks describe a process from idea generation right through to implementation, evaluation, and then monitoring. For most innovations, such frameworks are followed over decades until an innovation is fully implemented and operational. Although several frameworks exist to guide the process [30], the New South Wales (NSW) Translational Research Framework was applied to develop a suitable Web-based tool for HCPs within the NSW and similar Queensland (QLD) health schemes [31]. Important initial steps of the framework are idea generation, feasibility, and efficacy [31]. Idea generation involves an integrated, multidisciplinary, collaborative approach to develop an innovative intervention [31]. Feasibility determines acceptability and viability of the intervention before further testing and attempts to answer the question of whether the intervention is practical to implement [31]. Implementation strategies known to change practice [14,16,32-35] may be used in this step to determine the practicality of implementing the intervention. During both idea generation and feasibility, stakeholder engagement is crucial to ensure suitability and acceptability of the intervention [31]. Finally, efficacy assesses whether the intervention can deliver expected outcomes under best circumstances. Results of these initial steps gather useful insights to inform further improvements and determine the capacity of the intervention to be successfully scaled up for greatest impact.

Process evaluation is an essential methodology that is used to evaluate the change process at each stage of intervention development and implementation [36,37]. This methodology assesses elements such as reach, effectiveness, and influencing factors to optimize the design and evaluation of the intervention [36,37]. Interventions developed following similar processes have been successful in delivering acceptable, easy-to-use, and effective Web-based tools for conditions such as rheumatoid arthritis [38], obesity [39], and cancer [40].

Objective

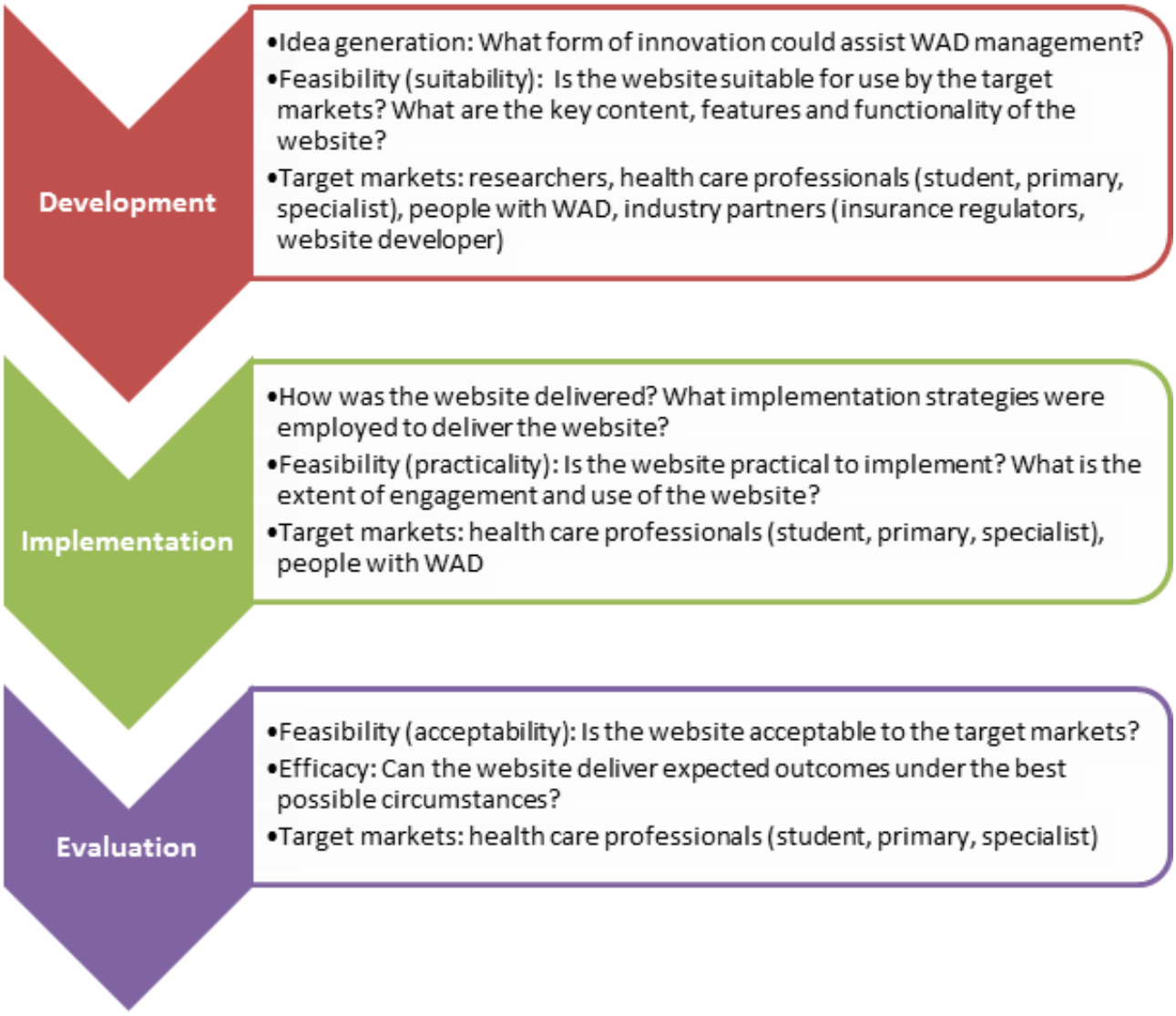
This study used process evaluation methodology to report on the development, implementation, and evaluation of a Web-based tool to support HCPs in the management of WAD.

Methods

Design

This study followed the stages of development, implementation, and evaluation, incorporating the first 3 processes of the NSW Translational Research Framework [31] within each stage (Figure 1). The study involved both quantitative and qualitative methodologies. Ethics approval was provided by the University of Sydney (2015-444) and Griffith University (2015-707) Human Research Ethics Committees.

Figure 1. Process diagram summarizing the key stages, research translation process, and target markets to deliver the My Whiplash Navigator website. WAD: whiplash-associated disorder.



Development

The aim of the development stage was to deliver a suitable website to support HCPs in WAD management. During this stage, the idea generation and feasibility processes of the framework were followed.

The idea generation process first involved stakeholder consultation. Initial consultations between researchers from the University of Sydney and University of Queensland identified key stakeholders, including industry partners, primary HCPs, specialist HCPs, and people with WAD. Second, face-to-face meetings were held with industry partners, the compulsory third party (CTP) insurance regulators (ie, NSW State Insurance Regulatory Authority and QLD Motor Accident Insurance Commission). Third, a survey (idea generation questionnaire) was conducted among primary and specialist HCPs and people with WAD to explore their perspectives about existing and ideal WAD resources. Primary and specialist HCPs and people with WAD were invited from our existing research databases. The survey was administered using the Research Electronic Data Capture (REDCap) tool hosted at the University of Sydney [41]. Participants rated their opinions on current resources using a 5-point Likert scale (1=strongly disagree to 5=strongly agree), and data were analyzed using descriptive statistics. The final step involved selecting and then consulting with a vendor who had experience in building interactive health education websites. A transparent tendering process was followed to select a suitable vendor to design the website.

The feasibility process in the development stage involved face-to-face meetings with industry partners and website designers, followed by focus groups discussions among primary and specialist HCPs. A total of 20 work-in-progress meetings were held over 8 months to develop the website, involving 4 policy makers, 8 researchers, 6 clinicians, and 4 website designers. Discussions included design concepts, content, functionality, maintenance and support, milestones, and administration. The researchers had input to the content and sought feedback from key experts during this process. The vendor's role was to ensure the content was adapted to be suitable for website and target market use.

A total of 6 semistructured focus group discussions were conducted among primary and specialist HCPs to explore perceptions on ideal features, functionality, and content that would facilitate HCP uptake and use. The discussions were run by 2 members of the research team, who were guided by a set of key questions (Multimedia Appendix 1). Proceedings were audio-recorded, transcribed verbatim, and analyzed thematically [42]. Focus group methods have been described in detail elsewhere [43,44].

Before implementation, the website was piloted with 5 HCPs to test the website features and functionality, resolve issues, and further refine the website.

Implementation

The aim of the implementation stage was to determine the most effective and feasible strategy that could inform future scalable implementation of the website before public release. At this stage, the feasibility process of the framework was followed to also evaluate the practicality of the website. Target markets for this stage were students and primary and specialist HCPs, ensuring a range of clinical experience from novice to experienced HCPs.

Student HCPs were engaged through classroom education. The website was integrated as a learning resource in a unit of study for physiotherapy students at the University of Sydney (n=215). Key components of the educational module included standard assessment for WAD, risk assessment, provision of treatments for people with WAD at low risk of nonrecovery, and timely and appropriate referral to specialist HCPs for people with WAD at medium and high risk of nonrecovery.

Primary HCPs were engaged through educational courses, educational outreach, and reminders. We targeted 3 professional development courses in WAD that were conducted by the Australian Physiotherapy Association over a 12-month period. A total of 110 physiotherapists attended these courses. The key features and components of the website were explained and integrated into the WAD educational modules. In addition, the website was promoted through 4 conference presentations. Primary HCPs who attended the courses and consented to participate were followed up with educational outreach, either face-to-face or over the phone, and provided with standard educational packages. In addition, reminders were sent through social media (eg, Facebook) and regular newsletters.

Specialist HCPs (n=20) were engaged through 2 targeted educational workshops. The content of the first educational workshop was based on results of a qualitative study, focusing on the role of specialist HCPs, management decisions for people with WAD at medium and high risk of nonrecovery, and effective communication with primary HCPs [43]. Key features and use of the website that facilitate the above were also discussed during the educational workshop. A follow-up face-to-face meeting was conducted after 6 months to address issues such as access to certain resources and documentation of management decisions.

Analysis of website use and the practicality of website implementation involved assessment of reach and extent of engagement by HCPs. Website traffic and trends (eg, registered users, total visits, total page views, and top landing pages) were collected through Google analytics and built-in website reports.

Evaluation

The aim of the evaluation stage was to investigate acceptability and preliminary efficacy of the website among HCPs. The framework processes followed were feasibility and efficacy. This was achieved by inviting all HCPs registered on the website to complete an evaluation questionnaire and determining actual practice through website logs.

The feasibility process in the evaluation stage assessed acceptability of the website by students and primary and specialist HCPs. The evaluation questionnaire asked questions regarding ease of access, use, and satisfaction with the website. At least 10 website users were necessary to obtain enough data for evaluation. This number was determined a priori and based on available evidence and previous studies that explored usability of Web-based resources for management of other conditions [38,45,46].

Efficacy was evaluated by measuring the extent to which the website assisted HCPs in gaining knowledge of key components of WAD management. Students and primary and specialist HCPs were asked about their self-rated improvement in knowledge of risk assessment and management of people with WAD at low risk and those at medium and high risk of nonrecovery. Furthermore, primary and specialist HCPs were asked about their opinion whether the website facilitated communication between HCPs. This item was specifically asked to primary and specialist HCPs, given their access to the website feature that allows documentation of management decisions in patient care. Actual practice was documented by reviewing website logs of decisions made by specialist HCPs.

Close-ended questions were rated using a 5-point Likert scale (1=strongly disagree to 5=strongly agree). Open-ended questions explored opinions on the best features of the website, barriers to use, and suggestions for further improvement. Survey data were analyzed using descriptive statistics, and responses to open-ended questions were grouped into common categories.

Results

Development

The stakeholder consultation generated ideas that informed website design and implementation. Key features and content

of the website were identified successively as a result of the consultation process.

Researchers and CTP insurance regulators determined that the website should assess the risk of nonrecovery and facilitate risk-based management. The clinical prediction rule (CPR) developed by researchers from the University of Queensland [18,19] was agreed to be used and automated on the website. Concurrently, consultation between researchers from the University of Sydney and CTP insurance regulators had developed a decision matrix for specialist HCPs to assist in the management of people with WAD at medium and high risk of nonrecovery. The decision matrix included 3 management decisions: (1) shared care (ie, continued treatment with the primary HCP monitored by a specialist), (2) specialist care (ie, direct treatment from specialist), and (3) referred care (ie, referral to other disciplines).

Researchers and CTP insurance regulators further identified that the website should consolidate evidence-based and risk-based resources for people with WAD and HCPs. Before the development of the website, patient versions of the WAD guidelines, educational and exercise videos, factsheets, and booklets were previously developed by the CTP insurance regulators with extensive involvement of people with WAD. Resources for HCPs who manage people at low risk were based on the most recent WAD guidelines and were available in various formats (eg, booklets, factsheets, and videos) [21,22]. Resources for HCPs who manage people at medium and high risk were to facilitate referral to specialist HCPs and assist in further assessment of physical and psychological factors.

The idea generation survey was returned by 94 HCPs (94/671, 14.0%) and 26 people with WAD (26/50, 52%). About half of the HCPs (53/94, 56%) and most of the people with WAD (25/26, 96%) surveyed had not seen the existing WAD resources. When these resources were shown to them, most HCPs (59/94, 63%) and people with WAD (21/26, 81%) agreed that these would help WAD management and applied to their injury (Table 1). In addition, the majority of the people with WAD who completed the survey agreed that they would appreciate access to the resources. About half of the HCPs (50/94, 53%) also indicated that a website would be the best platform to facilitate access to the resources.

Results of the focus group discussions, attended by 28 HCPs (16 primary and 12 specialist HCPs), endorsed some key features of the website and informed the types of resources that were added to the website (Multimedia Appendix 2). Themes that were generated can be broadly categorized as those relating to risk assessment, management of people at low risk of nonrecovery, and management of people at medium and high risk of nonrecovery. For example, HCPs suggested that if risk assessment was to be automated on the website, then guidance on what to say to people at different risk levels should be provided. In the low risk section of the website, primary HCPs suggested downloadable and customizable exercise sheets be provided. In the high-risk section of the website, primary HCPs indicated that a database of specialist HCPs incorporated into the website would facilitate the referral process. Finally, specialist HCPs suggested accessible and downloadable psychological screening tools (eg, Depression, Anxiety and Stress Scale [47], and Pain Catastrophizing Scale [48]) and other outcome measures (eg, Self-report Leeds Assessment of Neuropathic Symptoms and Signs pain scale [49], and Central Sensitization Inventory [50]) as well as incorporating a mechanism to document management decisions and communicate with primary HCPs. These results were considered, and the website incorporated content that provided suggestions on communicating risk level, downloadable resources (eg, screening tools, exercise sheets, and outcome measures) and a database of specialist HCPs.

The vendor consultation resulted in the delivery of an interactive, user-friendly website, the *My Whiplash Navigator* (Figure 2). Within the website, 3 sections were developed: patient, health care practitioner, and specialist practitioner. Each section was developed with the target market considered and the key components of WAD management embedded (ie, risk assessment and risk-based management; Multimedia Appendix 3). The patient section guides people with WAD through various steps within the clinical pathway, including risk assessment, and provides access to useful information, advice, and exercises. The health care practitioner section comprises guideline-based resources to assist in WAD management, particularly management of people at low risk and referral of those at medium and high risk of nonrecovery. The specialist practitioner section was designed to assist the specialist in making appropriate decisions for people who are at medium and high risk of nonrecovery.

Table 1. Perceptions of health care professionals (N=94) and people with whiplash-associated disorder (N=26) about available resources on whiplash before the project.

Target group	Strongly disagree/disagree, n (%)	Neutral, n (%)	Strongly agree/agree, n (%)
Health care professionals			
Factsheet			
Helpful in WAD[a] management	12 (13)	26 (28)	56 (60)
Would use the resource in practice	19 (20)	20 (21)	55 (59)
Educational video			
Helpful in WAD management	9 (10)	23 (25)	62 (66)
Would use the resource in practice	22 (23)	26 (28)	46 (49)
Exercise video			
Helpful in WAD management	12 (13)	22 (23)	60 (64)
Would use the resource in practice	24 (26)	25 (27)	45 (48)
People with WAD			
Factsheet			
Applicable to my injury	1 (4)	3 (12)	21 (84)
Would want access to the resource	1 (4)	1 (4)	23 (92)
Educational video			
Applicable to my injury	0 (0)	5 (19)	20 (80)
Would want access to the resource	1 (4)	4 (15)	20 (80)
Exercise video			
Applicable to my injury	0 (0)	5 (19)	20 (80)
Would want access to the resource	2 (8)	4 (15)	19 (76)

[a]WAD: whiplash-associated disorder.

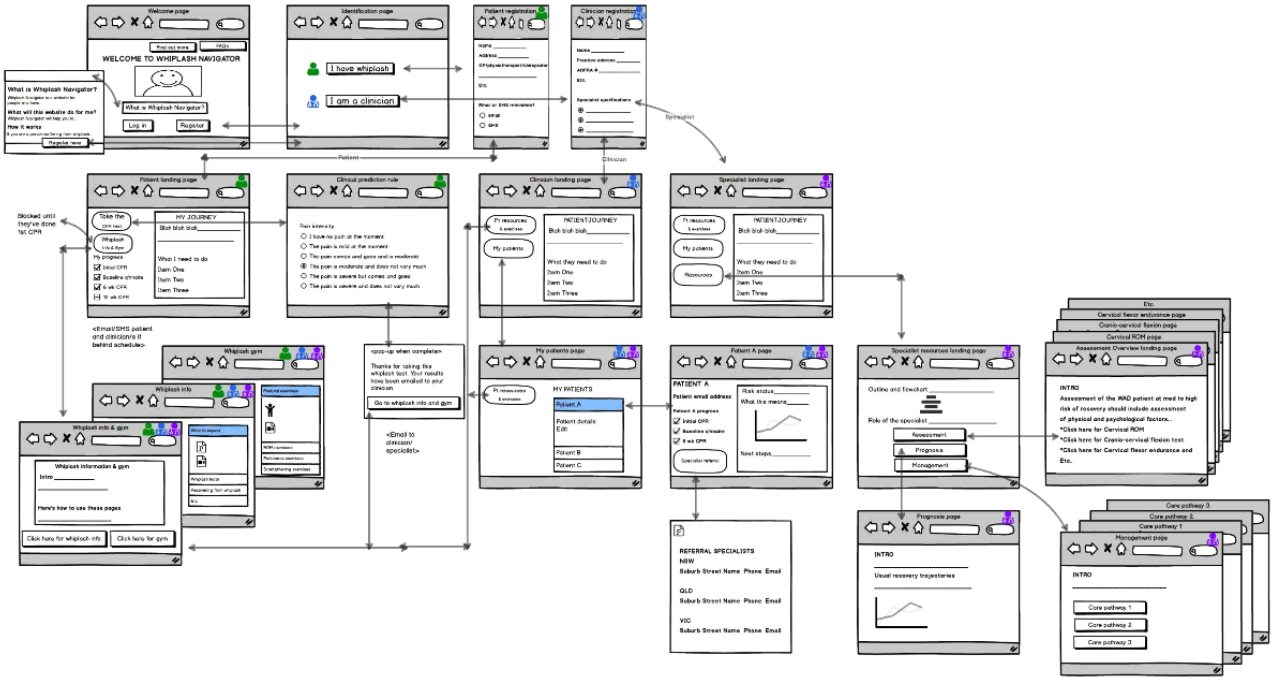
Figure 2. The *My Whiplash Navigator* website landing page.

Format, Layout, and Features

The content of the website was written in a professional and patient-friendly tone, included interactive and intuitive pages, and presented a positive and encouraging color scheme and layout. Pages were interactive, intuitive, and user friendly to facilitate ease of navigation. Information contained within the website were presented as navigation links and in a drop-down/accordion format, where appropriate. The interactions and access to various pages within the website are summarized in Figure 3.

The homepage of the website provided information about the *My Whiplash Navigator* and links to register and capture login details. Once registered or logged in, the patient or HCP is directed to their relevant page. The patient section includes an automated version of the whiplash CPR. The patient completes a questionnaire, and the score/risk status is computed. Feedback about the level of risk is provided to the patient and the treating HCP, with a link to information for matched treatments according to the risk of nonrecovery. Suggestions on how to communicate risk level to patients are provided to the treating HCP. A database of specialist HCPs is also incorporated on the website to facilitate referral of people with WAD at medium and high risk of nonrecovery. In addition, the website links the patient with the treating HCP, as well as the specialist HCP, allowing access to information and monitoring of recovery. Communication between the treating HCP and patient is facilitated through a comments section in the management page. Communication between the treating and specialist HCPs is further facilitated in the management page, where the specialist HCP logs the decisions made and advice for the treating HCP. The management section also allows the specialist HCP to upload relevant documents or reports that the treating HCP is able to view. Resources for patients and HCPs are downloadable, and a customizable exercise dosage chart is also available for HCPs to download.

Figure 3. The *My Whiplash Navigator* wireframes overview.



Permissions

The website was built on a Web platform called Drupal, which is a proven, secure application framework that has role-based permissions system. A tiered permission system was used for the *My Whiplash Navigator*. First-tier included *administrators* (eg, researchers and research assistants) who were able to access all information on the website. Other tiers include *patients* and *HCPs*. Patients were tagged as belonging to a particular HCP. Only those HCPs with a tagged relationship with a patient were able to review all the data on that particular patient. No facility exists for them to access other patient data, except through aggregated and anonymized data reports. No patient is able to access another patient's data. The data are stored on a MySQL (Oracle Corporation) server cluster that is run by a secure Australian data center hosted in Sydney. The physical location for this server has 24/7 on-site security and is ISO27001:2005 certified.

Implementation

Implementation of the website took place primarily in NSW, QLD, and Australian Capital Territory from June 2016 to March 2018. A total of 260 HCP registrations were recorded (Table 2). The majority of the registrations were from NSW (214/260, 82.3%) followed by QLD (26/260, 10.0%).

A total of 65 primary HCPs registered on the website, with most registrations recorded following educational meetings (47/110, 42.7%). All specialist HCPs engaged through educational workshops registered on the website (20/20, 100%). The majority of the student HCPs registered on the website (175/215, 81.4%) following classroom education.

Table 2. Summary of registrations on the *My Whiplash Navigator* website.

Target group	Implementation strategy	Total approached, N	Total registered on the website, n (%)
Student HCP[a]	Classroom education	215	175 (81.4)
Primary HCP	Educational meeting	110	47 (42.7)
	Educational outreach and reminders	51	18 (35)
Specialist HCP	Educational workshops	20	20 (100)

[a]HCP: health care professional.

Table 3. Summary of the number and duration of page views for the *My Whiplash Navigator* website.

Page title	Unique page views, N	Average time (seconds)
Assessment of risk		
Health professional assessment of a whiplash injury	280	160.94
Prognosis: identifying people at risk of poor recovery	200	128.46
Provision of appropriate management for people at low risk of nonrecovery		
Whiplash information and exercises	339	145.48
Whiplash exercises	192	260.59
Helpful facts and advice	102	161.99
Provision of appropriate management for people at medium and high risk of nonrecovery		
Specialist assessment of whiplash	94	143.38
Specialist care for whiplash	84	66
Other frequently visited pages		
Whiplash Navigator steps	375	83.68
Managing whiplash in your patients	217	199.23
What is *Whiplash Navigator*?	169	91.7
FAQs[a] for patients	88	119.31

[a]FAQs: frequently asked questions.

The website pages most commonly viewed were related to risk assessment, exercises, and information about WAD (Table 3). There were 1229 times when users were actively engaged with the website. The majority of website engagement was from new visitors (858/1229, 69.81%), and 30.19% (371/1229) were returning visitors. The total page views of the website were 7508 views, of which 5027 were unique page views. Users view, on average, 6 pages during a visit and stay approximately 3 minutes on each page.

Evaluation

The website evaluation survey was administered after the implementation stage, between April and June 2018, and returned by 24 primary HCPs (24/65, 37%), 13 specialist HCPs (13/20, 65%), and 60 student HCPs (60/175, 34.3%).

Most HCPs agreed that the website was accessible, easy to navigate, and was a useful resource to assist in WAD management (Table 4). Posthoc analyses showed that there was no difference among students and primary and specialist HCPs regarding the acceptability of the website (Table 5). Most HCPs agreed that they would use the website in their clinical practice (82/97, 85%). Furthermore, the majority of the primary and specialist HCPs would recommend the use of suitable Web-based tools to other practitioners (32/37, 87%). The best features identified were accessibility of the website, simple interface promoting ease of use and navigation, and capacity to link people with WAD with HCPs. Many perceived that the website was comprehensive and provided a *one stop shop* for HCPs.

In contrast, features that needed improvement were initial navigation difficulties and complicated registration process. A few HCPs suggested potential limitation of the reach of the website for HCPs or people with WAD who do not have access to technology. Accordingly, HCPs identified a number of additional features and content to further improve the website. Some HCPs suggested adding more exercise and assessment videos that can be used to further assist patient care. Features such as a search bar, site navigator, and information for first time users would further enhance navigation. Finally, some HCPs wanted to be able to customize exercises and resubmit forms within the website to make monitoring progress and designing exercise programs easier.

Table 4. Perceptions of health care professionals about acceptability and self-rated improvement in knowledge of whiplash-associated disorder management after using the *My Whiplash Navigator* website (N=97).

Outcome	Strongly disagree/disagree, n (%)	Neutral, n (%)	Strongly agree/agree, n (%)
Acceptability of the website			
Easy to access screening tools	5 (5)	20 (21)	72 (74)
Easy to access outcome measures	3 (3)	21 (22)	73 (75)
Easy to navigate	1 (1)	28 (29)	68 (70)
Easy to understand	0 (0)	13 (13)	84 (87)
Useful resource for WAD[a]	0 (0)	11 (11)	86 (89)
Will use the website in clinical practice	1 (1)	14 (14)	82 (85)
Self-rated improvement in knowledge			
Risk assessment	0 (0)	18 (19)	79 (81)
Using the C-Spine rule[b]	1 (1)	14 (17)	69 (82)
Standard assessment[b]	1 (1)	12 (14)	71 (85)
Risk-based advice	0 (0)	18 (19)	79 (81)
Appropriate exercises	1 (1)	11 (11)	85 (88)
Referral of high-risk patients[b]	1 (1)	13 (16)	70 (83)

[a]WAD: whiplash-associated disorder.

[b]n=84.

Table 5. Posthoc analyses of differences among student, primary, and specialist health care professionals regarding acceptability and self-rated improvements in knowledge of whiplash-associated disorder management after using the *My Whiplash Navigator* website.

Outcome	Difference between groups[a], chi-square (df)	Significance, *P* value
Acceptability of the website		
Easy to access screening tools	4.2 (2)	.12
Easy to access outcome measures	1.8 (2)	.41
Easy to navigate	1.8 (2)	.41
Easy to understand	0.6 (2)	.74
Useful resource for WAD[b]	0.6 (2)	.71
Will use the website in clinical practice	1.0 (2)	.59
Self-rated improvement in knowledge		
Risk assessment	0.7 (2)	.67
Risk-based advice	0.0 (2)	.99
Appropriate exercises	0.6 (2)	.74

[a]Test statistic: Kruskal-Wallis test.

[b]whiplash-associated disorder.

Most HCPs agreed that the website helped them gain knowledge about key aspects of WAD management (Table 4). The highest self-rated improvement was around provision of appropriate exercises (85/97, 88%), whereas the lowest was in the identification of risk of nonrecovery and provision of risk-based advice (79/97, 81%). Similarly, the majority of the specialist HCPs agreed that the website assisted in gaining knowledge about management decisions for people with WAD at medium and high risk of nonrecovery (11/13, 85%). Posthoc analyses demonstrated that there was no difference among student, primary HCPs, and specialist HCPs regarding self-rated improvements in knowledge (Table 5). The majority of the primary and specialist HCPs agreed that the website facilitated communication between the primary health care provider and specialist (25/37, 68%).

In terms of actual practice, there were a total of 24 recorded management decisions logged by specialist HCPs on the website. The most commonly chosen pathway decision was shared care (15/24, 63%). Provision of specialist care was chosen by specialist HCPs in 33% of the decisions logged (8/24), mainly

because the people with WAD that they saw did not have primary HCPs at the time of consultation.

Discussion

Principal Findings and Comparison With Previous Work

Results of this study demonstrate that the *My Whiplash Navigator* is innovative, practical to implement, acceptable, and assisted in improving knowledge and practice of HCPs in WAD management. The rigorous process of development, implementation, and evaluation involving extensive consultations among stakeholders has led to the first Web-based tool for WAD that puts together comprehensive, evidence-based resources, automated risk assessment, and risk-based management. Stakeholder consultation from the outset is key in research translation [31,51], and incorporating the suggestions of each target market during idea generation and feasibility supported uptake and acceptability of the website. These results demonstrate that the *My Whiplash Navigator* may be scaled for wider implementation.

Most of the development and implementation strategies used for this website have succeeded in engaging the target markets and can be used in a future wider implementation program. Known implementation strategies such as classroom education [52,53] and educational meetings [14,16,32] used to improve practice in other conditions were also effective in engaging HCPs to use the website. Incorporating the website as part of assessable educational content further enhanced implementation, given higher uptake among student HCPs compared with primary HCPs. Second, an effective and efficient way to facilitate website use among people with WAD might be through primary HCPs and insurers. Compared with the fast-paced, high-stress environment in hospital emergency departments [54], the typical clinical encounter and the therapeutic relationship between people with WAD and their primary HCPs (Griffin et al, under review) would more likely assist in engaging people with WAD to use the website. Primary HCPs are also the first point of contact of people with WAD, with general practitioners consulted as early as 4 days and physiotherapists at 3 weeks after injury [8]. Finally, insurance regulators are equally in a position to engage people with WAD because most people who get injured from motor vehicle crashes in NSW and QLD submit claims after the accident to access benefits under the CTP insurance scheme.

Results also showed that implementation of the website improved HCP knowledge and practice across the health service delivery spectrum (ie, from novice to experienced HCPs) that could potentially improve outcomes for people with WAD. Preliminary efficacy demonstrated that the website improved self-rated knowledge of HCPs about key aspects of WAD management, specifically, self-rated knowledge of risk assessment and provision of risk-based advice. Although previous studies have shown that it has been difficult to improve knowledge on risk assessment among primary HCPs [14,16,32], use of the website appeared to support the delivery and implementation of these key messages. Similarly, use of the website appeared to improve actual practice of specialist HCPs through the promotion of a shared care approach in managing people with WAD at medium and high risk of nonrecovery. This is in contrast to the results of a previous study where the same group of specialist HCPs preferred to provide direct treatment (60%) over shared care (22%) [43]. A shared care approach in management was perceived by primary HCPs to facilitate the referral process and recovery for people with WAD [43]. The strategies used to engage specialist HCPs along with the interactivity of the website may have contributed to the improvements in practice observed.

Next Steps

The positive results related to the feasibility and preliminary efficacy of the website demonstrated the potential for broader uptake and implementation. Results further identified website content and features that need to be improved before more widespread implementation. The next process in translation would be that of replicability and scalability [31]. Replicability involves testing whether the website could deliver the same outcomes in other circumstances. Ideally, the aim is to implement the website in other states in Australia to test its application for WAD in different motor accident CTP insurance schemes. In addition, implementation of the website could involve other key target markets such as people with WAD, the insurance industry, and HCPs from other disciplines involved in WAD management (eg, chiropractors, osteopaths, and general practitioners). Finally, the suggestions from HCPs to incorporate additional features such as search or navigator bar and access to outcome measures would be considered to facilitate easier navigation and better clinical decision making.

Limitations

The response rate for the idea generation survey among HCPs was low; however, the survey was meant to be exploratory to supplement the other processes used during the development stage of the website. Despite a low response rate, the responses received from HCPs captured divergent opinions allowing us to understand the needs and expectations related to resources to assist HCPs in WAD management. People with WAD were not included in the implementation and evaluation stage, mostly because access to the website was limited to patients enrolled in a concurrent randomized controlled trial (RCT) [20] that the website supports. However, before this work, people with WAD were extensively involved in the development of the patient version of the WAD guidelines, education and exercise videos, factsheets, and booklets for people with WAD. These resources formed the patient section of the website. Implementation and evaluation of the website among people with WAD will be conducted and reported on after completion of the RCT.

Conclusions

In summary, a robust process resulted in an innovative, interactive, user-friendly website, the *My Whiplash Navigator*. Implementation with HCPs was best achieved through classroom education and educational meetings. Evaluation suggested that the website was acceptable and improved knowledge and practice of HCPs in WAD management. These positive results provide sufficient evidence to scale implementation nationally

and involve other target markets such as people with WAD, insurers, and insurance regulators.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group discussion questions for health care professionals during the idea generation process of website development.
[PDF File (Adobe PDF File), 63KB - formative_v3i3e12216_app1.pdf]

Multimedia Appendix 2
Summary of themes, codes, and illustrative quotes from the focus group discussions.
[PDF File (Adobe PDF File), 63KB - formative_v3i3e12216_app2.pdf]

Multimedia Appendix 3
Design features, content, and functionality of key pages of the *My Whiplash Navigator* website.
[PDF File (Adobe PDF File), 489KB - formative_v3i3e12216_app3.pdf]

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Abbreviations

CPR: clinical prediction rule
CTP: compulsory third party
HCP: health care professional
NSW: New South Wales
QLD: Queensland
RCT: randomized controlled trial
WAD: whiplash-associated disorder

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Original Paper

Use of Smartphone-Based Video Directly Observed Therapy (vDOT) in Tuberculosis Care: Single-Arm, Prospective Feasibility Study

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Abstract

Background: India accounts for nearly one-quarter of the global tuberculosis (TB) burden. Directly observed treatment (DOT) through in-person observation is recommended in India, although implementation has been heterogeneous due largely to resource limitations. Video DOT (vDOT) is a novel, smartphone-based approach that allows for remote treatment monitoring through patient-recorded videos. Prior studies in high-income, low disease burden settings, such as the United States, have shown vDOT to be feasible, although little is known about the role it may play in resource-limited, high-burden settings.

Objective: The goal of the research was to assess the feasibility and acceptability of vDOT for adherence monitoring within a resource-limited, high TB burden setting of India.

Methods: We conducted a prospective, single-arm, pilot implementation of vDOT in Pune, India. Outcome measures included adherence (proportion of prescribed doses observed by video) and verifiable fraction (proportion of prescribed doses observed by video or verbally confirmed with the patient following an incomplete/unverifiable video submission). vDOT acceptability among patients was assessed using a posttreatment survey.

Results: A total of 25 patients enrolled. The median number of weeks on vDOT was 13 (interquartile range [IQR] 11-16). Median adherence was 74% (IQR 62%-84%), and median verifiable fraction was 86% (IQR 74%-98%). More than 90% of patients reported recording and uploading videos without difficulty.

Conclusions: We have demonstrated that vDOT may be a feasible and acceptable approach to TB treatment monitoring in India. Our work expands the evidence base around vDOT by being one of the first efforts to evaluate vDOT within a resource-limited, high TB burden setting. To our knowledge, this is the first reported use of vDOT in India.

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KEYWORDS

Video DOT; mHealth; tuberculosis; medication adherence; telemedicine; India; mobile phone; smartphone

Introduction

Globally, tuberculosis (TB) is the leading cause of infectious disease-related mortality, responsible for 1.6 million deaths annually [1]. The incidence of TB is higher in India than anywhere in the world, with roughly 2.8 million cases reported in 2017, nearly 27% of the global TB burden [1]. To achieve positive treatment outcomes, adherence to TB therapy is critical [2,3]. However, socioeconomic and health system barriers in India are common and negatively impact adherence [4-6]. Failure to complete treatment can lead to relapse and the emergence of multidrug-resistant TB (MDR-TB), resulting in further disease transmission.

The World Health Organization (WHO) encourages the tailored use of multidimensional adherence interventions, including social, material, and psychological support, and emphasizes monitoring through directly observed treatment (DOT) [7]. Compared with self-administered therapy, those managed with DOT have demonstrated an improved rate of treatment completion [7,8]. Completion of therapy is vital not only for the patient but also the community, as public health efforts to mitigate disease spread require treatment success.

Unfortunately, DOT is often burdensome for patients and, paradoxically, can have a negative impact on adherence for some [9]. In India, DOT has historically been largely clinic-based (although there are differences in the public and private sector), wherein patients are required to bear the financial and logistical burden of frequent travel to and from the clinic for treatment monitoring. In doing so, patients risk lost wages due to time away from work. Additionally, providers must record and dispense daily treatments, a process that can be onerous and prohibitive in resource-constrained settings. While DOT is formally recommended under the current TB treatment guidelines set forth by India's Revised National Tuberculosis Control Program (RNTCP), in practice, DOT implementation (ie, observing and documenting each prescribed dose) in the community is inconsistent, and associated barriers can lead to treatment default [10-15].

More recently, video directly observed therapy (vDOT) has been introduced as a patient-centered alternative to in-person DOT, with pill ingestion monitored remotely via digital video capture. vDOT has been implemented using synchronous technologies [16-19] such as Skype and FaceTime as well as asynchronous technologies [20,21], where recorded videos are uploaded and digitally stored for future review. This latter method allows for video capture to occur at times convenient for the patient and eliminates the need for vDOT to be scheduled around staff availability. Recent work has shown asynchronous vDOT to be feasible, well received by patients and providers, and associated with high rates of treatment adherence [20-27]. Further, two economic evaluations in the United States have suggested vDOT to be cost effective over in-person DOT [20,27]. These encouraging findings have led both the US Centers for Disease Control and Prevention and WHO to suggest vDOT as a viable alternative to in-person DOT [28-30].

While data on vDOT are becoming increasingly robust, vDOT has yet to be rigorously evaluated within low- and middle-income countries of high disease burden such as India. Despite resource constraints, cellular technology has spread rapidly through India. As of 2017, there were a recorded 1.2 billion cellular connections and 291.6 million smartphone users within the country, suggesting that vDOT may have a role in this setting [31,32]. Additionally, recent changes to RNTCP guidelines have prioritized daily therapy (ie, 7 days per week) over three-times-per-week therapy, a change that further questions the feasibility of in-person DOT within a system already stretched thin and underscores the need for alternative approaches to adherence monitoring and support [14,33,34].

To address this critical knowledge gap, we conducted a prospective pilot of vDOT in Pune, India. Specifically, we addressed the feasibility and acceptability of vDOT within this resource-limited setting of high disease burden.

Methods

Overview

We conducted a prospective, single-arm, pilot implementation of vDOT in Pune, India. The mobile app emocha vDOT (emocha Mobile Health Inc) was used for treatment monitoring and adherence support (Figure 1). The patient-facing portion of the platform (ie, the mobile app) allows patients to record and transmit treatment videos. The interface also prompts patients to report any medication-related side effects (by checking off relevant symptoms from a prepopulated list). Through a calendar function, patients are able to review treatment progress and track adherence. Use of the software requires a camera-enabled tablet or smartphone device with at least intermittent access to Wi-Fi or cellular data. The app supports both Android and iOS operating systems. The provider portion of the platform can be accessed on a desktop, laptop, tablet, or smartphone (using a mobile browser) and is used by medical staff to review treatment videos. Providers are notified of any patient-reported treatment side effects. Given the system's asynchronous nature, submitted videos can be reviewed at any time following digital capture and transmission.

The emocha app is compliant with US Health Insurance Portability and Accountability Act (HIPAA) regulations and allows for asynchronous vDOT (Figure 2). Video capture occurs via the app. In the event that the device loses internet service or does not have access to internet service during video capture or upload, the videos (or any untransmitted component) remain encrypted on the device; all videos are uploaded automatically to secure servers when connection is restored (Wi-Fi or cellular data). Following transmission, videos are automatically wiped from the smartphone memory. Encrypted patient data, therefore, remain within the device only for the period between video capture and Web upload. Providers are able to access uploaded data via a secure Web interface through which they review submitted videos and track treatment progress.

The study was conducted at the Dr DY Patil Medical College Center and took place between January 2017 and June 2018. Study procedures were approved by the local institutional ethics committee and the institutional review board at Johns Hopkins University in Baltimore, Maryland.

Figure 1. The patient-facing portion of the emocha video directly observed therapy mobile app allows patients to record and transmit treatment videos, report any medication-related side effects, and review treatment progress and track adherence. The provider portion of the platform can be used by medical staff to review treatment videos and accessed from multiple devices.

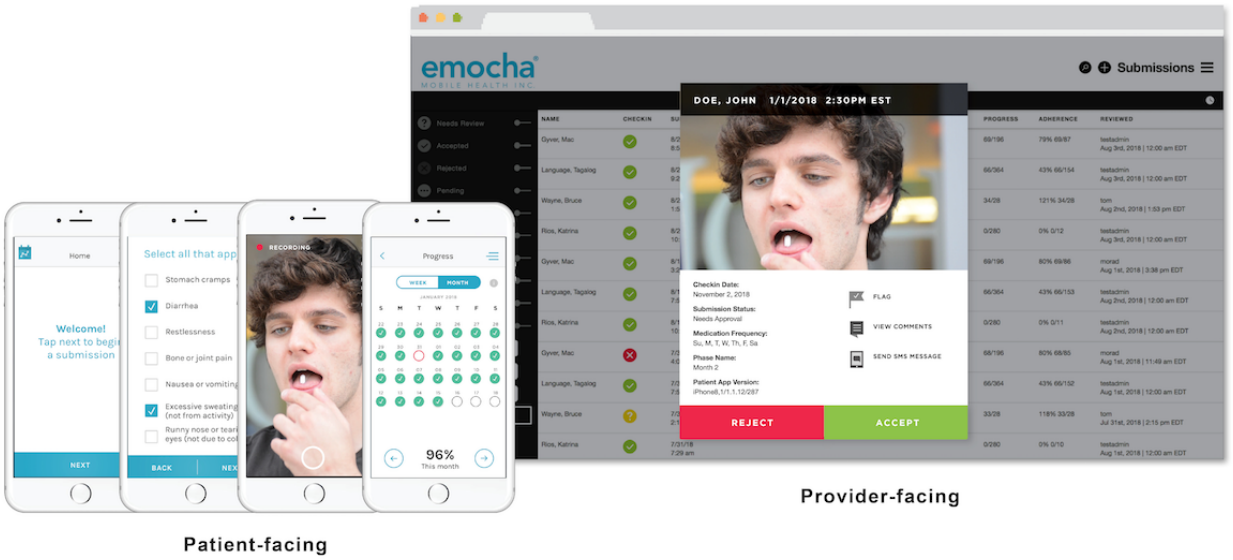
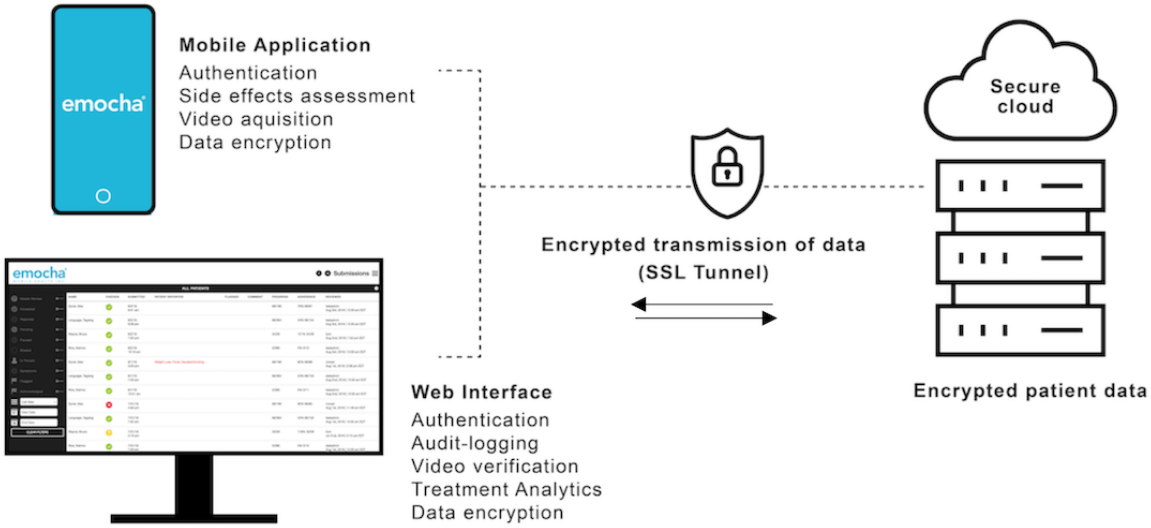


Figure 2. Data flow and security with the emocha video directly observed therapy mobile app.



Participants

Dr DY Patil Medical College Hospital is a private hospital that contains a government (public) TB treatment center (directly observed treatment, short-course, or DOTS center) as a public-private mix initiative. Patients diagnosed with or treated for TB at either Dr DY Patil or local DOTS centers were eligible for the study. Inclusion required age >18 years, signed informed consent, and >2 remaining months of TB therapy. Patients with MDR disease and HIV were excluded. Given this was a pilot study, we enrolled a convenience sample. Some patients were approached at the time of diagnosis, although many were assessed for eligibility midtreatment. Those not participating in the study received treatment and observation as per the local standard of care. Local guidelines recommend DOT for all intensive phase doses and for at least one dose per week during the continuation phase [14], although implementation is heterogenous and largely determined by local resources and patient preference (oral communication, T Sahasrabudhe, MD, November 2018).

Prior to enrollment, patients were required to establish basic smartphone proficiency and demonstrate the ability to successfully navigate the emocha app. A version of emocha translated into Marathi (the primary local language) was available to those with limited English. Patients without access to a smartphone were provided one by the study. Regardless of the device used, each participant was provided Rs 200 (US $3) each month to cover the cost of video submissions and a one-time incentive payment of Rs 100 (US $1.50) to cover travel expenses.

Study Procedures

A total of 35 patients were selected for this study based on a convenience sampling method. All patients provided written informed consent and were permitted to withdraw from the study at any time. Demographic information including

participant medical history and TB diagnosis were collected using a standardized case report form. Data were subsequently entered into a digital database by study staff. During their first study visit, participants were introduced to vDOT by a study staff member who provided each with a unique username and password and conducted a step-by-step tutorial outlining the process for how to create and submit a treatment video. Patients were then observed as they attempted to submit a dummy video independently. Additional training was provided on an as-needed basis.

Prior to formal enrollment, patients underwent a conditional 1-week run-in period, during which they were closely monitored for their continued ability to successfully record and submit videos. Any technical or logistical barriers arising during this period were addressed prior to formal study enrollment, which was only able to occur following successful completion of this trial period. For those enrolled, vDOT continued through treatment completion or until consent was withdrawn. Text message reminders via the emocha app were automatically sent to patients in the absence of expected video submissions. All incomplete or unverifiable videos (eg, medication could not be seen or video did not transmit due to network issue) were followed up with a staff phone call to verbally verify whether the dose was taken.

Feasibility

Feasibility was assessed by two primary outcomes. The first was treatment adherence, or the proportion of all prescribed treatment doses directly observed by video. As noted above, incomplete or unverifiable videos were followed up with a phone call for verbal verification. As such, a second metric, verifiable fraction, was used to describe the proportion of all prescribed doses that were either directly observed (by video) or verbally confirmed (following incomplete/unverifiable videos). All data analysis was completed in Stata 14 (StataCorp LLC).

Acceptability

To assess vDOT acceptability among patients, a posttreatment survey was administered comprising a series of categorical and Likert scale questions addressing issues such as mobile phone and internet access, emocha ease of use, convenience, and privacy. To increase our understanding of potential implementation barriers, patients were also informally asked to comment on their experiences and highlight any challenges or concerns they had related to the use of vDOT. Patient responses were noted by study staff at the time of survey administration. Staff were also asked to comment on patient-level barriers observed during the study.

Results

Study Participants

Of 35 patients who were consented and initiated the run-in phase (Figure 3), 10 did not complete the run-in and left the study. Reasons for run-in failure were related to technological (eg, inability to effectively use platform or poor cellular/Wi-Fi connectivity) and psychosocial (eg, concerns regarding privacy) barriers. Twenty-five patients were ultimately enrolled and formally initiated on vDOT with emocha. There was no study drop out, and all 25 patients completed therapy on vDOT.

Patient characteristics are described in Table 1. The median age was 27 (interquartile range [IQR] 24-42) years, 40% (10/25) were female, and 72% (18/25) reported their local language as Marathi. Most patients were low income with a monthly income less than Rs 16,000 (US $225). The majority of patients (22/25, 88%) had access to a smartphone and the internet. Three patients (3/25, 12%) required the use of a study phone. Almost three-quarters (18/25, 72%) of patients had pulmonary TB, and the remainder (07/25, 28%) had extrapulmonary disease.

Figure 3. Study flow diagram. vDOT: video directly observed therapy.

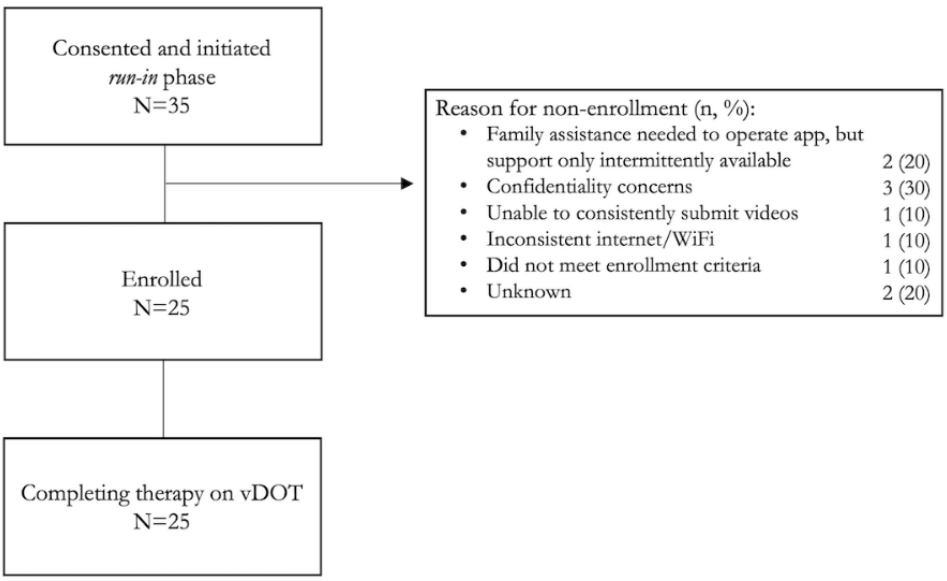


Table 1. Patient and disease characteristics (n=25).

Variable	Value
Age, year (median, IQR[a])	27 (24-42)
Female, n (%)	10 (40)
Indian state of origin, n (%)	
Maharashtra	18 (72)
Haryana	2 (8)
Karnataka	1 (4)
Tamil Nadu	1 (4)
Other	3 (12)
Primary language, n (%)	
Marathi	18 (72)
Hindi	6 (24)
Kannada	1 (4)
Employed, n (%)	10 (40)
Average monthly income (Rs), n (%)	
<2000	6 (24)
2000-4000	0 (0)
4000-8000	6 (24)
8000-16,000	13 (52)
>16,000	0 (0)
Homeless, n (%)	1 (4)
Residence, n (%)	
Urban	21 (84)
Rural	4 (16)
Married, n (%)	13 (52)
Primary mode of transportation, n (%)	
Private vehicle	0 (0)
Bus/train	0 (0)
Auto-rickshaw	8 (32)
Other private transportation	17 (68)
Substance use, n (%)[b]	
Alcohol	1 (4)
Tobacco use	0 (0)
Illicit drug use	0 (0)
Medical comorbidities, n (%)[b]	
Diabetes	3 (12)
Hypertension	1 (4)
Cancer	0 (0)
Technology, n (%)	
Regular access to a smartphone	22 (88)
Daily access to Wi-Fi or cellular data	22 (88)
Used personal device for study	22 (88)

Variable	Value
Tuberculosis category, n (%)	
Pulmonary[c]	
Smear positive	14 (56)
Smear negative	4 (16)
Exclusively extrapulmonary	7 (28)

[a]IQR: interquartile range.

[b]Categories not mutually exclusive, each out of 25 total participants.

[c]Pulmonary disease with or without extrapulmonary involvement.

The majority of patients were initiated on vDOT during the continuation phase (20/25, 80%), with 20% (5/25) beginning during the intensive phase. The median number of weeks on vDOT was 13 (IQR 11-16), with a range of 9 to 23 weeks (Table 2). A total of 80% (20/25) of patients received daily (7 times per week) therapy, while 20% (5/25) received an intermittent (3 times per week) regimen. No in-person DOT was documented either before or after implementation of vDOT. Overall, 60% (15/25) of patients reported at least one treatment-related side effect. The most commonly reported symptoms were nausea/vomiting (8/15), abdominal pain (3/15), and itching (2/15).

Table 2. Video directly observed therapy outcomes and data utilization (n=25).

Variable	Value
Adherence[a] (%), median (IQR[b])	74 (62-84)
Verifiable fraction[c] (%), median (IQR)	86 (74-98)
Dosing frequency, n (%)	
3 times per week DOT[d]	5 (20)
7 times per week DOT	20 (80)
Treatment phase at enrollment, n (%)	
Intensive	5 (20)
Continuation	20 (80)
Number of weeks on vDOT[e], median (IQR)	13 (11-16)
Total uploaded videos[f] (n)	1722
Mean uploads per patient, mean (SD)	91 (53)
Number of rejected videos per patient	
Mean (SD)	1.6 (2.4)
Range	0-8
Video length (seconds), median (IQR)	44 (31-52)
Video size (MB), median (IQR)	1.5 (1.1-1.7)

[a]Proportion of total prescribed doses completed under video observation. Of note, no in-person directly observed therapy was noted either before or after the implementation of video directly observed therapy.

[b]IQR: interquartile range.

[c]Proportion of total prescribed doses verified by any means, including successful observation by video upload and verbal dose confirmation (by phone or in person) following the submission of an incomplete or poor quality video.

[d]DOT: directly observed therapy.

[e]vDOT: video directly observed therapy.

[f]Total video (accepted + rejected + run-in phase) uploads across all patients over the length of the study.

Feasibility

Median adherence on vDOT was 74% (IQR 62%-84%, Table 2). After including verbally verified doses (following unverifiable or incomplete videos), the median verifiable fraction was 86% (IQR 74%-98%). An average of 91 (SD 53) videos were submitted per patient. The average number of rejected videos per patient was 1.6 (SD 2.4), with 56% (14/25) having no rejected videos at all. The most common reasons for video rejection were poor quality of video and medication not

fully seen. The median video length was 44 (IQR 31-52) seconds and associated with a median file size of 1.5 (IQR 1.1-1.7) MB.

Acceptability

A total of 22 posttreatment surveys were completed; 3 patients declined participation. Study outcomes for those declining involvement were similar to those of the general study population; each patient completed >14 weeks on vDOT with an adherence >70%.

A total of 91% (20/22) of surveyed patients described emocha as easy to use (Table 3). All patients (22/22, 100%) reported being able to record videos without difficulty, 95% (21/22) were able to upload without difficulty, and 91% (20/22) found text message reminders helpful. Further, all found they were able to communicate concerns and medication side effects effectively through the emocha platform. The majority felt vDOT would be more convenient (20/22, 91%) and preferred (20/22, 91%) over in-person DOT (Table 4). While 82% (18/22) felt vDOT would preserve patient privacy over in-person DOT, 18% (4/22) disagreed and felt in-person DOT would be more private.

Table 3. Responses from patient agreeability survey (n=22).

Survey statements (rated on a 5-point Likert scale)	Agree[a] n (%)	Disagree[b] n (%)
emocha was easy to use	20 (91)	2 (9)
I was able to record videos without difficulty	22 (100)	0 (0)
I was able to upload videos without difficulty	21 (95)	1 (5)
emocha text message reminders were helpful	20 (91)	2 (9)
I was able to communicate concerns and side effects using emocha effectively	22 (100)	0 (0)

[a]Agree/strongly agree were grouped.

[b]Neutral/disagree/strongly disagree were grouped.

Table 4. Responses from patient preference survey (n=22).

Survey statements (categorical)	Value, n (%)
Videos were most often uploaded using	
Wi-Fi at the clinic	0 (0)
Wi-Fi at home or other location	0 (0)
Cellular data (3G/4G)	22 (100)
Which better preserves patient privacy?[a]	
vDOT[b]	18 (82)
In-person DOT[c]	4 (18)
No preference	0 (0)
Which is more convenient?[a]	
vDOT	20 (91)
In-person DOT	2 (9)
No preference	0 (0)
Preference for therapeutic monitoring[a]	
vDOT	20 (91)
In-person DOT	2 (9)
No preference	0 (0)

[a]In-person directly observed therapy (DOT), either prior to enrollment or while on video directly observed therapy (vDOT), was inconsistently performed and/or documented based on chart reviews. Answers referring to in-person DOT are therefore based on patient perceptions of what in-person DOT would be like.

[b]vDOT: video directly observed therapy.

[c]DOT: directly observed therapy.

Study coordinator notes were reviewed and summarized in Table 5. Broadly, these notes revealed patient-level barriers impacting the successful implementation and use of vDOT. Included were psychosocial factors, such as the privacy concerns and stigma, and mental health barriers. Despite survey data suggesting that most were able to record and upload videos without issue, poor

connectivity and cellphone-related challenges (eg, subscriber identity module [SIM] card malfunction) were noted in a few cases.

Table 5. Patient-level barriers to successful video directly observed therapy use as identified by study staff.

Barrier to vDOT[a] use	Representative patient quotes and/or problem details
Psychosocial	
Stigma	"Recently one of my close relatives expired. As you know, we need to be at home to complete all the rituals up to 15 days after death. All the relatives are there, around all the time, and it became difficult to go out as well. So I could not take videos. Otherwise they would have started asking. Due to that, sometimes I missed my medicines."
Hospital admission	One patient suffered from severe alcohol dependence. The patient was successful on vDOT for a period but later admitted for detoxification. The patient's phone was confiscated at the time of admission, leaving him unable to upload videos during his hospital stay.
Stress	"My 1-year-old son fell from the bed and his hand got fractured. He was unwell, so we were under stress. I took tablets but during that time, I did not record videos."
Technology-related	
Connectivity	"I went to my village for 8 days for some work. As we do not have range and connectivity to the internet, I could not send videos."
vDOT-related challenges	"The registration process is a bit complicated and time-consuming. Can it be simplified?"
	"The [vDOT] app got hanged in my mobile. I did not know how to reinstall it. So I could not send videos."
	"When [recording a] video, if I get a call, the application used to suddenly shut down. So the video [would get lost]."
SIM[b] card	"I did not submit Know Your Customer documents required for SIM verification. Hence my SIM card was deactivated for some time...I was not able to send videos."

[a]vDOT: video directly observed therapy.

[b]SIM: subscriber identity module.

Discussion

Principal Findings

Our pilot study suggests that vDOT may be a feasible option for verification of medication adherence for TB patients in India. Among enrolled participants who completed a short run-in period to assess technological literacy, we found that a median 74% of all prescribed doses were observed. Further, when including doses verbally confirmed (following incomplete video submissions), the proportion of verified doses (verifiable fraction) increased to 86% (based on 1722 submitted and reviewed videos), exceeding the adherence goal of >80% set forth by current treatment guidelines [28]. This degree of adherence is comparable to that described using vDOT in other settings, such as the United States, and advances current evidence supporting vDOT, as prior work has largely focused on implementation within resource-rich settings [16,20,27,35]. To the best of our knowledge, this is the first reported use of vDOT in India.

Our demonstration of vDOT feasibility within the Indian context is both timely and critical given the recent RNTCP guideline changes emphasizing the need for daily over intermittent (3 times per week) therapy [14,33,34]. While a DOTS strategy, based on the principle of direct treatment observation, has been in place in India for over two decades, in practice, DOT implementation has been inconsistent.

In Pune, our experience has been that patients are often provided medication weekly or biweekly, with adherence monitoring largely based on self-report. At best, clinic services, including in-person DOT, are generally available 6 days per week, permitting a maximum of only 85% of prescribed (daily) doses to be observed. In contrast, by decoupling video capture from provider review, asynchronous vDOT potentially allows for all (100%) doses to be observed and obviates the need to coordinate DOT around staff availability.

To successfully and sustainably implement DOT in India, alternatives to in-person DOT are clearly needed. vDOT has the potential to be this alternative and to fill the needed gap. Our study is among the first in a resource-limited setting to demonstrate that daily therapy can be confirmed through the use of innovative mobile technologies. vDOT saves health care worker time and obviates the need for in-person visits to observe treatment [22]. For settings where home visits are employed solely for DOT, vDOT may reduce costs and save time even further [18,20,27,36,37]. vDOT may also have other previously unrecognized benefits related to infection control. Provisions for personal protective equipment (ie, masks for health care workers) or environmental controls (isolation rooms) are limited in India; vDOT offers a mechanism to closely monitor patients while reducing potential transmission opportunities. Additionally, we observed that patients derived benefit from avoiding frequent clinic visits, for which associated travel leads to lost time and, often, wages. Most importantly, vDOT provides solid evidence of treatment adherence. Our study also highlights

a need for patient training (eg, run-in period with onboarding to the technology), counseling, and follow up in cases of missed doses to assure successful treatment completion.

Of note, India has already endorsed another electronic form of treatment monitoring, 99DOTS: when a patient removes a pill from a blister pack, a number is revealed that completes a toll-free phone number printed on the pack, which the patient then calls to report having taken daily medication [12,33]. While 99DOTS may be a feasible means for basic adherence monitoring [38], vDOT has the distinct advantage of providing video confirmation of pill ingestion. It is also important to consider that the use of vDOT allows for adherence support in addition to adherence tracking. The platform used in this study captures side effects and TB symptoms, and videos can also be used to notify providers of treatment concerns, such as rashes, which can be preliminarily evaluated from afar through submitted videos. Moreover, the current platform allows automated messaging reminders, which patients reported to be a benefit. Newer versions of the software offer secure chat functionality (with health care providers) and case management tools that may further support treatment adherence. India recently rolled out a direct benefits transfer scheme that encourages treatment adherence through the use of financial incentives (Rs 500 per month while on therapy) [39,40]. 99DOTS is currently being used as a mechanism to monitor treatment adherence, but it is limited. For the reasons noted above, a more reliable tamper-proof means of adherence monitoring would be beneficial.

Limitations and Strengths

While our work supports further evaluation of vDOT within India, we acknowledge several study limitations. First, our sample size was small and, while we have shown vDOT to be feasible in one location, its acceptability and feasibility in other parts of India remain unknown. Second, we were unable to compare adherence on vDOT to that under the existing standard of care, which at our site was primarily self-administration (thus precluding documentation of prestudy adherence). Our findings, however, suggest that vDOT implementation could substantially improve adherence documentation compared with current practice. Through broader implementation, vDOT has the potential to enable enhanced accountability among TB clinics with regard to treatment adherence. Improvements in documentation would also increase the availability of high-quality data on TB treatment completion for public health reporting practices. Whether vDOT is associated with improved patient outcomes compared with standard of care is still unknown and was not assessed within the scope of this pilot study.

We also acknowledge a significant attrition over the course of our run-in period. One-third of those who consented did not ultimately participate in the study. Drop out during this period was largely driven by technological barriers related to infrastructure (eg, inconsistent cellular coverage) or inability/unease with smartphone operation. Further, despite the fact that we used a HIPAA-compliant app (emocha) with stringent security controls, several participants withdrew consent over privacy concerns. Some patients noted a fear that their treatment videos might end up publicly viewable on the internet. While cellphone technology has spread rapidly across India, cellular coverage remains incomplete and not all have become immediately facile with the technology. With time, these barriers may diminish. A strength of our study was the use of a run-in period, which was advantageous in that it allowed for rapid identification of those with sufficient mobile phone literacy to be candidates for vDOT. In our study, all those who completed the run-in period and enrolled in the study successfully finished therapy on vDOT.

Conclusions

Despite its promise, there remain questions regarding vDOT that must be addressed. Larger controlled and comparative trials will be needed to better evaluate the effectiveness of vDOT against the current standard of care or alternative technologies in resource-limited, high disease burden settings. Future studies addressing cost and cost effectiveness are also needed. Last, in other settings such as the United States, vDOT has successfully been coupled with individualized case management to allow real-time intervention after missed doses; the role of this approach in India is unknown [20]. Overall, our work has shown that despite socioeconomic and structural barriers, vDOT may be a feasible approach for treatment monitoring in India.

Acknowledgments

We would like thank all those working hard to provide quality clinical care at the Dr DY Patil Medical College Center and the local DOTS centers throughout Pune. In particular, we thank Dr Madhusudan Barthwal, Dr Shailesh Meshram, and Dr Sudhir Dahitankar. We would also like to thank the team at emocha Mobile Health Inc for providing technical support and leadership throughout the study. Specifically, we would like to thank Sebastian Seiguer, JD, MBA, Katrina Rios, and Gorkem Sevic, MSE.

Authors' Contributions

MS created the study concept and design. SA, SBH, SA, DJ, TS, SM, MB, and AK were responsible for the acquisition of data and SA and SBH for statistical analyses. SBH, MS, SA, and TS performed data interpretation. SA and SBH drafted the initial manuscript, and all authors participated in manuscript revision.

Conflicts of Interest

MS is one of the inventors of the miDOT technology. Under a license agreement between emocha Mobile Health Inc and Johns Hopkins University, MS and the university are entitled to royalties on technology described in this article. This arrangement has

been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. To mitigate any potential conflicts of interest, all clinical decision making regarding use of miDOT or enrollment in the study was made by nonconflicted department of health clinicians and staff; MS recused himself from all data analysis but assisted with results interpretation.

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Abbreviations

DOT: directly observed treatment
DOTS: directly observed treatment, short-course
HIPAA: Health Insurance Portability and Accountability Act
IQR: interquartile range
MDR-TB: multidrug-resistant tuberculosis
RNTCP: Revised National Tuberculosis Control Program
SIM: subscriber identity module
TB: tuberculosis
vDOT: video directly observed therapy

WHO: World Health Organization

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Original Paper

Developing a Digital Solution for Dengue Through Epihack: Qualitative Evaluation Study of a Five-Day Health Hackathon in Sri Lanka

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Abstract

Background: Dengue is a mosquito-borne viral disease that has increasingly affected Sri Lanka in recent years. To address this issue, dengue surveillance through increasingly prevalent digital surveillance applications has been suggested for use by health authorities and the general public. Epihack Sri Lanka was a 5-day hackathon event organized to develop a digital dengue surveillance tool.

Objective: The goal of the research was to examine the effectiveness of a collaborative hackathon that brought together information technology (IT) and health experts from around the globe to develop a solution to the dengue pandemic in Sri Lanka.

Methods: Ethnographic observation and qualitative informal interviews were conducted with 58 attendees from 11 countries over the 5-day Epihack to identify the main factors that influence a collaborative hackathon. Interviews were transcribed and coded based on grounded theory.

Results: Three major themes were identified during the Epihack Sri Lanka event: engagement, communication, and current disease environment. Unlike other hackathons, Epihack had no winners or prizes and was collaborative rather than competitive, which worked well in formulating a variety of ideas and bringing together volunteers with a sense of civic duty to improve public health. Having health and IT experts work together concurrently was received positively and considered highly beneficial to the development of the product. Participants were overall very satisfied with the event, although they thought it could have been longer. Communication issues and cultural differences were observed but continued to decrease as the event progressed. This was found to be extremely important to the efficiency of the event, which highlighted the benefit of team-bonding exercises. Bringing expert knowledge and examples of systems from around the world benefited the creation of new ideas. However, developing a system that can adapt and cater to the local disease environment is important in successfully developing the concepts.

Conclusions: Epihack Sri Lanka was successful in bringing together health and IT experts to develop a digital solution for dengue surveillance. The collaborative format achieved a variety of fruitful ideas and may lead to more hackathons working in this way in the future. Good communication, participant engagement, and stakeholder interest with adaptation of ideas to complement the current environment are vital to achieve the goals of the event.

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KEYWORDS

Epihack; civic engagement; dengue; digital epidemiology; participatory surveillance; participatory epidemiology; participatory design; workshop

Introduction

Dengue is a mosquito-borne viral disease that globally affects an estimated 390 million people each year [1]. In 2013, dengue was estimated to be responsible for 1.14 million disability-adjusted life years (DALYs) worldwide [2].

Situated in the tropics, Sri Lanka has an elevated risk of dengue endemics because mosquitoes thrive in warm, humid areas [3]. The severity of dengue in Sri Lanka has been increasing over the years. In 2010, 2012, 2014, 2016, and 2017, there were 34,188, 44,461, 47,502, 55,150, and 186,101 reported cases, respectively [4]. In the first half of 2017, the number of dengue cases was 4.3 times higher than the typical number of dengue cases for the same time period in previous years, leading to 215 deaths, with capital city Colombo having the most reported cases [5]. This may have resulted from the heavy rain and flooding that affected Sri Lanka, as well as the many construction developments that are underway in the rapidly changing urban landscape of Colombo.

A potential method to reduce dengue is to monitor the disease through surveillance by tracking the number of cases and investigating the outbreak source, and then tracing and eliminating the potential mosquito breeding grounds that could spread the disease [5]. However, health authorities are struggling to monitor and control the spread of the disease using their outdated and time-consuming paper-based systems [6].

To address this, Nanyang Technological University (NTU), Singapore, developed an integrated digital surveillance tool called Mo-Buzz to target dengue in the Colombo region. The application was made available to the local health authorities to integrate predictive surveillance, dengue hotspot mapping, civic engagement, and health education through social media. The health inspectors who would normally use paper-based forms to input potential breeding sites and paper maps to pinpoint dengue hotspots were able to report through the system, reducing reporting time considerably. A similar Mo-Buzz application was piloted with the general public to encourage reporting of potential breeding sites to the health authorities and educate them on how to prevent the spread of dengue. However, although Mo-Buzz was successful with Colombo health authorities, uptake of the application was not fully operationalized with the general public. The application had also become dated having been launched in 2013 and needed upgrading, both conceptually and technologically [7].

To make the Mo-Buzz applications contemporary and more effective, the research term organized a 5-day hackathon event, Epihack Sri Lanka, in Colombo in November 2017 with funding received from Skoll Global Threats Fund. Local and international information technology (IT) and health experts participated in Epihack Sri Lanka to improve capacities and capabilities of the existing applications. They collectively brainstormed, shared expert information and experiences, and guided each other in stimulating vibrant discussions to create prototyped digital tools to prevent the spread of dengue.

Typically, requirements to develop a health application are compiled by health experts and given to IT experts to develop independently with no additional input from the health professionals until an early prototype has been created. Due to the collaborative nature of Epihack, experts in both IT and health fields work together to mutually collaborate on the application, ensuring that requirements of the health experts are met in conjunction with the capabilities of the IT professionals. This allows for instant updates of any issues that arise.

The main aim of Epihack Sri Lanka was to develop a cutting-edge participatory reporting tool by building on the existing features of Mo-Buzz. The goal was to implement prevention strategies to battle dengue, bridge communication gaps in dengue control, and achieve effective communication between health authorities and the public.

Epihack Sri Lanka was the first of its kind in Sri Lanka and had the uniqueness of bringing together experts from different fields (health communication, doctors, information technology, etc) to develop a digital health solution in a collaborative manner rather than the usual competitive hackathon format. Little research has been done to observe what works and what can be improved in an event such as this, and, therefore, the objective of this paper was to examine the effectiveness and value of a 5-day Epihack workshop based on grounded theory approach, through field observations and qualitative interviews with the attendees of the event.

Methods

Data Collection: Sample and Procedures

This research was conducted among Epihack Sri Lanka attendees, and ethical approval was obtained from the university's review board. Participants were observed in their area of work in ethnographic format and qualitatively interviewed in an informal manner to gather their experiences and opinion of the event during the 5-day period. The interviews were audio recorded to ensure descriptive validity, and observations and themes were noted.

Participants

A total of 58 facilitators and participants (16 women) from 11 countries attended Epihack Sri Lanka; 22 attendees were health experts, and 36 were IT experts. The event consisted of participants from Sri Lanka, India, Pakistan, United States, Albania, Laos, Thailand, Singapore, Australia, Belgium, and Cambodia; 16% had taken part in a previous Epihack. Participants included 7 international health facilitators, 5 international and 8 local health participants, 4 international and 4 local IT facilitators, and 3 international and 27 local participants.

Participants included industry technological experts and epidemiologists from the epidemiological units in Colombo and local hospitals. In addition, participants consisted of public health inspectors; faculty and computer science students from NTU, University of Colombo School of Computing, and the Computer Society of Sri Lanka; and representatives from the Ministry of Health and Colombo Municipal Council.

Interview Guide

A basic interview guide containing a set of open-ended questions was prepared in English so we could understand the interviewee, the type of work they are involved in, and how that work impacts (if it does) health communication. Respondents were asked to take part in the informal interview and after we received their consent, they were briefed about the interview and its purpose. Interviews were guided by the following themes: general questions about the interviewee and their work, the reason for their participation in such an event, and the benefits of having an event like this.

The average duration of conversations was 15 to 20 minutes; conversations were moderated by an experienced researcher. During the interview sessions, the researcher often summarized and clarified the answers that were vague. The researcher also encouraged the participants to verify the summarized statements before moving to the next question. Interview sessions were documented with audio recordings and were later transcribed.

Qualitative Analysis

Transcripts were coded line by line based on grounded theory, a data analysis process that starts with the collection of data that is interpreted and developed into themes and explanatory theory. The analysis process consists of steps such as "coding data; developing, checking, and integrating theoretical categories; and writing analytic narratives throughout inquiry" [8]. Codes were further elaborated as new themes developed during the coding procedure. The key purpose of the research was to uncover crucial factors that work best and what needs improvement in an event such as this.

Epihack Format

The 5-day Epihack event was held November 6-10, 2017, in Colombo. The experts took on the roles of facilitators and participants to share information, experiences, and guide teams during discussions to stimulate vibrant conversations and formulate best practices.

Daily Schedule of Events

Day 1 of the event consisted of an introduction to the dengue problem within Sri Lanka and examples of various digital health surveillance solutions that have been implemented around the world to educate facilitators and participants about the challenges at hand. Talks covered topics such as global dengue prevention methods, current dengue issues facing Colombo, and existing applications such as Mo-Buzz. As the talks were predominantly health-based with focus on educating those who were not aware of the problems, a brainstorming session was organized—particularly for IT participants—to clarify information presented to them on the current dengue issues.

Day 2 entailed visiting dengue hotspots around Colombo. Three groups were each taken to two sites that have had high levels of dengue outbreaks such as construction sites, temples, parks, and schools to interview the locals and view the area. The aims of the field trips were to observe mosquito breeding sites and collect information from the site staff members or individuals to get a clearer picture of the dengue situation.

The goals of the field trips can be encapsulated into two main questions:

- What do they have (ie, what problems is the site currently facing and what current dengue prevention systems are in place)?
- What do they need (ie, what are the problems with the existing dengue systems and how feasible are their ideas to improve the situation)?

A mini discussion session was organized to share information gathered from the field trips, where each group presented their findings and brainstormed the issues and requirements at hand. Both health and IT experts contributed to the conversation to ensure that the requirements were valid and the technology was achievable. Possible work topics were also discussed during the session.

Days 3 and 4 consisted of amalgamating ideas and creating groups consisting of IT and health experts to develop the chosen work topics. First, facilitators met to discuss, categorize, and divide the project into 5 achievable subprojects or modules. Then one IT and one health facilitator were assigned to each group based on their expertise. This is different from usual hackathons where groups are typically created before ideas are defined due to the more collaborative nature of the event. The subprojects were then presented to the whole team, which was asked to select the group they wanted to work in, and ideas were explored further. Work topics that formed were all different facets of the same surveillance system to prevent similar ideas being redeveloped. Groups then began working on their ideas which included the following:

- Developing a database for public health officials
- Developing a framework for work management and visualization for public health officials and other stakeholders
- Creating a centralized database to consolidate all of the various information from different sources into one dashboard
- Creating educational content to educate construction workers, schools, and the general public

Each group consisted of approximately 12 members, of which approximately 8 people were IT experts. Throughout the two days, each group presented their ideas to the attendees at regular intervals to gather opinions, ideas, and potential issues from the other groups. The groups worked closely together throughout the process to ensure that each facet was developed in parallel with ideas that could be incorporated with the others.

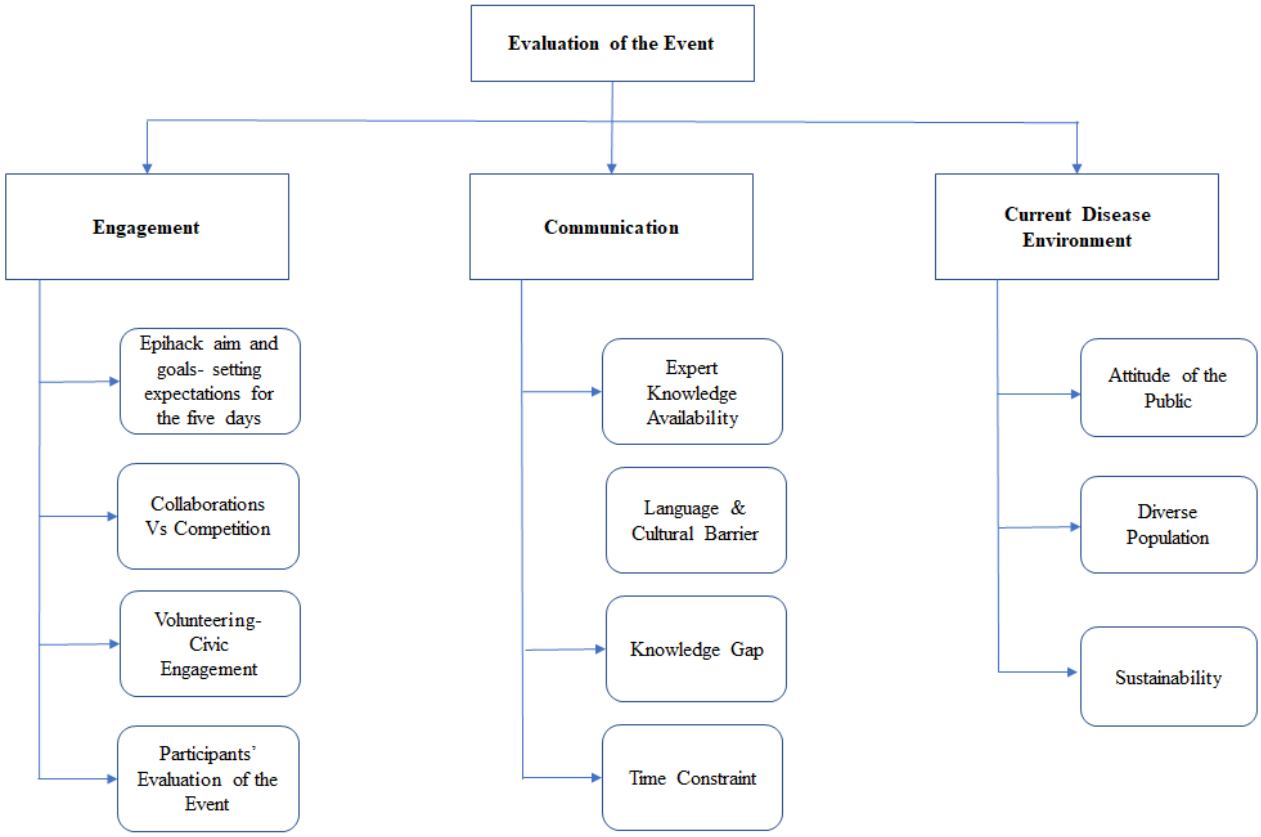
Day 5 of the event involved each group presenting the developed ideas to invited guests and VIPs.

Results

Major Factors

The main aim of the study was to uncover the major factors that contributed to the effectiveness and value of the 5-day Epihack workshop. Three main themes were identified: engagement, communication, and environment (Figure 1).

Figure 1. Themes and subthemes identified during the Epihack from qualitative interviews and observations.



Engagement

Epihack Aim and Goals: Setting Expectations for the Five Days

Leading up to the event, a skilled Epihack organizer with experience in coordinating previous Epihacks assisted in the organization of this event. Facilitators were selected based on expertise, experience, and leadership qualities, with many facilitators having attended previous Epihacks. All facilitators were required to complete online training in Epihack facilitation before the event and attend pre-event meetings to ensure they were prepared to guide participants. During Epihack Sri Lanka, organizers and facilitators explained the aim and goals of the event to participants with examples from previous Epihacks conducted in other countries to clarify the nature of the event to participants.

One of the Epihack Sri Lanka organizers stated that the Epihack aimed to create a platform for effective communication and collaboration. The local health facilitators and health participants were encouraged to consider how to convey their needs in an understandable way to the IT experts to prevent a communication gap on the expected outcome.

A facilitator mentioned that "The future is not to work hard but to work smart," and another facilitator added "The wheel has already been invented, but we want to make it faster." They explained that the idea of an event such as Epihack Sri Lanka was to understand what had been previously done around the world, learn what had worked and had not worked, and borrow ideas and strategies used by previous teams rather than spending time on redeveloping the same ideas. Although the organizing team addressed the fact that it is difficult to come up with a perfect solution, they stressed that only by endeavoring and working together in this way to eradicate the disease can there be a step toward positive change: "It is one step closer to a perfect solution."

Even though Epihack Sri Lanka was considered a hackathon, which traditionally focus on technology, it also welcomed nontechnology solutions. The primary goal was to create and brainstorm any ideas that could be possible solutions for reducing the spread of dengue.

Collaboration Versus Competition

The Epihack organizers and facilitators believe that Epihack works better if it is executed in a collaborative format instead of a competitive format. One of the facilitators suggested that competition and collaboration were needed in equal amounts for a workshop like this to work:

> *Collaboration and competition go hand in hand—they create team spirit and camaraderie. You need competition between the groups, so [that] the team gets more cohesion and self-identity to compete with the other team. It differentiates your team from the other. On the other hand, you are collaborating not on an individual level but at a team level; after you create the team identity, then at the next stage you start collaborating between the teams. It is a two-level logical approach. Collaboration and competition are not exclusive to one another. For this kind of event, you need both. You motivate the teams, one of the*

> *means is to say "Look, the other guys are doing better, we need to show [we can do better] ourselves." It will put more morale into the team; it also makes the team more cohesive. So, people get to work with each other [everyone becomes a team player], as they have this common goal to compete with other teams. On the other hand, you are collaborating with other teams as each team depends on the other teams to get input and each team's output is going as input to the other teams. So, you need to be very careful keeping a balance between the teams. The process is interconnected like an instrument [in an orchestra]. Each instrument plays its music, but all combined make the orchestra. You need to have the diligence of the orchestra.* [Facilitator]

One of the organizers mentioned that when she was getting participants to go and eat, one participant told her to give him five more minutes as he was finishing a task for another team so that they could start their work.

Volunteering: Civic Engagement

The Epihack core team believe that all the local and international facilitators and participants needed to volunteer their time to take part in the event:

> *People who come to do this volunteer their time to do so. We don't pay anything because we need people who think it is for a good cause.* [Organizer]

One international facilitator mentioned that he came down to take part in the hackathon mainly because of his altruistic attitude. He felt he had done something good for society:

> *...it feels good, even though my feeling good goes along with creating something good for the society. On the other hand, I learn and develop a life experience which you don't get in other settings.* [International facilitator]

He continued:

> *...participants and facilitators benefit from each other, the health participants get to learn technical stuff from the IT facilitators and participants, and, on the other hand, IT facilitators and participants get to learn health issues, possible solutions, etc. Additionally, participants get to learn from the local colleagues such as doctors. You understand the difficulties, you understand the setups, you understand the issues that are transposed to different sides of the world, [you may find] usable solutions: there are people everywhere.* [International facilitator]

Getting IT participants to volunteer for 5 days has been one of the toughest tasks in executing a collaborative Epihack event where there is no prize to be won in the end. Push notifications were sent out explaining the event details and inviting people working in IT sector to be part of the event. Even though the IT experts understood that it was an important cause and needed attention, they had busy schedules, previously committed deliveries, and deadlines. Potential participants were informed that Epihack Sri Lanka was an intensive 5-day workshop and that it was mandatory to participate in the full event, which put limits on the number of people who could take part in an event like this. However, it was the first event of its kind in Sri Lanka, making it a unique opportunity. Being a pioneering event, some IT participants could not gauge the event with the information provided at the time of registration. One of Epihack Sri Lanka organizers mentioned that getting IT experts to volunteer their time continued to be a major challenge in conducting Epihacks and therefore recruitment was ongoing until close to the event date. This was one of the reasons for the organizers not getting the complete profile and capabilities of the IT participants until the last minute, as they were the last group to be recruited to the event. However, when participants realized that their active participation and contribution could create a solution for the severe dengue problem in Sri Lanka, it boosted their involvement.

Participant Evaluation of the Event

After the event, attendees were briefly interviewed to gauge their opinion on the proceedings. Half of the participants thought that the event was an appropriate length and the majority of attendees were somewhat satisfied or extremely satisfied with the overall event:

> *I think that Epihack really showed attendees that many public health problems can be meaningfully engaged when there is a platform for interdisciplinary communication among professionals from multiple fields.* [Health expert]

However, some respondents believed the event could have been longer to support further development of the application, and 45% of respondents felt that the information given to them before their arrival at the event was not sufficient. Reasons for this include: "too short", "didn't have a much clear idea about what's happening in 5 days. The target outcome and rough project ideas could have been shared with the event...with discussions" and there could have been "more explanation as to the agenda and details of what the hack entailed."

The issues should be noted and improved for future Epihacks, with more information being given before the event to help attendees form a clearer picture of the event.

Communication

Expert Knowledge Availability

The workshop brought experts from different parts of the world together for 5 days and created an environment where the international experts could assist and collaborate with the local team to come up with better solutions for solving a health problem. The international experts brought knowledge, expertise, and lessons learned from previous workshops and similar projects they had been part of in different countries. So, when ideas were proposed, they were able to give suggestions based on their previous experience of whether something would work or not. At the same time, experts also understood that each country had its own unique problems, but solutions could be found from other countries. "Adapt and apply" was one of techniques that was used here.

Language and Cultural Barriers

As the event consisted of an international group of people of varying ages and expertise, researchers identified certain gaps in communication during the event. During the first day of the event, language was one of the barriers as different people have different accents and ways of communicating their ideas. As the days progressed, participants got more acquainted with each other and this barrier drastically dropped. Fortunately, English is an official language of Sri Lanka and is spoken well by the majority of local people; therefore, it could be used as the working language for the event. This has not been the case in other Epihacks, where working in English was difficult as locals tended to revert to their local language, which made it difficult to work with international participants. Language was not the only barrier identified:

> *Some people are shy, everyone has an opinion but when you mix the group, they don't want to tell, or sometimes they don't get to tell. When there are many high-ranking people who attend, local junior people don't want to speak.* [Facilitator]

As day 2 progressed, the imagined power-distance dropped, and participants and facilitators started talking to each other more freely. Even the student participants who had never worked before were working well with professionals and lecturers.

The research team noticed, however, that an informal hierarchy was perceived or practiced by the participants with white males at the top, followed by white females, local males, and females in that order. This perceived hierarchy and small number of female IT professionals on the team seemed to restrict them putting forth their viewpoints to the entire group.

Sri Lanka has a laid-back culture and people from various countries may have different working styles (preference to work alone, work in the morning or late at night, etc). As this was an event that ran on tight schedule, participants found it a bit rushed during the first couple of days. But they managed to put aside their preferences and come in on time as the event demanded their commitment.

Knowledge Gap

In an ideal world, the client would know what they want. However, in Epihack Sri Lanka the health team knew their disease burden and problem, but they didn't have the solution to help them fix the disease situation. This is where an event like Epihack can be a platform for health authorities to collaborate with international experts to discuss ideas and solutions from around the world and see if any could be adapted and applied in Sri Lanka. The event also brings together local health experts who do not usually get the time to talk to each other about the health and disease problems they handle. Officers from different areas of Colombo might face different problems (eg, dealing with more wealthy or commercial areas). While interacting with the local health experts, the research team also noticed that some offices were well equipped, but some others were not as well maintained.

There is another kind of knowledge gap that exists between the IT experts and health experts. The workshop was planned in such a way that the health facilitators would lead the first 2 days of the discussion, informing the IT team of the problems and challenges, and clarifying any queries from the IT team. It was mentioned that 2 days is very small amount of time to understand all the procedures and workflows; at the same time, the 2 days were conducted mostly in lecture style rather than group discussion format, which some of the IT people found overwhelming. However, the main goal was to let the developing teams understand critical problems and find ideas that can help to ease the disease burden. The whole idea of Epihack is to bring together multidisciplinary teams who never usually interact so that different angles can be used to see the big picture.

One of the IT facilitators mentioned that he preferred to use "bottom up approach, not top down approach" to bridge requirement and knowledge gaps. He explained further that this approach helps them to find the missing element in the whole system. Once they know the missing elements, it is easier to put the pieces together. The method helps them to formulate an action-oriented plan.

Time Constraint

After 2 days of discussion and brainstorming sessions between IT and health professionals, the IT facilitators and participants had 48 hours to create a tangible prototype of the proposed solution. The amount of time was so limited that the focus was to get all the ideas in and create a quick prototype, which could later be expanded to a workable solution. IT experts opined that it would take another 4 to 6 months of work for the prototype to be converted into a full-fledged working application. However, the health team experts were impressed by the amazing amount of effort that the IT team had put together in just 2 days in creating a prototype:

> *I would add an extra day and night of hacking in order to allow our participants more time in polishing up the prototypes developed.* [Participant]

Current Disease Environment

A doctor explained the current disease environment with the following quote.:

> *Dengue is a complicated problem, we can't pin point to what are the things we want.* [Local health facilitator, doctor]

Public Attitude

Currently, even if the public is aware of the dengue situation and how to reduce the spread, they do not necessarily follow dengue prevention methods. Civic engagement in preventing the spread would reduce the amount of time and work required from public health inspectors (PHIs). Presently, the PHIs must go from house to house doing inspections. PHIs are also bombarded with other problems such as garbage collection, which should be handled by the sanitation department. They are put in a situation where they feel that they are required to follow up on all the complaints as they need to keep a good relationship and good reputation with the public. Solutions suggested by the participants were to get the public involved in the process, make them feel empowered, and show them the value of their actions to make them feel like they are part of the dengue control activity group.

Diverse Population

As the public consists of a diverse group of people, such as people from different education backgrounds and migrant workers from China who don't follow the Sinhala language but work in highly dengue prone areas, it is important to think about the target audience, the purpose of the application, and the ways to get people to use the application. As one of the local doctors said, many members of the public don't even know "[basic] information and knowledge, like what the normal temperature is or what the color of blood is," suggesting that people in the capital belong to diverse population.

Sustainability

A few types of sustainability issues were identified during the workshop that will need local support and groundwork to keep the project running. One of the health experts mentioned that local stakeholders must be the ones to sustain the product as they know their environment:

> *The application is not the challenge; it is the social and government support that will be critical for a project like this.* [Health expert]

They believe that this project should be outlined as a social responsibility project, and the work needs to be continued after the workshop:

> *How to get the tools is difficult, but how to maintain and continue working with the tool is most difficult.* [Health expert]

Factors such as manpower and finding skilled collaborations also affect sustainability.

After the Epihack, another team will have to develop this prototype into a workable solution, and there needs to be continuous communication and collaboration between the hackathon participants and the solution developers for the process to be smooth. During the last day, the work done and ideas created during the hackathon were showcased to stakeholders, government representatives, and the media. Support from key stakeholders would go a long way in fruitful completion of the project.

Another important thing to consider is to get public attention and get them to use the app to report mosquito breeding sites. Campaigns, celebrity endorsements, gamifications, and social media presences were a few of the ideas that were developed as part of the brainstorming process.

Discussion

Principal Findings

An Epihack is a civic engagement–based health hackathon that brings different field experts and participants together from all over the world to work on health problems. Previous Epihacks focused on several health problems usually led by health experts such as epidemiologists, and the solutions created have been developed further and put to use to control the disease burden [9]. The current Epihack was the first ever Epihack to be led by health communication experts.

The main aim of Epihack Sri Lanka was to create a platform to reduce the health burden of an increasingly prevalent infectious disease through multidisciplinary teamwork. This was attempted through proper training and pre-event meetings to ensure that the facilitators were prepared to guide the participants. Epihack is unique in its format, as it is a collaborative event and not a competitive one. There was no winning team per se; the groups assisted one another to make the workshop successful. The culmination of ideas led to each group developing a facet of a larger digital health system. We observed many advantages to this type of hackathon format. It creates an environment where groups feel that they can share ideas and develop them further with each other rather than feel the need to hide their concepts from each other. Each group was able to work with others on different parts of a single system rather than producing and developing similar overlapping ideas. The realization that other teams were waiting for their inputs made each team speed up their work. It was clear that the concept of team-bonding was effective, because they were working toward one common goal rather than individual goals. The collaborative format may also be a potential method for other hackathons. In the future, this experience may lead to more hackathons working in this way, leading to a greater variety of ideas being produced.

Getting IT participants to volunteer was one of the major challenges that the organizers faced before the event. Better planning before the event can help in handling this challenge. From participants' feedback, we learned that more information needs to be given to the IT developers before the event so they can prepare better for the event.

The broad range of expert knowledge availability from different disciplines is one of the major advantages of the event and should be used to the maximum for idea development and implementation. However, it is crucial to understanding the level of knowledge of the attendees for a collaborative event that brings participants from different fields and expertise. Language and cultural barriers are also facets that need to be taken into consideration while preparing for an event, especially when the event consists of participants from diverse international backgrounds. This is to reduce communication issues and increase the effectiveness of the event. As the workshop is tightly planned, the organizers should also be aware of time constraints for developing and incorporating all ideas during the workshop and they should make sure attendees are aware of the limitation in development time.

Locals need to be completely invested in the event as they will be the key players after the Epihack is executed. During Epihack Sri Lanka, international participants were able to encourage the local participants with their ideas and experiences. After the end of 5 days, local participants from Sri Lanka created a Facebook page to keep in touch with all the other participants. This shows that the collectivist team mentality created a bond over the event period.

During disease outbreaks, when there is a time crunch, stakeholders may rush to produce an application or a solution in very little time and without much knowledge. This makes the application a part of a checklist rather than being a truly optimal solution for society's problem. Epihack could be a

potential way to help a community to get ideas and solutions within a small period of time, as it focuses on the creation of ideas to solve the disease problem rather than just quickly creating a prototype without much input from experts.

Sustainability is another key element that needs to be addressed as it will affect the work to be done after the Epihack. There are two kinds of sustainability concerns. First, the stakeholders need to get involved in the project to get proper funding and ground support. Second, public participation will be imperative when the mobile application goes public. So the team should be well prepared to motivate the public for continuous use of the application. In this paper, we identified the list of items that worked best as well as the items that could be improved. The list and our recommendations are provided in Multimedia Appendix 1.

Limitations

The total number of attendees for the event was less than 60, making this a study with a small participant pool. Future studies need to be planned to build on this knowledge from the workshop. By observing and interviewing more attendees of Epihack, a pattern of what works best can be developed and precisely streamlined.

Conclusion

Events such as Epihack are a great way to bridge gaps between different fields of work. Through qualitative interviews, the process was found to be largely positive and fruitful in the development of an integrated digital surveillance application. The application was developed by the local IT team from the system prototype created during the event and finished in Dec 2018. Frequent discussions with the stakeholders will ensure proper uptake of the application. Pilot testing and usability studies are scheduled to take place after the development phase. Future events such as these should focus on engaging attendees and being aware of communication issues within the workshop environment. The effectiveness of controlling dengue is linked to the number of dengue cases. There needs to be a long-term full commitment by the decision makers that can control and ensure the proper routine work flow of hotspot identification, insecticide use, fogging activities, patient management, enforcement of hotspot penalties, public cooperation, and disease surveillance with the assistance of technologies. From the success of this event, future hackathons may benefit by following this model.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Recommendations.
[PPTX File, 33KB - formative_v3i3e11555_app1.pptx]

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Abbreviations

DALY: disability-adjusted life year
IT: information technology
NTU: Nanyang Technological University
PHI: public health inspector

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Original Paper

Using Computer Tablets to Improve Moods for Older Adults With Dementia and Interactions With Their Caregivers: Pilot Intervention Study

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Abstract

Background: Persons living with dementia represent a significant and growing segment of the older adult (aged 65 years and older) population. They are often challenged expressively and may experience difficulties with sharing their feelings or moods. Availability of, and easy access to, tablets facilitates the use of information and communication technologies (ICTs) as a delivery mechanism for nonpharmacological interventions, especially for persons living with dementia. Evidence of the impact of ICTs in different community settings on mood with older adults and the impact of engagement on their caregivers is needed to promote broader adoption and sustainment of these technologies in the United States.

Objective: This study aimed to determine the extent of the effects of tablets on positive mood change and examine the effects of study variables on care recipients' mood changes and caregivers' daily interactions.

Methods: The tablet intervention was developed and evaluated in five programs. The primary outcome was caregivers' assessment of care recipients' mood (n=1089) before and after a tablet engagement session using an eight-point mood visual analog scale. Session influence on caregivers' daily activities was captured for a subsample of participants (n=542). Frequency distributions were computed for each study variables. Chi-square tests of association were calculated to determine the association of the variables on mood changes for all care recipients, as well as those being treated in skilled nursing facilities and in-home, and then for those that affected caregivers' daily activities.

Results: The study sample comprised 1089 care recipient and caregiver engagement sessions. Cumulatively, 50.78% (553/1089) of care recipients showed a transition from negative to positive moods, whereas another 41.78% (455/1089) maintained an already-positive mood after the caregiver engagement session. Chi-square analyses demonstrated that positive mood changes resulted from using music (χ^2_{10}=72.9; P<.001), using YouTube as the sole app (χ^2_{12}=64.5; P<.001), using multiple engagement strategies (χ^2_2=42.8; P<.001), and when cared for in a skilled nursing facility (χ^2_4=236.8; P<.001) across the entire care recipient sample. In addition, although many features of the engagement session positively influenced the caregivers' day, the largest effect was observed when care recipients' mood was considered to have improved following the session (χ^2_4=234.7; P<.001).

Conclusions: The study is one of the first in the United States to explore the impact of ICTs, in particular managed tablets and Web-based video services that can be used on a tablet through an app, on improving mood in persons living with dementia, and enhancing caregivers' perceptions about their care recipient interactions. Importantly, these pilot data substantiate ICTs as part of a personalized engagement approach, as beneficial alternatives to pharmaceutical interventions for mood enhancement. However, a more comprehensive study that explores the ICT's impact on additional clinical outcomes is needed to confirm these preliminary findings.

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KEYWORDS

mood change; caregiver interactions; older adults; Alzheimer disease; dementia; computer tablets; person-centered care

Introduction

Background

The number of people living with Alzheimer and related dementia is projected to triple by 2050 [1-3]. Persons living with dementia can have complex physical health concerns, comorbid medical conditions, and exhibit behavioral and psychological symptoms of dementia (BPSD) [4-11]. In fact, professional caregivers of persons living with dementia already note that responding to BPSD is one of the greatest care challenges and can negatively affect the health of caregivers [12-14] especially in long-term health care facilities, where two-thirds of residents have dementia [9,13,15,16]. Family caregivers of persons living with dementia are also are at risk for higher rates of depression, health and sleep issues, social isolation, and mortality [14,17].

Pharmacological or nonpharmacological interventions can help manage BPSD in older adults with moderate-to-severe cognitive impairment. Medications may control the physical aspects of BPSD but can have many side effects [18]. Nonpharmacological approaches, such as reminiscence therapy, music therapy, or behavior management techniques, are preferred because they sustain cognitive function, improve quality of life, and mitigate BPSD [19-25]. The growing number of persons living with dementia, overall care challenges, and the negative effects of pharmacological interventions combine to highlight the need, as well as the opportunity, for additional nonpharmacological interventions.

Availability of tablets and mobile phones has changed how nonpharmacological interventions can be delivered to older adults. Tablets can enhance residents' emotions through the use of multisensory activities. Individuals can now obtain informational content, interact socially (including participating in Web-based games), listen to music, or reminisce about the past or a recent special event. Easy access to information and communication technologies (ICTs) such as tablets facilitates the delivery of nonpharmacological interventions especially for persons living with dementia and their caregivers [26-28]. For persons living with dementia, ICTs such as YouTube, a Web-based video service, can be used to deliver reminiscence therapy interventions on a tablet through an app [29]. For these individuals, the use of ICTs mitigates motor and sensory impairments; compensates for memory deficits; or enhances latent skills and abilities for sensory awareness, musical responsiveness, and emotional memory [30,31]. Overall, the use of ICTs to deliver nonpharmacological interventions for persons living with dementia benefits care recipients' well-being and mood; communication and interactions; and caregivers' mental health (eg, depression and anxiety), self-efficacy, and relationship with the care recipient [26,28,29,32-39]. An additional benefit is the potential for persons living with dementia to remain in the home for as long as possible. This outcome is a widespread aspiration, with "Nearly 90 percent of people over age 65 [wanting] to stay in their homes for as long as possible" [40]. Therapeutic approaches that help persons living with dementia live at home longer also reduces overall health care costs [41].

Development of a Tablet Intervention

Although successful use of tablets originated and empirically documented about a decade ago in Great Britain, with investigations continuing into the present both in Europe and beyond [42-47], its adoption in the United States has been slow [34,48-55]. Two Great Britain studies offer a progressive look at how tablets can be applied to improve communications between persons living with dementia and their caregivers [56,57]. The first study compared a traditional reminiscence programs (noncomputer) with computerized touchscreen, one-on-one, reminiscence sessions and tested the hypothesis that caregivers offer greater choices and engage in more conversational activities during the touchscreen sessions than during the traditional one-on-one reminiscence sessions with physical properties [56]. After comparing the 2 types of sessions across both verbal and nonverbal parameters, such as laughter, singing, pointing, and eye gaze, the touchscreen system was shown to provide greater benefits for both caregivers and persons living with dementia. The second study was based on the central concept that "external memory aids have demonstrated a reduction in resistance to care..." [57], and using the iPad as the focus of joint attention not only relieves some of the burden of communication for caregivers but also provides the opportunity for the caregiver to support greater independence in persons living with dementia through scaffolding behavior.

The project described in this study extends this seminal international work to implement a tablet intervention using multiple device management and software apps in different community settings and document the effect on mood with older adults, as well as the impact of engagement on their caregivers. This manuscript reports aggregate findings from a pilot study evaluating the impact of personalized tablet engagement sessions. Four project aims represent the purpose of this study to examine study variables effects on mood changes in (1) the overall care recipient sample, (2) the subsample of care recipients being treated in skilled nursing facilities (SNFs), (3) care recipients in home care only, and (4) caregivers' daily activities.

Methods

Personalized Tablet Engagement

One of the primary advantages in using a tablet for engagement activities for persons living with dementia is the ability to personalize activities because every person has a unique lifetime of experiences. For this program, the term *personalized tablet engagement* reflects a tablet engagement session that is designed by a caregiver based on the personal history of the care recipient. The session is presented to the care recipient, who is given the

option of participating. In this way, tablet engagement is both based on an individual's interests, abilities, and preferences and allows the individual to exercise autonomy.

Study Settings

Since 2015, Generation Connect initiated partnerships to evaluate the effectiveness of tablet interventions in dyads of caregivers and persons living with dementia. The Music & Memory Foundation used tablet computers that were preconfigured with recommended apps, deployed with management software, and implemented with training resources created and facilitated by Generation Connect. These tablets allowed tailored interactions to residents' interests or hobbies to expedite engagement and enhance emotions through multisensory activities.

This study describes a naturalistic study in which the Music & Memory Foundation and a Visiting Angels in-home care agency franchise collaborated with Generation Connect to develop and conduct an ongoing tablet engagement pilot study involving 5 different programs across time (2017-2018). Multimedia Appendix 1 describes the 5 programs contributing the tablet engagement session data analyzed for this study.

Participants' Attributes

The intervention was designed to be useful for persons living with dementia, and all participating communities opted into the pilot study and self-selected the residents that participated, no standardized test was used to record non-normative memory loss. The sessions were not limited restricted to a dementia population and contained a variety of other conditions as well. However, participants' demographics beyond these primary challenges were not collected in the pilot programs.

Data Collection

Caregiver Training for Tablet Engagement Sessions

Caregivers were trained to gather personal history and take personal lifestyle into consideration when selecting the activities for care recipients. As a result, caregivers were better able to provide multisensory tablet engagement for specific and prior positive life events, such as reminiscing or listening to personal music. All training was conducted by members of Generation Connect in a series of live webinars, Web-based courses, and printable handouts. Instructors demonstrated apps and talked through best practices for meeting the engagement training elements of discovery, engagement, and planning, emphasizing that the engagement process is guided by care recipient needs (see Multimedia Appendix 2). The training process was dynamic and changed over the course of time as new information was gathered.

Engagement

Personalized Tablet Engagement

Many older adults are hesitant to interact with a device or computer but are comfortable watching videos. The caregiver's goal for engagement is to *make the tablet disappear* and provide an enjoyable personalized experience. The most successful engagement sessions reflect a *best friend* approach, and engagement is based on mentoring not care recipient mastery. This study did not provide official tracking of session frequencies or lengths.

Selection of Apps

This project was conceptualized over a number of years, based on supporting research at that time. As a result, apps available in the public domain (see Multimedia Appendix 3) were chosen because they represented at least 1 of 4 basic types of traditional activity-based engagement activities that evidence suggests can be beneficial for people with dementia: reminiscing, music, images, and games [58-63].

Engagement Session Feedback Survey

Data collection in the programs was to improve residents' socialization, personalized care, and mood management through nonpharmacological interventions and make the day better for caregivers. The short, 5-question survey was available in a Web app on the tablets' homepage for easy caregiver access (see Multimedia Appendix 4). Instructors demonstrated how to use the app survey to record session feedback information.

Mood Rating

Persons living with dementia are often challenged expressively and may experience difficulties with sharing their feelings or moods. A visual analog mood scale (VAMS) represents a valid tool to assess baseline and changes in mood, especially in those with expressive disabilities [48,52,55] and for dementia [64]. VAMS consists of a sequence of 8 faces (Figure 1) and was incorporated into the tablets used by Generation Connect. Caregivers reported changes in care recipient mood before and immediately after their tablet engagement activity.

For this analysis, individual moods were categorized into 2 domains: (1) negative moods (ie, angry, anxious, sad, confused, and indifferent) and (2) positive moods (ie, relaxed, happy, and joyful). *Indifference* was considered a negative mood because of its potential to adversely affect other aspects of the care recipients' functioning throughout the day, as well as influence caregivers' activities [65]. Mood changes were then categorized according to the mood assessed before the care recipient and caregiver engagement compared with the mood observed after engagement, resulting in 4 categories: worsening of mood (ie, transitions from positive to negative mood domains), maintaining negative mood (ie, changes remain within the negative mood domain), maintaining positive mood (ie, changes remain within the positive mood domain), or improvement of mood (ie, transitions from negative to positive mood domains).

Figure 1. Participants' mood rating scale.

Caregivers' Daily Activities

The impact of the sessions with older adults was captured for a subsample of caregivers across the 5 programs. Caregivers responded to the following question: how did the engagement session impact your day? Impact was rated using a 5-point scale anchored at 0 (made it worse), 3 (no impact), and 5 (made it better). Scale values for *2* and *4* had no assigned anchor label but were, in this analysis, assigned *slight worsening* and *slight improvement*, respectively.

Data Cleaning

All data were reviewed for accuracy and completeness. In addition, data cleaning and label standardization ensured response uniformity before analysis. Our team then reviewed and converted the variables into the following categories:

- Care recipients' primary physical challenge—memory loss, nonambulatory, movement disorder, communicative or expressive disorders, or other
- Method used for care recipient and caregiver engagement (either singularly or combined with other methods)—music, stories video, games, communication, photos, or other
- Type of strategy of care recipient and caregiver engagement (either singularly or combined with other strategies)—music, reminiscing, socialization, relaxation, or achievement
- Number of strategies used—either 1 or 2 or more
- Type of app used to facilitate strategies—YouTube only, Personal playlist only, Personal photos or videos only, Google only, Puzzles only, combination of apps, or other
- Number of apps used to facilitate strategies—either 1 or 2 or more

Facility type was self-reported as *skilled nursing*, *home care*, or *other* (which consist of Continuing Care Center, Assisted Living Facility, Long-Term Care Facility, and Veterans Hospital). Facility locations were classified as rural or urban using the US Department of Agriculture Rural-Urban Continuum Code, and for Canadian facilities, rural or urban status was determined through website search.

Statistical Analysis

Frequency distributions were computed for each of the study variables, including the type of care recipients' mood changes. All variables were collected as categorical and ranged from dichotomous, trichotomous, up to 6 categories. Chi-square tests of association were calculated to determine the influence of the variables on mood changes for all care recipients, as well as those being treated in SNFs and in-home, and then those that affected caregivers' daily activities.

Ethics Consideration

The project was determined to constitute quality improvement or program evaluation and in accordance with federal regulations, the project did not constitute research as defined under 45 Code of Federal Regulations 46.102(d).

Results

Posthoc Power Analysis

Posthoc power analysis for the chi-square tests demonstrated superior power for all analyses. The power levels calculated for

all 4 project aims conformed to Cohen's accepted standard of a four-to-one weighting between type II and type I error risks [66]. In addition, no significant chi-square results were associated with more than 33% of contingency table cells having expected counts of less than 5.

Descriptive Statistics

Frequencies were computed for each study variable and each of the analyzed samples (ie, full sample, SNFs only, and home care only), as shown in Multimedia Appendix 5, which also demonstrates a relatively unequal distribution of resident mood changes after use of the tablet.

Table 1 represents overall mood improvement after the use of the app technology among individuals with various disabilities and is further illustrated when examining frequencies within each of the mood change categories.

Table 1. Mood transitions for individuals.

Mood before session	Mood after session, n (%)							
	Angry	Anxious	Sad	Confused	Indifferent	Relaxed	Happy	Joyful
Angry (n=33)	2 (6)[a]	—[b]	—	—	—	2 (6)[c]	11 (33)[c]	18 (55)[c]
Anxious (n=52)	—	4 (8)[a]	2 (4)[a]	2 (4)[a]	4 (8)[a]	24 (46)[c]	11 (21)[c]	5 (10)[c]
Sad (n=64)	—	—	2 (3)[a]	1 (2)[a]	—	3 (5)[c]	30 (47)[c]	28 (44)[c]
Confused (n=70)	—	1 (1)[a]	—	3 (4)[a]	6 (9)[a]	29 (41)[c]	23 (33)[c]	8 (11.4)[c]
Indifferent (n=407)	1 (0.2)[a]	1 (0.2)[a]	—	7 (1.7)[a]	36 (8.9)[a]	91 (22.5)[c]	176 (43.2)[c]	95 (23.3)[c]
Relaxed (n=119)	—	—	—	1 (0.8)[d]	6 (5.0)[d]	28 (23.5)[e]	70 (58.8)[e]	14 (11.8)[e]
Happy (n=326)	—	—	—	—	—	7 (2.1)[e]	257 (78.8)[e]	62 (19.0)[e]
Joyful (n=18)	—	—	1 (6)[d]	—	—	—	5 (28)[e]	12 (67)[e]

[a]Not applicable as no care recipients transitioned to this mood from their beginning mood.

[b]Maintaining negative mood.

[c]Transition from negative to positive mood.

[d]Worsening of mood.

[e]Maintaining positive mood.

Worsening of Mood (Transition From Positive to Negative Mood Domains; n=8)

Any worsening of mood represented the mood change category with the fewest number of care recipients. One care recipient began an engagement session in a joyful mood but ended up confused after the tablet intervention, whereas another care recipient transitioned from relaxed to confused. The remaining 6 cases involved a transition from relaxed to indifferent.

Maintaining Negative Mood (n=72)

Within this category, 65% (47/72) of care recipients showed no mood change, and most (n=36) of these moods were viewed as indifference. The most frequent mood changes were found for transitions from indifferent to confused (n=7) and confused to indifferent (n=6).

Maintaining Positive Mood (n=455)

Within this category, 65.3% (297/455) of care recipients showed no mood change, and most (257/297, 86.5%) of these moods were viewed as happy. The most frequent mood transitions within the positive mood domain represented changes from relaxed to happy (n=70) and then from happy to joyful (n=62), and the most notable improvement was found for transitions from relaxed to joyful (n=14).

Improvement of Mood (Transition From Negative to Positive Mood Domains; n=553)

Two-thirds (362/553) of all care recipients began the sessions in an indifferent mood and then increased to relaxed (n=91), happy (n=176), or joyful (n=95). Furthermore, the proportion of care recipients achieving joyful mood after the session was noteworthy. Cumulatively, 21% of care recipients who began the session as either anxious (5/52) or confused (8/70) became joyful as a result of the session, whereas 44% (28/64) of care recipients who were sad ended the session in a joyful mood. Importantly, 18 of the 33 care recipients (58%) transitioned from being angry to being joyful, demonstrating the greatest movement possible within this mood category.

Chi-Square Analyses

Table 2 contains the frequencies for each study variable within the 4 separate mood change categories, which provides insight into the category of each variable that contributed to the mood effect.

Table 2. Chi-square comparisons of variables to mood change in full sample.

Variables	Mood change		
	Worse or maintaining negative mood (n=80), n (%)	Maintaining positive mood (n=455), n (%)	Mood improvement (n=553), n (%)
Primary challenge[a]			
Memory loss	61 (5.60)	424 (38.93)	300 (27.55)
Nonambulatory	6 (0.55)	6 (0.55)	93 (8.54)
Movement disorder	10 (0.92)	13 (1.19)	105 (9.64)
Communicative or expressive disorders	2 (0.18)	9 (0.83)	45 (4.13)
Other	1 (0.09)	4 (0.37)	10 (0.92)
Engagement method use (singularly or one of multiple)[b]			
Music	22 (2.3)	127 (13.4)	228 (24.1)
Stories video	12 (1.3)	101 (10.7)	86 (9.1)
Games	13 (1.4)	67 (7.1)	33 (3.5)
Communication	1 (0.1)	47 (5.0)	48 (5.1)
Photos	3 (0.3)	48 (5.1)	24 (2.5)
Other	6 (0.6)	21 (2.2	59 (6.2)
Type of strategies used[c]			
Music			
Singularly	15 (2.9)	89 (17.3)	95 (18.5)
One or more	26 (5.1)	81 (15.8)	207 (40.4)
Reminiscing			
Singularly	2 (0.7)	5 (1.6)	36 (11.8)
One or more	7 (2.3)	93 (30.6)	161 (53.0)
Socialization			
Singularly	9 (1.7)	119 (22.2)	58 (10.8)
One or more	15 (2.8)	129 (24.07)	206 (38.4)
Relaxation			
Singularly	2 (0.8)	4 (1.7)	7 (3.0)
One or more	21 (8.9)	60 (25.4)	142 (60.2)
Achievement			
Singularly	10 (4.0)	60 (23.9)	33 (13.1)
One or more	6 (2.4)	62 (24.7)	80 (31.9)
Number of strategies used[d]			
1	40 (3.75)	276 (25.89)	225 (21.11)
≥2	33 (3.10)	170 (15.95)	322 (30.21)
Type of app used for strategies[d]			
YouTube only	10 (0.94)	117 (10.98)	178 (16.70)
Personal Playlist only	36 (3.38)	115 (10.798)	157 (14.73)
Personal photos or videos only	0 (0.00)	35 (3.28)	41 (3.85)
Google only	3 (0.28)	53 (4.97)	35 (3.28)
Puzzles only	6 (0.56)	48 (4.50)	24 (2.25)
Combinations of apps	10 (0.94)	52 (4.88)	45 (4.22)

Variables	Mood change		
	Worse or maintaining negative mood (n=80), n (%)	Maintaining positive mood (n=455), n (%)	Mood improvement (n=553), n (%)
Other	11 (1.03)	27 (2.53)	63 (5.91)
Number of apps used for strategies[e]			
1	66 (6.20)	394 (37.00)	498 (46.76)
≥2	10 (0.94)	52 (4.88)	45 (4.23)
Urban or rural status[a]			
Rural	39 (3.58)	64 (5.88)	306 (28.10)
Urban	41 (3.76)	392 (36.00)	247 (22.68)
Facility type[a]			
Skilled nursing	28 (2.57)	42 (3.86)	303 (27.82)
Home care	46 (4.22)	393 (36.09)	227 (20.84)
Other	6 (0.55)	21 (1.93)	23 (2.11)

[a]Percentages for primary challenge in the chi-square analysis are based on a sample of 1089 care recipients. Differences as compared with the total sample is based on missing data, which were excluded from the chi-square analysis.

[b]Percentages for engagement method use in the chi-square analysis is based on a sample of 946 care recipients.

[c]Percentages for type of strategy used in the chi-square analysis varied based on the strategy. The sample sizes are music (n=513), reminiscing (n=304), socialization (n=506), relaxation (n=236), and achievement (n=251), respectively.

[d]Percentages for number of strategies used and the type of app used for the strategies in the chi-square analysis is based on a sample of 1066 care recipients.

[e]Percentages for number of apps used for strategies in the chi-square analysis is based on a sample of 1065 care recipients.

Project Aim 1: Analysis of Full Sample

Chi-square analyses of all care recipients were conducted to determine the extent that significant mood changes occurred for those receiving the intervention (n=1089). When examining the effects of the care recipients' primary health care challenges on their observed mood, memory loss was associated with maintaining positive mood (χ^2_8=191.5; *P*<.001). Engagement methods demonstrated some effect on care recipients' mood, with music being more likely involved in care recipients' improvements from negative to positive moods (χ^2_{10}=72.9; *P*<.001). Characteristics of the apps used to engage also influenced mood. When using YouTube as the sole app, care recipients' mood transitioned from negative to positive after the engagement sessions (χ^2_{12}=64.5; *P*<.001). Results also suggested that some strategies implemented to evoke mood changes were effective. Specifically, using music as a single method (χ^2_2=20.1; *P*<.001) or reminiscing (χ^2_2=9.9; *P*=.007) as a component of additional strategies was associated with maintenance of positive mood; socialization (χ^2_2=38.3; *P*<.001) and achievement (χ^2_2=12.9; *P*=.002), when used as a component, were related to care recipients having improved mood. These findings support the separate analysis showing that care recipients using multiple strategies were more likely to be associated with negative to positive mood transitions (χ^2_2=42.8; *P*<.001). Examining the influences of facility characteristics revealed that care recipient placement in an SNF was linked to changes from negative to positive moods following engagement (χ^2_4=236.8; *P*<.001), whereas placement in an urban setting was associated with maintaining positive mood (χ^2_2=186.4; *P*<.001).

Project Aim 2: Analysis of Care Recipients in Skilled Nursing Facilities

Subsample analyses were designed to reveal the effects of the study variables on mood changes for care recipients from SNFs only (n=373). Notably, fewer significant results emerged from this sample compared with either the full sample or the home care subsample analyses; however, these results demonstrated a consistent effect on mood. Engagement sessions involving reminiscing were more likely to facilitate care recipients' going from negative to positive moods as a result of the engagement sessions (χ^2_4=12.0; *P*=.02). Socialization, when used as a component of additional strategies, also was related to care recipients having positive mood changes (χ^2_2=11.0; *P*=.004). Overall, care recipients using multiple strategies were associated with improvements from negative to positive moods (χ^2_2=8.5; *P*=.014). This trend substantiates the finding derived from the full sample, employing 2 or more strategies is an effective approach for positive moods. Finally, engagement sessions occurring in SNFs operating in an urban setting was associated with maintaining positive mood (χ^2_2=18.4; *P*<.001).

Project Aim 3: Analysis of Care Recipients in Home Care

A subsample analysis also was conducted for care recipients involved only in in-home care (n=666). Care recipients with a

movement disorder as their primary challenge were associated with negative to positive mood changes as a result of the intervention (χ^2_2=115.7; *P*<.001). Engagement sessions involving music were more likely linked to care recipients' improvements from negative to positive moods (χ^2_{10}=112.7; *P*<.001). Furthermore, using combinations of strategies involving music was associated with mood improvement (χ^2_2=34.4; *P*<.001). The only other strategy achieving significance was the sole use of socialization, which was shown to maintain positive mood (χ^2_2=45.5; *P*<.001). Overall, although, any strategy used in combination with others was related to sustaining positive moods (χ^2_1=75.8; *P*<.001). When considering specific apps, Personal Playlist, as the sole app, was more likely to be associated with care recipients transitioning from negative to positive mood (χ^2_{12}=135.5; *P*<.001). Finally, home care occurring in urban settings was associated with care recipients sustaining positive mood as a result of the intervention (χ^2_2=57.5; *P*<.001).

Project Aim 4: Analysis of Caregivers' Daily Activities

A subsample of caregivers also rated the impact of the intervention on their day (n=542). When care recipients had a movement disorder, the engagement session made the day better for caregivers (χ^2_2=10.1; *P*=.006). Music, when used singularly, slightly improved the caregiver's day (χ^2_2=17.2; *P*<.001), whereas socialization as a component of other interventions made the day better for the caregiver (χ^2_2=37.2; *P*<.001). Using only 1 strategy (χ^2_2=39.4; *P*<.001) or using apps multiple times (χ^2_2=12.7; *P*=.002) slightly improved the caregiver's day, but using only Personal Playlist apps made the caregiver's day much better (χ^2_{12}=91.9; *P*<.001). In urban settings, the positive impact of the engagement session was only slight (χ^2_2=119.8; *P*<.001). When engagement occurred in other than SNFs or home care, the session made the day better for caregivers (χ^2_4=11.0; *P*=.03). Importantly, when care recipients' mood was observed to improve, the engagement session was more likely to make the day better for staff (χ^2_4=234.7; *P*<.001).

Discussion

Principal Findings

This study is one of the first in the United States to focus on the implementation of tablets across institutional (eg, SNFs) and in-home settings for persons living with dementia. The most apparent implication from this study was the substantial benefit of the tablet interventions to most care recipients. Less than 8% of the entire sample evidenced either the transition of positive to negative mood (8/1089, 0.73%) or the sustainment of negative moods (72/1089, 6.61%) after caregiver engagement sessions. That is, for the vast majority of the entire sample, positive care recipient moods were either maintained or enhanced or were achieved after beginning the session in a negative mood. The unequivocal therapeutic benefit of personalized tablet engagement with music and other approaches seems a function not only of the effectiveness of the particular intervention but also of caregiver commitment to and compassion for the care recipient.

Caregiver supports that maintain interest and participation, as well as promote feelings of achievement and mastery, create a positive experience for participants and caregivers with tablets [33]. Successful interactions should provide achievable goals facilitating feelings of self-worth, which require the caregiver to be *in the moment* and select apps based on resident mood to promote engagement [33]. Study results extend this concept further, indicating that app selection should target multiple strategies (eg, reminiscing or socialization) to facilitate improvements in resident moods.

Our findings also offer guidance around the care recipient and caregiver engagement process. Specifically, the use of a single app, especially YouTube, resulted in moderate to substantial improvements in resident mood across the entire sample. This influence of YouTube supports additional research, indicating that exposure to YouTube videos improves participants' well-being and mood, as well as their communication, interaction, and engagement [29]. In our study, YouTube was primarily used to share music or stories through video and strategies related to reminiscing, socialization, or music. One resident encounter convincingly illustrates tablet impact on resident mood:

> *Listened and watched a YouTube video with headphones and closed caption in Navajo. Elder was happy and smiling. He sang along in Navajo and tried [to] teach me the words in Navajo.* [From one resident encounter]

This session successfully targeted all 3 strategies, and the resident's mood improved the greatest extent possible, from sad to joyful. Years of experience has shown that YouTube holds great potential for personalization because of the nearly unlimited number of topics available. When given the choice of activity, caregivers are choosing to work with YouTube.

Interestingly, using gaming apps (eg, Puzzable or Solitaire) to engage care recipients did not statistically improve mood, especially compared with other engagement strategies. For these care recipients, the complexity of *playing the game* may have undermined mood improvement. For example, one resident reported the following:

> *the worst part [of the game] was there were too many questions - wanted too much information before getting to anything interesting.* [One resident]

Although an unfortunate reaction, this finding supports research suggesting that gaming apps are not as useful for promoting engagement as apps targeting relaxation or telling an individual's life story in this population [34]. Conversely, other research demonstrates that interactive computer games (eg, a Nintendo Wii) affected participant cognition [67]. These contradictory findings warrant further research to examine the specific gaming features and the interaction of these features with care recipient characteristics and cognitive conditions that prompt mood changes.

Mood changes differed by location. Overall, 82.9% (339/409) of care recipients in rural areas reported more negative moods (sad, confused, angry, anxious, or indifferent) at baseline versus those in urban areas (286/680, 42.1%). Similarly, 88.2% (329/373) of care recipients in SNFs began sessions with a negative mood compared with 40.1% (267/666) of individuals in home care settings. However, after tablet engagement, only 7.5% (28/373) of individuals were assessed with a negative mood. A potential explanation for this finding is a greater continuity of care existing between caregivers and care recipients in home care sessions, including more frequent and sustained interactions. How facility-setting characteristics influence care recipient or caregiver mood and mood changes, along with their feelings of isolation or loneliness, remains crucial research topics when implementing tablets or other ICTs.

Limitations

Although illustrating numerous areas for investigation, this study had limitations. First, to ease data collection burden on caregivers, no resident or caregiver attributes (such as gender, age, or duration of the primary challenges) or years of caregiving service were documented. Second, although efforts were made to systematize training and data collection, there may have been variability in these processes either across or within programs. For example, the key strategy (eg, music or reminiscing) may have been recorded inconsistently. Third, as caregiver observations determined mood baseline and changes, knowledge of study objectives or varying assessments of residents' mood could, even unintentionally, introduce bias. Fourth, the time allotted for the care recipient and caregiver interaction may have affected mood changes but was not collected. Finally, findings related to the caregivers' day suggest that the intervention was beneficial overall, but the effect may differ for larger samples or other care recipient or caregiver samples.

Conclusions

This study documents further evidence that ICTs, in particular, tablets such as iPads and apps such as YouTube or using a Personal Playlist, improve mood in older adults and enhance caregiver perceptions about their care recipient interactions, especially with persons living with dementia. Importantly, these pilot data substantiate ICTs, as part of a personalized engagement approach, as beneficial alternatives to pharmaceutical interventions for mood enhancement. As was done for this study, matching engagement methods and types of strategies and apps, based on care recipient preferences or other features to maximize their mood effects, is critical for strengthening the utility of this approach. Accumulating evidence and the additional research questions emerging from this nascent examination offer exciting prospects for continued empirical inquiry and bettering care recipient well-being.

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Conflicts of Interest

DD and MP work for Generation Connect, which is a gerontology-driven technology company with an intergenerational team that works together with forward-thinking care organizations to build engagement solutions that promote person-centered care through technology innovation. All other authors report no conflict of interest.

Multimedia Appendix 1
Description of tablet engagement programs.
[PDF File (Adobe PDF File), 247KB - formative_v3i3e14530_app1.pdf]

Multimedia Appendix 2
Caregiver training process.
[PDF File (Adobe PDF File), 221KB - formative_v3i3e14530_app2.pdf]

Multimedia Appendix 3
Description of the apps included on the tablet.
[PDF File (Adobe PDF File), 43KB - formative_v3i3e14530_app3.pdf]

Multimedia Appendix 4
Feedback survey questions.
[PDF File (Adobe PDF File), 131KB - formative_v3i3e14530_app4.pdf]

Multimedia Appendix 5
Frequency of study variables.

[PDF File (Adobe PDF File), 288KB - formative_v3i3e14530_app5.pdf]

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Abbreviations

BPSD: behavioral and psychological symptoms of dementia
ICT: information and communication technology
SNF: skilled nursing facility
VAMS: visual analog mood scale

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Original Paper

Psychiatry Outpatients' Willingness to Share Social Media Posts and Smartphone Data for Research and Clinical Purposes: Survey Study

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Abstract

Background: Psychiatry research has begun to leverage data collected from patients' social media and smartphone use. However, information regarding the feasibility of utilizing such data in an outpatient setting and the acceptability of such data in research and practice is limited.

Objective: This study aimed at understanding the outpatients' willingness to have information from their social media posts and their smartphones used for clinical or research purposes.

Methods: In this survey study, we surveyed patients (N=238) in an outpatient clinic waiting room. Willingness to share social media and passive smartphone data was summarized for the sample as a whole and broken down by sex, age, and race.

Results: Most patients who had a social media account and who were receiving talk therapy treatment (74.4%, 99/133) indicated that they would be willing to share their social media posts with their therapists. The percentage of patients willing to share passive smartphone data with researchers varied from 40.8% (82/201) to 60.7% (122/201) depending on the parameter, with sleep duration being the parameter with the highest percentage of patients willing to share. A total of 30.4% of patients indicated that media stories of social media privacy breaches made them more hesitant about sharing passive smartphone data with researchers. Sex and race were associated with willingness to share smartphone data, with men and whites being the most willing to share.

Conclusions: Our results indicate that most patients in a psychiatric outpatient setting would share social media and passive smartphone data and that further research elucidating patterns of willingness to share passive data is needed.

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KEYWORDS

social media; smartphone; outpatients; psychiatry; psychotherapy; digital health; mhealth; digital phenotyping; privacy; user preferences

Introduction

Background

Psychiatry research and clinical assessments often rely on patients' retrospective reports. Passively collected smartphone and social media data offer a potential alternative to support such measures. Obtaining information on patients' willingness to provide social media and passive smartphone data for research or clinical purposes would inform potential patient recruitment for studies, as well as eventual clinical use. Here, we present a dual focus on researchers and providers' use of social media and passive smartphone data.

Problems with behavior/symptom self-report have been documented extensively [1]. For example, social desirability is

a major concern; participants may be too embarrassed to fully reveal private thoughts/feelings/symptoms or, alternatively, may misrepresent symptoms to ensure study enrollment or treatment continuation. Apart from accuracy concerns, clinical providers have limited time to collect patient information. Calls have been made for a new vantage point and improved assessment methods [2].

A potential alternative, or support, lies in utilizing social media and/or digital device information [3]. Data collected from both patients' social media and smartphone activity may provide continuous, robust, and ecologically valid insights into mental health. Such insights, which do not rely on retrospective recall, might provide a more nuanced and holistic understanding of behavior and may hold promise for increased accuracy. For example, in clinical care, social media may potentially be used as collateral information to illuminate current stressors, inform diagnoses, and monitor emerging issues. Collateral information, such as input from important people in a client's life, is commonly used in clinical settings. Moreover, using patients' own smartphones for data collection, as opposed to providing a phone or bringing patients in for extensive clinical interviews, has the potential for scalability at little additional cost.

Utilizing patients' social media data and personal smartphones is not without precedent. Many psychiatric care providers are already searching for patients' electronic communications on the Web, and discussions have begun to explore the implications of utilizing smartphone apps, social media monitoring, etc, in psychiatry [4]. In addition, patients' phones have already been used for an ecological momentary assessment, in which patients are prompted to answer questions about their current state [5]. In particular, patients' smartphones have become popular in both research and clinical contexts for monitoring health [6], including an umbrella of mHealth technologies (mobile health) such as activity tracking products that link to the patients' smartphones [7]. Mental health smartphone apps are on the rise in clinical care and beyond in a rapidly developing marketplace [8].

The potential use of smartphones does not end here; technology exists allowing smartphones to be used for data collection without any user effort, for a field called digital phenotyping. Digital phenotyping is the "moment-by-moment quantification of the individual-level human phenotype in situ using data from smartphones and other personal digital devices" [9]. It includes measures of traditional phone usage (calls and texts), as well as measures that utilize smartphone functions, such as patient movement and activity (derived from a smartphone's built-in global positioning system [GPS] and accelerometer) [9,10]. The use of digital phenotyping may increase as research groups develop and test smartphone assessments for research measures [9,11] and because of the support expressed by the National Institute of Mental Health for such endeavors in digital health [12]. Social media activity may have similar benefits as it can be mined without patient burden.

Concerns have been expressed that personal digital devices such as smartphones are not widely used by some subgroups of psychiatric patients (eg, those with serious mental illness) [13]. However, recent studies indicate relatively high rates of smartphone usage even among those with schizophrenia [14-16]. A review of 24 studies of health monitoring smartphone apps revealed high levels of retention and acceptability [17]. However, acceptability data on passive smartphone assessment in particular has not been reported. Beyond the logistical concerns, acceptability also involves recognizing concerns about privacy (for a review of research on consumer attitudes toward/reactions to information privacy, see [18]). Particularly relevant to current methods for digital phenotyping data collection, research suggests that even top ranked mental health apps do not accurately convey to users how their personal data may be harvested and shared [19]. Such irresponsibility with sensitive data represents a need to further develop thoughtful research and clinical protocols.

Objectives

Given the possibility of investigating and incorporating social media and passive smartphone data in psychiatry, several nuanced questions need to be asked about patient acceptability. For example: How comfortable are psychiatric outpatients with the broad spectrum of smartphone data that could be collected for digital phenotyping (ranging from the duration of sleep to how often they answer their phones—an example of data that may be seen as more invasive)? Do publicized breaches in data confidentiality influence the willingness to share personal social media and smartphone information? Would psychiatric outpatients also share such social media and/or passive smartphone data with their provider? It is also useful to consider social media and passive smartphone data collection acceptability simultaneously, as these data sources are complementary.

The purpose of this survey study was to investigate the psychiatric outpatients' acceptability of social media and passive smartphone data collection (for researchers or clinicians). A survey was administered in a psychiatric outpatient clinic in a large Northeastern city. We asked questions about the participants' phone use and social media engagement, as well as how comfortable they felt with the researchers and their own therapists having access to data from their smartphones and social media accounts.

The relation of demographic factors (age, race, and sex) to the willingness to share passively collected data (ie, data relevant to digital phenotyping) was also examined. The analysis was exploratory as we did not find extant research on such a relationship. Building upon previous studies that suggested that women are less likely to share private social media information [20], we hypothesized that women would be less likely to share passive data as well. Although relevant research findings are mixed [21], we hypothesized that people of racial minority groups, compared with whites, would be less likely to share, given similar research on health research participation (eg, a study investigating African American participation [22]). Finally, on the basis of research on age and interest in mental health apps [23], we hypothesized that older patients would be less willing to share passive data.

Methods

Participants

Participants were patients recruited from a university-based psychiatric outpatient waiting room. Research assistants visited the clinic throughout the day. All people (excluding young children) in the waiting room during a research assistant's visit were offered the survey. Potential participants who mentioned that they did not own a smartphone were still encouraged to complete the survey. People who completed the survey but did not indicate that they were receiving services from the clinic were excluded as they were not patients (ie, they were waiting with someone who was a patient). Therefore, study participants were all those who (1) returned a survey and (2) indicated that they were patients in the clinic.

The clinic provides psychiatric services to individuals aged 18 years or older. Services include diagnostic evaluations, medication management, and individual and group therapies. The clinic provides specialized treatment for bipolar disorder, treatment-resistant depression, anxiety disorders, substance abuse, psychosis, geriatrics, and medical-psychiatric conditions. Approximately 500 new patients seek services from the clinic each year. Clinic staff includes 15 psychiatric residents, 6 attending physicians, 5 full-time staff psychologists, and 4 part-time psychologists.

The study was approved by the institutional review board; participants provided informed consent. No compensation was provided.

Measures

The survey was designed in partnership, through discussions among clinical researchers, a digital phenotyping researcher, and the director of outpatient services at the partnering clinic.

Demographics/Services

A demographic questionnaire asked for age, sex, race, Hispanic ethnicity, and the services the patient was receiving at the outpatient clinic.

Smartphone Ownership

Participants were asked to indicate smartphone ownership, including which model they owned (Apple or Android). Owing to the importance of functioning smartphones for digital phenotyping, we also asked if a participant's smartphone was in good working condition (participants were asked to select "no" if their phone company frequently shut off their phone or if their phone, for example, did not turn on or was too cracked to read).

Smartphone Use

As digital phenotyping relies on consistent device use, we asked if patients usually have their phone with them when they leave home. Responses were: "Yes – I almost never leave my house without my phone," "In between – I leave my house without my phone about half the time," and "No – I often leave my house without my phone." Participants were also asked if their phone served as their alarm clock, if they used their phone before bed, if they looked at their phone upon waking up, and how they communicated via phone (phone calls, texting, Facebook Messenger, Google Chat, KakaoTalk, WhatsApp, WeChat, and other).

Social Media Use

Participants were asked to indicate which social media platforms they posted/commented/interacted on. Options were selected by a Web search of currently popular social media options: Ask.fm, Facebook, Instagram, Musical.ly, Pinterest, Reddit, Snapchat, Tumblr, Twitter, and YouTube (if they posted their own videos). "Other" and "I do not use any social media" were also options. We asked the participants to choose from the following options: photos, videos, links (to articles, videos, other peoples' posts, etc), my mood/feelings, opinions or personal recommendations, reactions (to news, events, other people, etc), important life updates, everyday things that happened in your life, activities, goals/plans for the future, comments/*likes* of other posts, other, and "I never post anything on social media."

Willingness to Share Social Media

Participants were asked if they would share social media posts with their therapist if their therapist was concerned about how they were doing. If they would, they were asked what they would share: "Only the postings that I make public," "Both my public and my private postings," and "I would pick-and-choose posts from both my public and private postings."

Publicized Privacy Breach Influence

We selected the Cambridge Analytica scandal as an example of a publicized social media data privacy breach as the media story was a particularly publicized example at the time of survey administration. A brief description was provided: "Recently, Facebook has been in the news for its use of personal data from Facebook Accounts through a company, Cambridge Analytica." Participants were asked if this privacy violation made them more hesitant about "your smartphone data being collected by the university?" "sharing your smartphone data with your therapist (as part of a research study)?" and "sharing your social media with your therapist (as part of a research study)?"

Willingness to Share Passive Smartphone Data

Patients who had a smartphone were asked to specify what parameters would be acceptable to them to be collected via a smartphone app in the context of a research study. One category was information collected using GPS: "amount of time you spend at home," "amount of time during your day you spend not moving," "distance you travel," and "maximum distance you travel from your home." Patients were asked if it was acceptable to collect information on how long they sleep each day, as assessed by tracking how long the phone screen is turned on/off. Patients were also asked if it would be acceptable for researchers to collect the number of texts and calls sent/received, the length of texts and calls sent/received, and how often the phone is answered. Finally, participants were asked if it would be acceptable for their therapist to also have access to this information. The sum of the digital phenotyping–relevant data items that a participant was willing to share was calculated.

Statistical Analyses

Questions were summarized descriptively with percentages or means, as appropriate. Information relevant to passive smartphone data collection was summarized for the sample of patients who specifically indicated that their phone was in good working condition. Information relevant for social media activity was summarized for those who had at least one social media account, and information relevant to sharing data with therapists was summarized for those who were receiving talk therapy. A multiple regression was conducted to evaluate the relation of age, sex, and race to the willingness to participate in a digital phenotyping study. Race was dichotomously coded as white and everyone who selected another race.

Results

Characteristics of the Sample

A total of 238 patients agreed to participate and returned a survey. Characteristics of the sample are presented in Table 1. Ages of the participants ranged from 18 to 84 years; the average age was 39.4 (SD 15.7) years.

Smartphone Ownership and Use

A high percentage of patients (219/235, 93.2%) owned a smartphone. Most (201/214, 93.9%) indicated that they had a working smartphone (24/238, 10.1% did not respond to the working smartphone item; 84.4%, 201/238, of the full sample thus had a working smartphone). Considering those with a working smartphone, 69.8% (139/199) owned an Apple model, whereas 30.2% (60/199) owned an Android model. Smartphone use characteristics are reported in Table 2; modes of mobile phone communication are presented in Table 3.

Social Media Use

Table 4 gives the percentages of social media activities for those who indicated that they used at least one social media platform (N=199).

Table 1. Patient demographic characteristics.

Characteristics[a]	Participants, n (%)[b]
Sex, female (N=198)	141 (71.2)
Ethnicity, Hispanic (N=231)	17 (7.4)
Race (N=238)	
American Indian or Alaska Native	5 (2.1)
Asian	6 (2.5)
Black or African American	56 (23.5)
Native Hawaiian or Pacific Islander	1 (0.4)
Others or unknown	10 (4.2)
White	167 (70.2)
Services (N=238)	
Only medication management	78 (32.8)
Only talk therapy	37 (15.5)
Receiving both services	123 (51.7)

[a]Percentages for race/ethnicities are greater than 100% as participants were welcome to select more than one response.

[b]Results were summarized as the total count of people who indicated the answer listed in the table over the total count of people who answered the specific question (ie, participants who skipped a question were excluded from the analysis of that particular question; hence, the denominators fluctuate).

Table 2. Phone use relevant to leaving home and sleep habits.

Characteristics	Participants, n (%)[a]
Never leave home without phone (N=201)	196 (97.5)
Sometimes leave home without phone (N=201)	4 (2.0)
Often leave home without phone (N=201)	1 (0.5)
Use phone as alarm clock (N=199)	157 (78.9)
Look at phone before bed (N=198)	173 (87.4)
Look at phone when they wake up (N=183)	162 (88.5)

[a]Results were summarized as the total count of people who indicated the answer listed in the table over the total count of people who answered the specific question (ie, participants who skipped a question were excluded from the analysis of that particular question; hence, the denominators fluctuate).

Table 3. Modes of mobile phone communication (N=201).

Means of communication on mobile device	Participants, n (%)[a]
Phone calls	193 (96.0)
Texting	196 (97.5)
Facebook Messenger	109 (54.2)
Google Chat	16 (8.0)
KakaoTalk	1 (0.5)
WhatsApp	44 (21.9)
WeChat	1 (0.5)
Others	52 (25.9)

[a]Results were summarized as the total count of people who indicated the answer listed in the table over the total count of people who answered the specific question (ie, participants who skipped a question were excluded from the analysis of that particular question; hence, the denominators fluctuate).

Table 4. Patient social media use (N=199).

Social media platforms used	Outpatients who use social media, n (%)[a]
Social media platforms used	
Ask.fm	1 (0.5)
Facebook	164 (82.4)
Instagram	123 (61.8)
Musical.ly	4 (2.0)
Pinterest	40 (20.1)
Reddit	28 (14.1)
Snapchat	56 (28.1)
Tumblr	19 (9.5)
Twitter	58 (29.1)
YouTube	25 (12.6)
Other	13 (6.5)
Content of social media posts	
Photos	152 (76.4)
Videos	77 (38.7)
Links (to articles, videos, other peoples' posts, etc)	105 (52.8)
Mood/feelings	51 (25.6)
Opinions or personal recommendations	63 (31.7)
Reactions (to news, events, other people, etc)	80 (40.2)
Important life updates	72 (36.2)
Everyday things that happened in life	39 (19.6)
Activities	53 (26.6)
Goals/plans for the future	25 (12.6)
Comments/*likes* of other posts	123 (61.8)
Others	13 (6.5)
Never post on social media	13 (6.5)

[a]Results were summarized as the total count of people who indicated the answer listed in the table over the total count of people who indicated having at least one social media account.

Of those who had a social media account and were receiving talk therapy, 74.4% (99/133) indicated that they would be willing to share their social media posts with their therapists, if their therapist were concerned about how they were doing. In a follow-up question, 20.2% (19/94) indicated that they would only share the postings that they make public, 53.2% (50/94) would share both public and private posts, and 26.6% (25/94) would pick-and-choose public and private posts.

Willingness to Share Passive Smartphone Data

Table 5 gives the full reporting of the patients' willingness to share passively collected data parameters.

Table 5. Passive smartphone data participants are willing to share with researchers.

Data comfortable sharing with researchers	Participants, n (%)[a]
Amount of time spent at home (N=201)	100 (49.8)
Amount of time during the day spent not moving (N=201)	102 (50.7)
Distance traveled (N=201)	113 (56.2)
Maximum distance traveled from home (N=201)	93 (46.3)
How long one slept each day (N=201)	122 (60.7)
Number of texts sent (N=201)	105 (52.2)
Length of texts sent (N=201)	85 (42.3)
Number of texts received (N=201)	98 (48.8)
Length of texts received (N=201)	82 (40.8)
Number of calls made (N=201)	101 (50.2)
Length of calls made (N=201)	89 (44.3)
Number of calls received (N=201)	99 (49.3)
How often one answers their phone (N=201)	94 (46.8)
Length of calls received (N=201)	88 (43.8)
Willing to share same data with therapist (N=184)	123 (66.8)

[a]Results were summarized as the total count of people who indicated the answer listed in the table over the total count of people who indicated that they had a working smartphone.

Demographic Correlates of Willingness to Participate in a Passive Smartphone Assessment Study

Multiple regression analyses on those with a working smartphone revealed that sex and race, but not age, were significantly associated with the composite variable measuring how many types of passive smartphone data patients would be willing to share in a research study. Partial correlations were as follows: age, r_p=0.03 (P=.69); sex, r_p=−0.16 (P=.04); and race, r_p=−0.16 (P=.05). Men (mean 8.6, SD 5.9) were more willing to share more information than were women (mean 6.3, SD 5.6). People who were of any race other than white (mean 5.2, SD 4.8) were less willing to share more information than whites (mean 7.4, SD 6.0). The results of analyses predicting the willingness to share individual parameters from the demographic variables yielded similar results as found with the summary score.

Publicized Privacy Breach Influence

Of the patients with a working smartphone, 30.4% (59/194) indicated that Facebook's Cambridge Analytica privacy breach made them more hesitant about researchers collecting their passive smartphone data. Similarly, 27.3% (35/128) of those who had a working smartphone and who were in talk therapy believed that the privacy breach made them more hesitant about their therapist receiving that data. Considering the outpatients who indicated that they used at least one social media platform and who were receiving talk therapy at the clinic, 23.4% (30/128) were more hesitant about their therapist receiving that data.

Discussion

Principal Findings

Psychiatry researchers and practitioners have an invested interest in outpatients' willingness to share certain parts of their lives and in the various ways in which that *data*, broadly speaking, may be collected and shared. From allowing a researcher to collect information on how long they sleep as measured by phone activity to permitting a concerned therapist to view their social media, the sharing of passive smartphone and social media data by patients presents a potentially well-supplied opportunity. To date, research studies have not explicitly investigated outpatients' acceptability of specific passive smartphone parameters. One study that did inquire about specific parameters was qualitative and more broadly interested in the affective and thought response to digital phenotyping [24].

Our survey results indicate that research involving the collection of social media and passive smartphone data with patients in psychiatric treatment is acceptable, but not all patients are willing to share such data with their therapist or with researchers. As a starting point, we assessed the willingness to share social

media and smartphone data without a particular research purpose or proposed design. More targeted surveys can probe the willingness to share within specific contexts—some of which might generate greater or lesser willingness than we found. Within our sample of outpatients in therapy and with social media, 74.4% (99/133) were willing to share social media data with their therapists if their therapists were concerned, and 40.8% (82/201) to 60.7% (122/201) were willing to share various passive smartphone parameters with the researchers. We did not ask if the patients would routinely share their social media information with a therapist (regardless of any ongoing concern by the therapist about how the patient was doing). Presumably, even fewer people would share all their social media content all the time.

At 93.2%, the overwhelming majority of outpatients indicated that they owned a smartphone. Although this finding is a higher rate than previously estimated for the US population as a whole [23,25], considering that 95% of our participants were aged between 18 and 64 years, our finding is more comparable with the national data (ie, Pew Research has reported a national rate of about 85% for this age group [25]). It is important to note that our reporting of smartphone-relevant data sharing is limited to those who have a smartphone. If it is the case that people without a smartphone were, for any reason, less likely to participate, then this situation would not affect the results, as those without a smartphone were excluded from the analyses. The methods of recruitment can always bias results. In our case, patients who mentioned that they did not have a smartphone were always requested to continue with the survey and indicate on the survey that they did not own a smartphone.

Considering smartphone ownership, we went one step further to specifically ask if the participants' smartphones were in good working condition (ie, that they were usable and equipped with a consistent phone plan). Not only did the outpatients frequently own smartphones in good working condition, they frequently took those phones with them when they left their homes (an especially important consideration when planning on using smartphones). Collecting passive data from smartphones is therefore theoretically possible in this population. However, approximately 40% to 60% of the patients (depending on the parameter) were willing to share specific passive smartphone data with researchers. Overall, 66.8% (123/184) were willing to allow a therapist to have access to the same information that they would share with a researcher. Researchers and providers interested in clinical applications of passive smartphone data will need to consider that about one-third of the patients would hesitate to share such information with their therapists.

Contributing to this level of nonsharing, over one-fourth of our outpatient sample reflected that they were more hesitant about sharing passive smartphone data as a result of Facebook's Cambridge Analytica scandal. We chose to inquire specifically about the Cambridge Analytica media story as, when the survey was administered, it was a well-publicized example of a privacy/security misuse. Although 30.4% (59/194) of the people shared that it was an issue, it is unclear if the issue had not been brought up, whether the patients themselves would have spontaneously identified this example of a media privacy concern. Identifying the specific media story ourselves may have resulted in the scandal being perceived as a greater barrier than what would have actually occurred in a study that actually used social media and passive smartphone data.

It may also be the case that some survey participants are particularly attuned to privacy concerns related to health/ apps, either by a propensity to worry about privacy or through prior knowledge of private data breaches. Even beyond the Cambridge Analytica breach, health-related apps found in public app stores may have extensive data sharing concerns, shrouded in a lack of transparency [19]. Future survey research should include items that explore how much a participant is already mindful of their health data sharing. Indeed, we would have also done well to inquire about how concerned people were with the content of what would be shared through an app (ie, some people may be aware that they display behavior on their phones that is more, perhaps, noteworthy than others).

Although still keeping in mind that, by asking about Cambridge Analytica, we chose a specific example connected to 1 specific social media platform (Facebook), we posit that our finding suggests that publicized data scandals in general may be associated with outpatients' willingness to participate in relevant research. The broader issue at hand, then, is that data handling in the corporate sphere, as well as in the academic research sphere, has ramifications that influence the other. Dealing with personal social media data (and, considering our interests, smartphone data as well) is a privilege that should not be taken lightly.

We examined the overall willingness to share passive smartphone data based on the demographic variables of sex, age, and race. We did not locate previous studies that conducted these analyses. Our exploratory findings therefore need to be confirmed in future studies and, if confirmed, the potential reasons for any differences should be examined.

Our finding that women may be more hesitant to share passive data is consistent with previous studies suggesting that women are less likely to share private social media information [20]. In our exploratory analyses, owing to our sample sizes, we compared whites with everyone who did not fall under that category (a diverse group of people who selected anything other than white). Our exploratory finding might build on extant research exploring potential differences by race in willingness to participate in research, broadly. Such existing research most often involves comparisons of African Americans and whites and indicates that African Americans may be more hesitant to participate in health research [22], though further studies questioning the assumption that willingness might differ by race is emerging [21]. We encourage more specific research in this area.

Limitations

Several limitations of this survey require notice. People who anonymously indicate that they would share data may not actually do so when presented with an imminent opportunity. Demographic predictors of the willingness to share passive smartphone data were conducted on an exploratory basis and therefore would need replication. Sample sizes were not large enough to examine the influence of specific identities on the

willingness to share. We were interested quite broadly in outpatients; we did not collect data on specific mental health concerns. It is unknown if recruiting participants in the waiting room influenced results.

Conclusions

Our results indicate that work seeking to collect social media and passive data in a psychiatric outpatient sample is largely acceptable for outpatients. About half of our sample was willing to share data that, for some, may seem particularly invasive and unacceptable to patients for researchers and providers to collect. However, our results indicate that the work involving social media use in this population may be challenging owing to a lack of engagement with multiple platforms and that research involving passive data collection from smartphones may call for targeted recruitment strategies.

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AR participated in survey development, data collection, data summary, interpretation of findings, and the writing of the manuscript. AG was involved with data collection and editing of the manuscript. IB was involved with survey development and study design. CFB participated in survey development and data collection. MBCG was involved with survey development, interpretation of the findings, and editing of the manuscript. PCC designed the study and participated in survey development, data summary, interpretation of findings, and writing of the manuscript. The study was funded by the Once Upon a Time Foundation.

Conflicts of Interest

None declared.

Multimedia Appendix 1
To be used in publication: the original survey administered to participants.
[PDF File (Adobe PDF File), 89KB - formative_v3i3e14329_app1.pdf]

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Abbreviations

GPS: global positioning system

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Original Paper

Technology-Enabled Mental Health Service Reform for Open Arms – Veterans and Families Counselling: Participatory Design Study

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Abstract

Background: The impact of mental ill-health on every aspect of the lives of a large number of Australian Defence Force (ADF) personnel, their partners, and their families is widely recognized. Recent Senate inquiries have highlighted gaps in service delivery as well as the need for service reform to ensure appropriate care options for individuals who are currently engaged with mental health and support services as well as for those who, for a variety of reasons, have not sought help. To that end, successive Australian governments generally and the Department of Veterans' Affairs specifically have prioritized veteran-centric reform. Open Arms is an Australia-wide service that provides counseling and support to current and former ADF personnel, and their family members, for mental health conditions.

Objective: The aim of this study was to develop and configure a prototypic Web-based platform for Open Arms – Veterans & Families Counselling (formerly Veterans and Veterans Families Counselling Service) with the Open Arms community to enhance the quality of mental health services provided by Open Arms.

Methods: The study aimed to recruit up to 100 people from the Open Arms community (current and former ADF personnel and their families, health professionals, service managers, and administrators) in regions of New South Wales, including Sydney, Canberra, Maitland, Singleton, and Port Stephens. Participants were invited to participate in 4-hour participatory design workshops. A variety of methods were used within the workshops, including prompted discussion, review of working prototypes, creation of descriptive artifacts, and group-based development of user journeys.

Results: Seven participatory design workshops were held, including a total of 49 participants. Participants highlighted that the prototype has the potential to (1) provide the opportunity for greater and better-informed personal choice in relation to options for care based on the level of need and personal preferences; (2) ensure transparency in care by providing the individual with access to all of their personal health information; and (3) improve collaborative care and care continuity by allowing information to be shared securely with current and future providers.

Conclusions: Our findings highlight the value of actively engaging stakeholders in participatory design processes for the development and configuration of new technologies.

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KEYWORDS

veterans; mental health; technology; community-based participatory research; health care reform; stakeholder participation

Introduction

Veteran-Centric Reform

Successive Australian governments have been concerned about the mental health and well-being of current and former Australian Defence Force (ADF) personnel and their families and have committed to improve policies and services to prevent and treat mental health conditions and support individuals and families in need [1]. However, recent government inquiries concerning the mental health of the ADF [2] and suicide by current and former personnel [3] have revealed the enormous impact of mental ill-health on every aspect of the lives of a large number of ADF personnel, their partners, and their families. The inquiries highlighted gaps in service delivery as well as the need for service reform and also strategies and services that can appropriately deal both with those currently engaged with mental health and support services and those who, for a variety of reasons, have not sought help [1,2].

In March 2015, the Department of Veterans' Affairs (DVA), including services provided by Open Arms – Veterans & Families Counselling (formerly Veterans and Veterans Families Counselling Service; renamed October 2018), was supporting 49,668 veterans who had 1 or more mental health disabilities [4]. In light of the service gaps noted in the recent Senate Inquiry reports, DVA has prioritized veteran-centric reform [5] to ensure dramatic improvements in the way DVA connects with veterans and to provide the former service community with a greater standard of service through business processes, culture, and government-endorsed best practice mental health service delivery.

Regarding access to mental health and support services for current and former ADF personnel, the 2017 Senate Inquiry report highlighted the vital role of Open Arms as a trusted provider of high-quality mental health services for the Defence community [3]. Open Arms is an Australia-wide service that provides counseling and support to current and former ADF personnel, and their family members, for mental health conditions (such as posttraumatic stress disorder, anxiety, depression, sleep disturbance, and anger). Open Arms also provides relationship and family counseling. In 2017, Open Arms provided support to 27,000 current and former ADF personnel and their families [6]. On the basis of the outcomes of an independent Service Functional Review commissioned by DVA in 2014 [7], Open Arms has identified a number of critical challenges related to service quality, including prevention and early identification, fast tracking support, need for engagement outside the health care system, capacity to provide the right care at the right time, and complex psychosocial needs of persons accessing the service.

Technology Solutions for Mental Health Services Reform

In June 2017, the University of Sydney's Brain and Mind Centre and DVA partnered to engage the Open Arms client base (current and former ADF personnel and their family members) and staff (health professionals, service managers, and administrators) in participatory design workshops to explore how a prototypic Web-based platform could be tailored to realize a technology-enabled solution for the Open Arms service.

Originally, the prototype was designed, built, and evaluated through a partnership between the Young and Well Cooperative Research Centre and the University of Sydney's Brain and Mind Centre [8] known as Project Synergy. Project Synergy (Phase I: 2014-2016) was originally commissioned by the Australian Government Department of Health (DOH) in 2014, with the broad aim of transforming the provision of mental health care across Australia by harnessing the potential of new and emerging technologies to reach all people, regardless of location, and provide them with access to timely and evidence-based treatment to improve their mental health and well-being. The Funding Agreement provided for the establishment of a Research and Development (R&D) Group as well as a Product Group for the development of the prototypic Web-based platform.

This prototype links integrated and interoperable resources (eg, apps, etools, and Web-based and in-clinic health services, most with data-sharing functionality) to enhance service quality; track real-time health and social outcomes; and bring integrated, high-quality, and personalized service experiences to the person seeking care. It operates through existing health providers, such as Open Arms, to promote access to high-quality and cost-effective mental health services.

Importantly, the goal of the prototype is to offer immediate Web-based assessment (all individuals complete a tailored self-report questionnaire) resulting in a personalized dashboard of results. The results give individuals an overall profile of their health and well-being (including mental health), which can be shared with their health professional, other health care providers, and family members, among others (dependent on permission being granted by the individual). The prototype uses staged care on the basis of the transdiagnostic clinical staging model [9,10] to identify the extent of progression of disease at a point in time. This enables the platform to match recommendations including apps, etools, and clinical interventions to an individual's level of need.

At its core, the prototype promotes person-centered health care and its principles highlight that individual clients of a service are equal partners in their health care. To that end, to promote transparency, individuals have access to all information that directly concerns them. Furthermore, all information is presented in plain language (including avoiding jargon), and individuals are presented with sufficient information to understand all components of the prototype (eg, initial self-report questionnaire, dashboard of results), with options for obtaining further information if desired. Critically, decisions about an individual's care are made collaboratively with a health professional or service, taking into account both clinical needs and personal preferences. The prototype helps minimize variability in care provision between individual health professionals and services

by using evidence and data rather than solely relying on clinical opinion, which can be variable and fallible. Finally, the prototype is being designed to maximize the use of resources and minimize the duplication of services and wastage of time, for all individuals.

A key feature of the prototype is that it is able to be configured to meet the needs of all end users, including individuals and supportive others, health professionals, service managers, and administrators. By engaging potential end users through the iterative use of participatory design, the prototype can be continuously redeveloped to best meet the needs of a health care service.

Research has shown that the active participation of all stakeholders throughout the design of technical systems and services helps ensure that the end product meets the needs of its intended user base, improves usability, and increases engagement of all individuals [11,12]. Through the engagement of stakeholders in participatory design, technical solutions to practical problems related to health care are generated as a means to effect organizational (ie, service) reform [13]. Importantly, end users (in this instance, all members of the Open Arms community) have the opportunity to actively co-design the technology solution in conjunction with researchers and product designers with the aim of developing Web-based tools and systems that are more likely to be engaging and effective for all users [11,14].

The aim of the current research was to actively engage individuals from the Open Arms community, via participatory design, to collaboratively develop and configure the prototype to enhance Open Arms service quality.

Methods

Ethics

The research study was approved by the DVA Human Research Ethics Committee (project number: E016/027).

Participants

The study aimed to recruit up to 100 people from the Open Arms community, including current and former ADF personnel and their families, as well as health professionals (including Open Arms counselors and Outreach Program Counselors [OPCs]), service managers, and administrators in regions of New South Wales, including Sydney, Canberra, Maitland, Singleton, and Port Stephens.

Inclusion criteria for current and former ADF personnel and their families were as follows: aged 16 years or older and eligible for Open Arms services (all current and former ADF personnel who have at least 1 day continuous full-time service are eligible for care through Open Arms; having met this criterion, their family members are also eligible for care).

Representatives from the Australian Government, including senior executives in the DOH, DVA, and Open Arms, as well as members of Project Synergy's R&D and Product Groups, were also included in the participatory design workshops as key stakeholders; however, the data presented in this paper reflect the population (ie, current and former ADF personnel and Open Arms health professionals, service managers, and administrators).

Recruitment Strategy

To recruit current and former ADF personnel and their families, the recruitment strategy included the distribution of postcards and A3/A4 posters with information about the participatory design workshops in the lead up to each scheduled workshop in each of the 5 regions. Targeted social media (location matched to each relevant region and age more than 16 years) was also used to circulate information about the workshops. To avoid any perceived coercion, recruitment was passive such that a potential participant needed to contact the Research Project Manager who, only upon a potential participant's request, then forwarded the Study Information Sheet and Participant Consent Form.

For the recruitment of health professionals (including Open Arms counselors and OPCs), service managers, and administrators, information was distributed to potential participants directly by the relevant Open Arms Centre managers in each of the 5 regions.

All participants were provided with detailed information about the study both before attending a participatory design workshop and upon arrival at the workshop. At the beginning of each workshop, the facilitators provided the participants with an opportunity to ask questions and clarify details of the research before providing written informed consent. Potential participants were reminded that participation was entirely voluntary, and that if they agreed to participate, they could withdraw their consent at any time without being required to provide any reasons and with no impact on their relationship with Open Arms or the University of Sydney's Brain and Mind Centre.

Participatory Design Workshops

The workshops brought together members of the Open Arms community, Australian Government representatives, and representatives from Project Synergy's R&D and Product Groups to explore how the prototype could be developed and configured to enhance mental health services provided by Open Arms. All workshops were coordinated by at least 2 facilitators, 1 of whom was a mental health professional whose role was to respond to any participant concerns or distress as a result of the subject matter. An additional Open Arms counselor was also present for this purpose. A scribe was present to take handwritten notes throughout the workshop.

Each workshop (4-hour duration) was designed to actively engage participants in interactive discussions about how to co-design potential technology solutions for the Open Arms service. The facilitators used a variety of methods within the workshops, including prompted discussion, review of working prototypes (wireframes), creation of descriptive artifacts, and group-based development of user journeys (a series of steps illustrating how an individual might interact with the prototype). Importantly, user journeys help to understand user behavior and identify other possible functionality at a high level and define taxonomy and interface. They refer to personas and real people and feedback into a number of technology-building activities

including information architecture and sitemaps, the development of wireframes, and functional specifications.

To ensure maximum coverage of a number of critical issues to develop the technology solution, several areas of focus were explored, including: the intake; triage and waitlist processes at Open Arms; typical pathways to care at Open Arms; expectations of care provided by Open Arms; and potential for technology use for health and well-being as well as health-related emergencies. The above-listed topics reflected potential areas for service reform identified through an independent functional review of Open Arms commissioned by DVA in 2013-2014 [7]. Through weekly meetings, the agenda items and methods were then collaboratively refined by the joint Project Management Team, comprising researchers, health professionals, and members of Open Arms to determine how best to discover how the technology-enabled solution might enhance or reform Open Arms for improved outcomes for clients and their families.

Data Analysis

At the conclusion of each workshop, the notes taken by the scribe were transcribed into a report documenting the participant profile (ie, gender and participant type such as health professional or veteran) as well as the content of the discussion relative to the agenda. These reports in combination with the visual artifacts collected during the participatory design workshops (nonidentified and presented in aggregate to ensure confidentiality) were analyzed by members of the R&D Group using knowledge translation processes to identify themes and key learnings and inform the development and configuration of the prototype for the Open Arms service, particularly in relation to improved service quality.

Knowledge translation is defined as the synthesis, exchange, and application of knowledge by stakeholders to enhance the benefits of innovation in strengthening health systems and improving health outcomes [15]. Broadly, knowledge translation promotes translation of research findings into clinical practice, organizational management, technology development, and policy reform, bridging what has been coined *the know-do gap* [15]. It is an interactive process between researchers and health care systems to pinpoint R&D priorities that will benefit a service, including clients, health care professionals, and administrative personnel [16].

The analysis was guided by research questions related to the critical challenges identified in the Service Functional Review [7], including elements of the Open Arms service pathway, such as intake, assessment, and treatment. Categories relating to required prototype functionality (including data security and confidentiality) were also explored as they were likely to critically inform development and configuration. Using the above identified areas of interest as a guide, 2 researchers (HL and CR) independently analyzed the data. In accordance with knowledge translation processes previously used by our group [17], observations were tallied, and those observations with 3 or more independent tallies were considered to be consistent themes. Observations included comments by individual participants (eg, current and former ADF personnel and their families as well as Open Arms health professionals, service managers, and administrators) as well as comments generated during small group discussions, including when developing user journeys or prototypes. As the participatory design workshop agendas varied, building on the learnings from each previous session, consistency in themes across workshops was not examined. Although members of the Project Synergy R&D and Product Groups were active participants in the workshops to drive the collaborative development and co-design process, their comments were not included in the analyses.

The primary researchers came to a consensus on any themes that were not agreed upon during the independent analyses. A third independent researcher (TD) subsequently checked the themes against the available data and in relation to the research questions.

The quotes referenced in the paper are representative of all participant types (ie, current and former ADF personnel and their families, health professionals, service managers, and administrators); however, as the majority of the quotes were derived from small, mixed group discussions (ie, a spokesperson relaying the views of a group) and are not reflective of a single individual's or participant type's point of view, coding has not been used within the paper.

Results

Demographics

A total of 7 participatory design workshops (all of 4-hour duration) were held between August and September of 2017. The aim of each workshop was to actively engage the Open Arms community in discussions about how to collaboratively develop and configure technology solutions aimed at enhancing the Open Arms service.

A total of 49 Open Arms–recruited participants attended the workshops, comprising a mix of participants from the Open Arms community, including current and former ADF personnel and their families as well as Open Arms health professionals, service managers, and administrators (Table 1). No participants expressed concern or experienced any distress in any of the workshops.

Table 1. Participant demographics (N=49).

Demographic	Statistics
Participants	
Female, n (%)	28 (57)
Role[a], n	
Former personnel	13
Current serving personnel	6
Family of current or former personnel	10
Health professional	17
Representative from Australian Government Department of Health	9

[a]Some participants fulfilled multiple roles (eg, ex-serving personnel and health professional).

The results presented below highlight the consistent themes identified by participants in relation to the potential impact of the prototype for Open Arms clients and the service pathway, particularly in relation to the intake process, provision of personalized recommendations matched to level of need, and routine progress monitoring. In addition, possible technology solutions to improve risk detection and suicide prevention were evaluated.

Principles of the Prototype for the Open Arms Service

Personal Choice

Participants highlighted the potential for the prototype to promote personal choice among clients of the Open Arms service:

> *[The prototype] could support clients to make choices on intake about service engagement and options for care.*
>
> *Clients should be able to make their own choices about what aspects of their health and wellbeing is most important for them to work on.*
>
> *It is important to provide the client with the choice to share his or her data with a counsellor.*

Transparency

In particular, participants noted that critical information should be provided to ensure informed decision making and transparency (eg, limitations to confidentiality, details about the assessment and reporting processes, clear terms and conditions, and background information about how recommendations have been generated):

> *[The prototype] should be straightforward and transparent. For example, the [prototype] needs to provide details about the length of any and all assessments, how the suggested apps are rated, and how the dashboard is generated.*
>
> *Data security needs to be highlighted, particularly that the information is not shared with DVA.*

Collaborative Decision Making

Participants supported the concept of shared treatment planning, frequently noting that this approach to care would promote engagement, adherence, and communication:

> *[The prototype] will enable shared treatment planning, giving the client ownership over their care.*
>
> *The Shared Care Plan will promote engagement and facilitate communication between the client and health professional.*

Continuity of Care

Participants agreed that a prototype that eliminates the need for an individual to have to repeat *their story* to multiple care providers would be highly valued by the Open Arms community:

> *[The prototype] will limit the need for people to have to tell their story over and over again.*
>
> *The process of repeatedly writing out your story to each service is extremely traumatic. To have the option of having it written down, or already existing within a [prototype], would reduce the distress associated with this process.*
>
> *Veterans want to avoid telling their story multiple times. Data and information should be stored in [the prototype], ready to be shared with another service, if needed.*
>
> *For individuals with a history of trauma, repeating their story is particularly upsetting.*

Staged Care

Participants recognized the potential benefits of employing a staging model in the prototype to align recommendations (eg, apps, etools, and clinical interventions) with an individual's current level of need:

> *Clinical services can be matched to the degree of need. It will be important to highlight that the services provided are evidence-based solutions.*
>
> *Just because someone does an intake, doesn't mean they need to use the service. Providing the individual with psychoeducation and self-management techniques could be appropriate.*

Configuration of Content for the Open Arms Community

Participants consistently noted that the design and content of the prototype needs to be specific to the veteran community in recognition of their unique experiences and needs from a health care service:

> *The importance of the need to customise tone, language and aesthetic to the individual based on their age, relationship to the military and/ or to the veteran was emphasised.*
>
> *Anything that is offered to [veterans] needs to be seen to have some level of veteran specificity.*

Plain English

The need to provide all information to individuals in a clear and straightforward manner was emphasized by participants:

> *It is imperative to avoid clinical jargon. The language needs to be geared towards the veteran community.*

Open Arms Service Pathway Themes

Intake

As part of 4 of the participatory design workshops, participants jointly created user journeys to characterize how a client might engage in care with Open Arms, through different points of intake depending on their persona (Figure 1). As highlighted (Figure 1), an individual may be prompted to make contact with Open Arms for the first time in several ways including by a health professional, social media, their partner, or other family member; however, participants reported that most frequently, a significant other, or family member, prompts the initial contact with Open Arms.

The participants made several suggestions for how the prototype could improve or support the Open Arms intake process, which, at the time this research was conducted, included a pre-enrollment screening, an intake assessment, allocation to a health professional, and appointment scheduling:

> *[The prototype] could help with triage, fast-tracking clients when needed (eg, if a client scores above a pre-specified threshold on a psychometric instruments, the [prototype] could escalate/ prioritise them for an appointment or contact their health professional).*
>
> *When the initial online assessment is completed, [the prototype] could use that assessment to direct the client to a health professional with the specific expertise required or whom is most suitable.*
>
> *Online intake process may also make services more accessible as it may be a way to engage individuals in care who are fearful of coming in to a physical [Open Arms] Centre.*

Furthermore, participants recognized that the prototype could provide resources to individuals (such as recommended apps and etools) while they were on a waitlist to see a health professional (Figure 2).

In addition, participants suggested that the prototype could check-in with individuals routinely to ensure they were safe while waiting for care (Figure 3).

Figure 1. Possible points of Open Arms service entry based on user journeys.

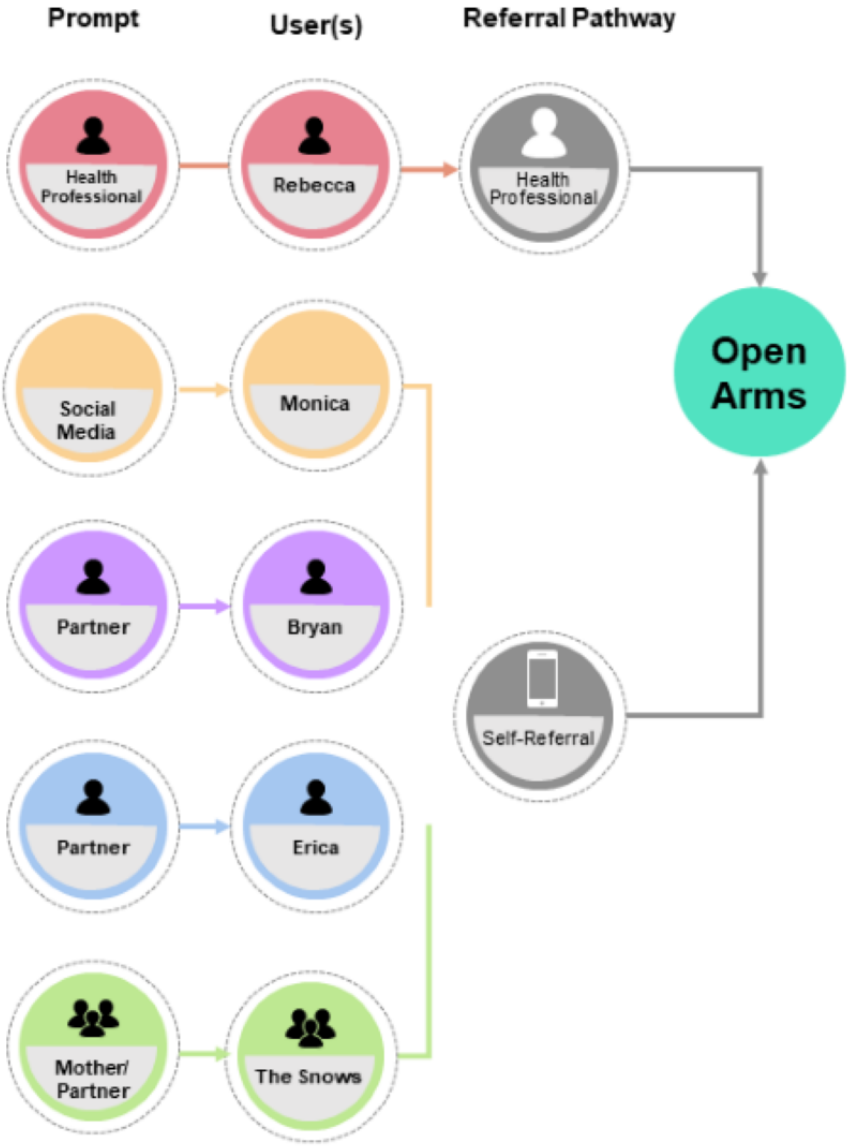


Figure 2. Recommendations based on an individual's personalized dashboard of results.

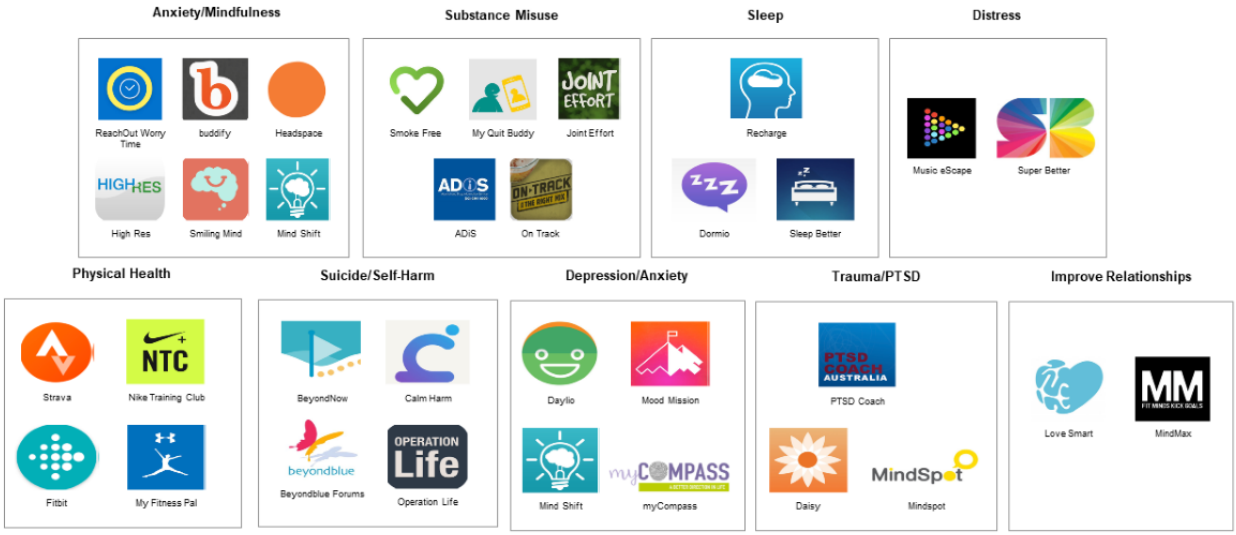
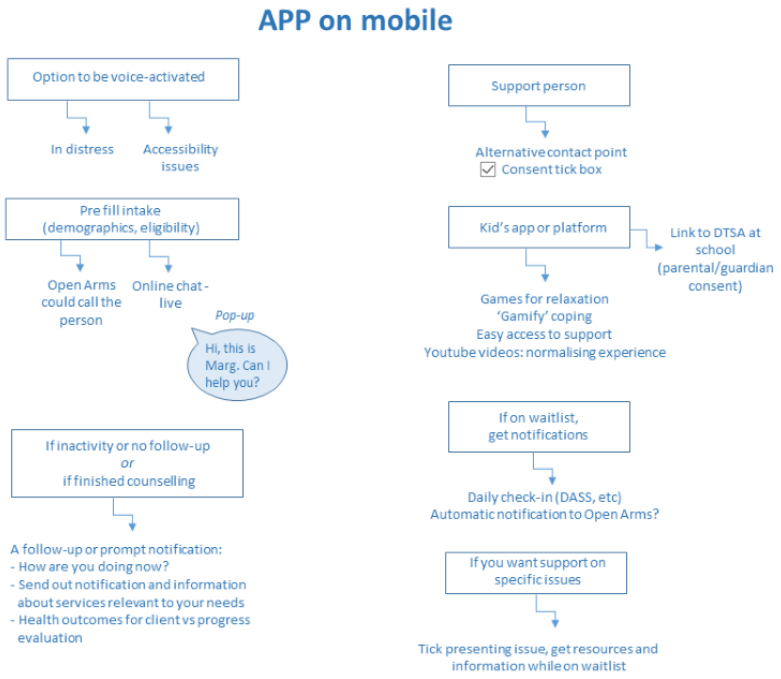


Figure 3. Sample wish list by participants for the technology.



Progress Monitoring

Participants valued the potential for the prototype to offer progress monitoring to assess and prompt discussions about treatment effectiveness and provide individuals with feedback about their progress:

> *Progress monitoring is important to explore the effectiveness of treatments so changes in approach can be made as needed as well as to evaluate client satisfaction. If the client is achieving goals, this can also be reinforced.*
>
> *While data tracking was indicated to be an important element of [the prototype] as a means to show progress, it was indicated that this may be alarming to clients showing a downward trajectory. It was suggested that [the prototype] might flag an alert in the platform for the service or primary health professional to check in with the client.*
>
> *This feature is very helpful as it allows health professionals to make connections between a client's dashboard as well as visualise a client's progress.*
>
> *The [prototype] should provide the individual feedback on their progress. The individual should have a sense that the [prototype] remembers them over time.*

In addition, participants highlighted the potential for the prototype to check-in with clients for numerous reasons (Figure 3), which are as follows: (1) a period of inactivity or disengagement from the prototype, (2) progress monitoring in relation to health outcomes, and (3) notifications regarding relevant service offerings.

Feedback on a Prototype for Immediate Risk Response, Known as the Need Help Now Button

Given the call for improved risk detection and suicide prevention in the recent Senate inquiries [4], feedback on the *Need Help Now* button is particularly relevant. As pictured (Figure 4), the prototype included a 3-tiered support feature [18], including a list of geolocated mental health services, a Web-based chat feature, and a list of contact details for emergency services (eg, Triple 000, Lifeline, etc). Participants appreciated the tiered approach to risk response and provided suggestions for how this aspect of the technology could be improved upon, including personalization of the resources by an individual:

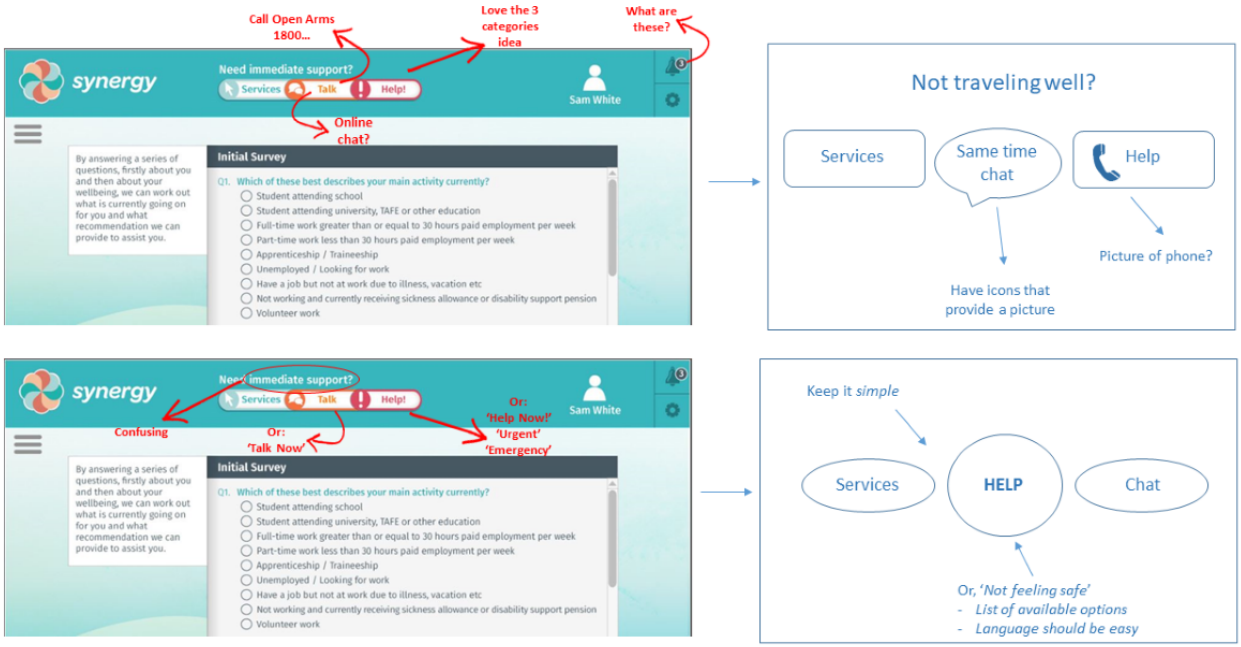
> *It is good that different options/ levels of care are presented.*
>
> *Include the ability to list a buddy or partner here to be contacted in an emergency (ie, build your own "Need Help Now" button).*
>
> *If a client does not like any of the resources that are included in the "Need Help Now" section, there needs to be an "other" option. This may be a phone service, a website, or an option to call a friend. You cannot leave people without an alternate option.*
>
> *"Less is more." If you are in crisis, there cannot be too many resources from which to choose. The selection process must be simple and clear.*

Participants emphasized the need to ensure language in this feature is client centered:

> *The language used to label the buttons should be focused on what the client is experiencing or may be able to relate to (eg, not feeling safe).*
>
> *"Emergency" is a more indicative term than "help."*

Participants provided specific comments on the *Need Help Now* prototype through annotating wireframes and by suggesting alternative designs (Figure 4).

Figure 4. Combined feedback on Need Help Now button: annotated wireframes and suggested alternatives.



Technical Functionality

Data Security and Confidentiality

Integral to the design of any Web-based technology is the security of the data stored within the prototype. Within the context of Open Arms, participants consistently highlighted the need to ensure that their health information remains confidential and is not shared, for example, with other government organizations such as DVA, except with their express permission:

> *The terms and conditions and limitations to confidentiality need to be clearly explained.*
>
> *Concerns about data confidentiality, including storage, access, ownership and accountability, will directly impact on how much the [prototype] is trusted.*
>
> *Who has access to the data? How is it stored? Permissions need to be modifiable by the participant.*

Discussion

User Engagement Through Participatory Design

Through the use of participatory design methodologies, members of the Open Arms community (including current and former ADF personnel and their family members, health professionals, service managers, and administrators) were actively engaged in the investigation of how to develop and configure a prototypic Web-based platform for Open Arms with the aim of enhancing the quality of the Open Arms service. A total of 7 participatory design workshops were conducted with a mix of members from the Open Arms community, as well as other key stakeholders, including representatives from the Australian Government (ie, DOH, DVA and Open Arms) and Project Synergy R&D and Product Groups, resulting in a wealth of information regarding current service practices and how to approach the co-design process for the Open Arms service.

Consistent with previous research, our findings highlight the value of engaging potential end users in the co-design process of new technologies [11,14]. Furthermore, the results of this study align with our previous experience working collaboratively with different stakeholders to increase access to and the effectiveness of mental health services for young people [17]. A review of the aggregate qualitative data (eg, feedback on wireframes, descriptive artifacts, and group-based development of user journeys) revealed that the prototype could provide the opportunity for greater and better-informed personal choice in relation to options for care based on level of need and personal preferences. To ensure transparency in care, the reconfigured prototype for Open Arms could allow individuals to have complete access to all of their individual health data presented in plain language as opposed to clinical jargon. Furthermore, the client would also have the option to share this information securely via the prototype with current and future health professionals to facilitate shared treatment planning, collaborative care and care continuity within and between services, and reduce the need for clients to repeat their clinical history or *story*.

The principles of the prototype align with the objectives set forth by DVA and Open Arms following the 2017 Senate inquiry [6,19]. In addition, participants identified several ways in which the prototype could enhance the Open Arms service pathway. In relation to intake, it was noted that a Web-based intake

process could serve to fast-track individuals based on level of need and facilitate allocation of individuals to health professionals with the expertise matched to the identified mental health concerns. The potential benefits of progress monitoring over the course of care was also highlighted, particularly as a means by which to track and evaluate treatment effectiveness and provide active feedback to individuals and health professionals about progress and/or deterioration.

Importantly, the participatory design work completed with Open Arms has resulted in immediate service pathway redesign, highlighting the value of stakeholder engagement in research as a means to facilitate service-level changes [13]. Specifically, Open Arms has designed and implemented a revised intake process with the aim of reducing the time between initial service contact and the first appointment with a health professional. The previous intake process typically included 3 points of telephone contact (ie, pre-enrollment, intake, and allocation or appointment scheduling), whereas potentially only 2 points of contact will be required with the new process. Individuals, who are eligible for care through Open Arms, now contact a National Intake Service and have immediate access to an intake clinician, thus streamlining allocation to a health professional.

Notably, the research questions explored in this study are not unique to Open Arms but rather reflect universal themes related to technology-enabled mental health services reform. The configurable and customizable prototype will continue to be co-designed with input from individuals with lived experience, health professionals, and service staff (including administration and management) to support the prevention, early intervention, treatment, and continuous monitoring of mental ill-health and maintenance of well-being in people aged 2 years and older, including members of the veteran community [20]. Therefore, although Open Arms may develop a particular solution, such as a Web-based intake process specific to their service, the general concept of improved access to care is important universally, and thus will be explored with different groups to validate the thinking and further evolve the solution for broader use and applicability.

Although the co-design process is invaluable for the purposes of stakeholder engagement, the findings from this study are limited by their breadth. Further stakeholder engagement is now required to inform the co-design process of technology-enabled solutions aimed at addressing the critical challenges identified by Open Arms, including prevention and early identification, fast-tracking support, and capacity to provide the right care, first time.

End-user involvement in the co-design process is fundamental for the production of a relevant and usable technology solution [21,22]; however, the role of stakeholders must not end here. Existing literature highlights the necessity of establishing a feedback process to ensure the opportunity for critical assessment and iterative redesign of the solution [23]. As such, user testing is required to ensure the acceptance of the technology-enabled solution before implementation in the service as well as to facilitate the iterative redevelopment of the solution to adapt to the changing needs of the service and its consumers. This ongoing collaborative process of engagement will help ensure that members of the Open Arms community directly inform the development and configuration of the technology solution to help remove any barriers to help seeking, intake, assessment and treatment planning; enhance service delivery; and help improve the mental health and well-being of all individuals within the Open Arms community.

Future Directions

An evaluation study to determine how new and emerging technologies could be used to enhance the Open Arms Sydney Centre, including safety and clinical quality, was approved by the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC; project number: 017-17) and commenced in May 2018. This study allows for the continued active engagement of the Open Arms community through novel and innovative technologies, including service mapping, participatory design, and user testing. In addition, an impact evaluation research study has also been approved by DDVA HREC (project number: 056-18) and commenced in November 2018 with the aim of evaluating the quality of the revised intake process compared with the previous procedure. The primary objective will be achieved through an audit of service metrics, including time to first appointment, as well as potential differences between the phone-based intake process and an alternative offered by the prototype. Outcomes will include improved identification of individuals at risk of suicide. Allocation of clinical service and intervention intensity relative to an individual's level of need (as identified using the clinical staging model at intake) will also be evaluated.

Conclusions

Active engagement of individuals from the Open Arms community via participatory design methods demonstrated that the principles of the prototypic Web-based platform align with the recommendations made by DVA and Open Arms in response to 2017 Senate Inquiry report [6,19]. The breadth and depth of the information gathered through stakeholder engagement will now guide the development and configuration process of the technology-enabled solution for the Open Arms community, with the aim of ensuring high-quality, cost-effective, evidenced-based, person-centered mental health services for current and former ADF personnel and their family members.

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Authors' Contributions

Authors TD, JB, SC, SH, JV, and IB obtained funding to support the study. The study was designed and conducted by TD, SC, JB, and HL. Authors JV and SH assisted with study recruitment. HL managed the literature search, contributed to knowledge translation, and prepared the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

Conflicts of Interest

IH was an inaugural Commissioner on Australia's National Mental Health Commission (2012-18). He is the Co-Director, Health and Policy at the Brain and Mind Centre (BMC) University of Sydney. The BMC operates an early intervention youth services at Camperdown under contract to headspace. IH has previously led community-based and pharmaceutical industry-supported (Wyeth, Eli Lily, Servier, Pfizer, and AstraZeneca) projects focused on the identification and better management of anxiety and depression. He was a member of the Medical Advisory Panel for Medibank Private until October 2017, a Board Member of Psychosis Australia Trust, and a member of Veterans Mental Health Clinical Reference group. He is the Chief Scientific Advisor to, and an equity shareholder in, InnoWell. InnoWell has been formed by the University of Sydney and PwC (Australia) to deliver the Aus $30 million Australian Government-funded *Project Synergy*. Project Synergy is a 3-year program for the transformation of mental health services through the use of innovative technologies.

JB is the Chair of the National Advisory Council for Open Arms, Veterans and Families Counselling Service. She is a well-being and digital health consultant to Bupa, a member of the Veterans Mental Health Clinical Reference group, and a Chief Investigator and author of the Defence and Veterans Transition and Well-being Study. She is the Founder of, and an equity shareholder in, InnoWell. She is the Professor of Social Innovation and Chair of the Centre for Mental Health at Swinburne University and Adjunct Professor of Social Impact and Entrepreneurship at RMIT. The remaining authors do not have any conflicts of interest to declare.

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Abbreviations

ADF: Australian Defence Force
DDVA HREC: Departments of Defence and Veterans' Affairs Human Research Ethics Committee
DOH: Department of Health
DVA: Department of Veterans' Affairs
OPCs: Outreach Program Counselors
R&D: Research and Development

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Original Paper

A Mobile Patient-Reported Outcome Measure App With Talking Touchscreen: Usability Assessment

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Abstract

Background: In the past years, a mobile health (mHealth) app called the Dutch Talking Touch Screen Questionnaire (DTTSQ) was developed in The Netherlands. The aim of development was to enable Dutch physical therapy patients to autonomously complete a health-related questionnaire regardless of their level of literacy and digital skills.

Objective: The aim of this study was to evaluate the usability (defined as the effectiveness, efficiency, and satisfaction) of the prototype of the DTTSQ for Dutch physical therapy patients with diverse levels of experience in using mobile technology.

Methods: The qualitative Three-Step Test-Interview method, including both think-aloud and retrospective probing techniques, was used to gain insight into the usability of the DTTSQ. A total of 24 physical therapy patients were included. The interview data were analyzed using a thematic content analysis approach aimed at analyzing the accuracy and completeness with which participants completed the questionnaire (effectiveness), the time it took the participants to complete the questionnaire (efficiency), and the extent to which the participants were satisfied with the ease of use of the questionnaire (satisfaction). The problems encountered by the participants in this study were given a severity rating that was used to provide a rough estimate of the need for additional usability efforts.

Results: All participants within this study were very satisfied with the ease of use of the DTTSQ. Overall, 9 participants stated that the usability of the app exceeded their expectations. The group of 4 average-/high-experienced participants encountered only 1 problem in total, whereas the 11 little-experienced participants encountered an average of 2 problems per person and the 9 inexperienced participants an average of 3 problems per person. A total of 13 different kind of problems were found during this study. Of these problems, 4 need to be addressed before the DTTSQ will be released because they have the potential to negatively influence future usage of the tool. The other 9 problems were less likely to influence future usage of the tool substantially.

Conclusions: The usability of the DTTSQ needs to be improved before it can be released. No problems were found with satisfaction or efficiency during the usability test. The effectiveness needs to be improved by (1) making it easier to navigate through screens without the possibility of accidentally skipping one, (2) enabling the possibility to insert an answer by tapping on the text underneath a photograph instead of just touching the photograph itself, and (3) making it easier to correct wrong answers. This study shows the importance of including less skilled participants in a usability study when striving for inclusive design and the importance of measuring not just satisfaction but also efficiency and effectiveness during such studies.

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KEYWORDS

mHealth; eHealth; surveys and questionnaires; physical therapy specialty; qualitative research

Introduction

Digital Divide

Electronic health (eHealth) is developing rapidly [1]. It is defined as the use of information and communication technology (ICT) in health care [2]. A growing amount of literature indicates that using eHealth can improve the accessibility, quality, and efficiency of health care [3-5]. It seems to be effective for people who have access to it and are able to use it well, which is not the case for everybody [6,7]. For instance, people with low income or low education and people who are 65 years and older are vulnerable when it comes to effective eHealth use. In these populations, access to the internet and hardware, such as personal computers, tablets, mobile phones, and smartphones, and the experience and skills to use these devices is low [6-9]. Differences between people regarding digital skills and access to the internet and hardware is often referred to as the digital divide [10,11]. As eHealth technologies are usually primarily developed for people who are experienced and skilled in using ICT [12,13], people who do not have access to ICT or are not skilled in using it are at risk of being excluded from the use of eHealth. Looking at the widespread expansion of eHealth technologies, this encompasses the potential threat of contributing to the ongoing exacerbation of health inequalities in Western countries [1]. However, if the needs, preferences, capacities, values, and goals of potential users who do not have good access to the internet and digital technology or who are not well skilled in using this technology would be explored and taken into account during each stage of development of eHealth tools, eHealth could potentially *reduce* health inequalities [14].

Mobile Technology Reduces Digital Divide

The development of a specific form of eHealth technology, called mobile health (mHealth) technology, seems especially promising when it comes to reducing health inequalities [5,15-17]. mHealth has been defined by the Global Observatory for eHealth of the World Health Organization as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" [18]. A recent project called eSalud showed that mHealth can be cost-effective, help to overcome cultural and language barriers, and provide health information and services to low–health access areas [15]. Furthermore, recent publications indicate that the digital divide is narrowing because of the increased ownership of mobile devices such as smartphones and tablets [5,16,17].

Inclusive Mobile Health Design Could Potentially Reduce Health Inequalities

Still, having access to the internet and digital technology does not automatically mean that people are able and willing to use it effectively to increase their health or that different people use it in the same way [14,19-25]. Recent studies found ethnic and socioeconomic differences in mHealth usage [19,20], and it is known that older people use mHealth differently from younger people [14]. In addition, though the gap of people owning tablets and smartphones between groups is closing, still a substantial number of people do not own such devices. For instance, the percentage of Dutch citizens of 65 years and older owning a tablet computer in 2017 was 55.2% versus 75.8% citizens of 12 to 25 years of age [26]. Considering that vulnerable groups, such as people with low income and low education, bear a disproportionate burden of disease [27,28] and the number of health care visits increases with age [29], it is to be expected that a relatively large number of care recipients do not have a lot of experience in using mobile technology. To fulfill the promise of mHealth technology contributing to a reduction of health inequalities, it is very important to carefully test the usability of mHealth apps in research populations, which include members of the target populations that are at risk of being excluded from usage of the tested tool.

Development of the Dutch Talking Touch Screen Questionnaire

In the past years, a prototype of an mHealth app, called the Dutch Talking Touch Screen Questionnaire (DTTSQ), was developed in The Netherlands. The idea of developing a talking touch screen was inspired by the work of Hahn and Cella [30]. The aim of developing the DTTSQ was to enable Dutch physical therapy patients to autonomously complete a user-friendly health-related questionnaire regardless of their literacy and digital skills. As it is not to be expected that all physical therapy patients own a tablet computer, the DTTSQ is meant to be presented in a physical therapy practice on a tablet computer that is owned by the physical therapy practice concerned. Patients are asked to complete the DTTSQ in the waiting room of the physical therapist before their first visit. The development of the prototype of the DTTSQ, which runs on a tablet computer, was described in detail by Cremers et al in 2015 [31]. Before this study, the prototype was only tested in a sample *outside* of the physical therapy context.

The aim of this study was to test the prototype of the DTTSQ within the physical therapy context to see what parts of the prototype needed adjustment for it to be user-friendly for physical therapy patients regardless of their level of experience with operating mobile technology.

The research question underlying this study was:

> *What is the usability of the prototype of the DTTSQ for physical therapy patients with different levels of experience in using mobile technology?*

Methods

Design

A qualitative descriptive study was carried out. Observational data on the way participants operated the DTTSQ were collected through the Three-Step Test-Interview (TSTI) method [32].

This method includes both think-aloud and retrospective probing techniques.

Definitions

Usability was defined by the International Standards Organization as "the effectiveness, efficiency and satisfaction with which specified users can achieve goals in particular environments" [33]. *Effectiveness* is the accuracy and completeness with which users achieve certain goals [34]. In this study, problem rates and severity of problems were used as the primary indicator of effectiveness. *Efficiency* is the relation between the accuracy and completeness with which users achieve certain goals and the resources expended in achieving them [34]. In this study, completion time was used as an indicator of efficiency. *Satisfaction* is the users' comfort with and positive attitudes toward the use of a system [34]. In this study, participants were interviewed about their satisfaction with the ease of use of the DTTSQ. Ease of use was defined as the degree to which the usage of a particular system is free from effort [35].

Setting and Participant Selection

Data were collected in the same study population and at the same time as the data reported in a paper earlier published by Welbie et al [36]. Recruitment took place in 11 primary care practices in deprived areas of Utrecht, The Netherlands. Patients were invited by their physical therapists to participate in this study. The physical therapists shortly explained the goal of the study and provided the patients with an information letter that was written in plain Dutch language. If patients were interested, the physical therapist asked permission to give the patients' telephone number to researcher IT. Then researcher IT (1) contacted the patient by telephone, (2) again shortly explained the aim of the study, (3) made sure the patient understood what was asked of him/her, (4) answered any question the potential participant may have had, and (5) checked the inclusion criteria. The inclusion criteria for participants were as follows: aged 18 years or older, Dutch as their first language, and the patients and both their parents were born in The Netherlands. This last inclusion criterion was added because in a following study, the usability of a direct Turkish translation of the DTTSQ will be tested. For the outcomes of both studies to be comparable, it is important that the cultural background of participants of this study was not *mixed*. This last inclusion criterion excludes second-generation immigrants with a non-Dutch background. The sampling procedure was aimed at getting a broad variation in levels of education and age plus balance in our sample regarding gender. Age was used as a proxy for level of experience with using mobile technology because with increase in age, the experience with mobile devices decreases [26]. Taking age as a selection criterion was more practical for the recruiting physical therapists, as this is noted standardly in patient files. By making sure that there was variation in age, it was expected to find variation in experience with mobile devices in the study sample. Throughout the recruitment process, the recruiting physical therapists were constantly kept informed about the profiles of participants the researchers were looking for. In total, 24 physical therapy patients were included in this study [36]. Characteristics of the study population can be found in Tables 1 and 2.

Table 1. Characteristics of study population (N=24).

Characteristics	Study population
Age (years), mean (range)	56 (18-79)
Gender, n (%)	
Male	9 (38)
Female	15 (62)
Level of education, n (%)	
Low[a]	6 (25)
Moderate[b]	13 (54)
High[c]	5 (21)
Self-declared experience with using mobile technology, n (%)	
None	9 (37)
Little	11 (46)
Average/high	4 (17)

[a]Low: no or at most primary education finished.

[b]Moderate: lower secondary education, (upper) secondary education, or postsecondary nontertiary education (including vocational education).

[c]High: tertiary education (bachelor's degree or higher).

Table 2. Characteristics per participant.

Pseudonym	Experience with mobile technology	Age (years)	Level of education
Ida	None	66	Low[a]
Bill	None	72	Moderate[b]
Mia	None	73	Moderate
Dora	None	77	Low
Ilene	None	79	Low
Bob	None	68	Moderate
Jerome	None	47	Low
Helga	None	54	High[c]
Michelle	None	56	Low
Roger	Little	70	Moderate
Peter	Little	18	Moderate
Christine	Little	39	Moderate
Jill	Little	55	High
Lydia	Little	56	Moderate
Rose	Little	60	Moderate
Francine	Little	61	Moderate
Harald	Little	63	High
Henry	Little	64	Moderate
Ronald	Little	70	Low
Bernie	Little	76	High
Jude	Average/high	18	Moderate
Joline	Average/high	19	Moderate
Ellen	Average/high	32	High
Sandra	Average/high	39	Moderate

[a]Low: no or at most primary education finished.

[b]Moderate: lower secondary education, (upper) secondary education, or postsecondary nontertiary education (including vocational education).

[c]High: tertiary education (bachelor's degree or higher).

Content of the Dutch Talking Touch Screen Questionnaire

The prototype of the DTTSQ was a digital app on a tablet computer. It was developed during a co-design process [37], which in this case meant that a group of 10 low-literate people helped to design the questionnaire. As a result of the co-design process, questions on pain location and pain intensity were added to the original questions of an existing questionnaire which aims to select limitations in functioning and to formulate specific treatment goals [38,39]. Furthermore, visual (videos and photos) and auditory (speech technology) support were added to enable participants to see and hear the questions that were shown on separate screens. Response items could be selected by tapping on the touch screen and plain language was used in all spoken and written text within the DTTSQ [31]. An overview of all types of screens is given in Multimedia Appendix 1. The 8 questions of the questionnaire can be found in screenshots 2, 3, 4, 7, 9, 11, 12, and 13, which can be found in Multimedia Appendix 1.

Instructions

Instructions were given in the form of 3 video clips:

1. An introduction clip in which the purpose of the questionnaire and all functions of the questionnaire were explained (see Figure 1 and screenshot 1 in Multimedia Appendix 1).
2. An instruction clip in which the purpose of question 4 and a newly added navigation function were explained (see screenshot 6 in Multimedia Appendix 1).
3. A closing clip in which the participant is thanked, explained what the physical therapist would do next, and told that the questionnaire would close down automatically (see screenshot 16 in Multimedia Appendix 1).

Figure 1. Introduction movie.

Functions

Next Button

It is a navigation function to go to the next screen. It is not activated unless a response item is selected (except for question 4; see Figure 2 and screenshot 7 in Multimedia Appendix 1).

Help Button

It activates the help function: the text on the screen is read aloud, the purpose of the question is explained, and operating instructions for the particular screen are provided.

Correction Function

Tapping a second time on a response item, deselects the item.

Stop Button

It is an escape function: it shuts down the questionnaire. All previous given answers are saved.

Overviews

To help participants keep track of their answers, overviews of previous given answers were provided regularly during completion of the questionnaire (see Figure 3 and screenshot 5, 8, 10, 14 and 15 in Multimedia Appendix 1 screenshots).

Figure 2. Question 4: “Select the activities in which you are limited”.

Figure 3. Overview answers total questionnaire: “On the screen you see an overview of all your answers you provided until now.”.

Data Collection and Procedures

Data collection took place at the physical therapy practice or the participant’s home, depending on the preference of the participant. Researchers IT and JS were present. Researcher IT was in the lead during the interviews. Researcher JS asked complementary questions if she missed information.

The following steps were taken according to the TSTI method [32].

Step 1

Each participant was observed by researchers IT and JS while they were completing the DTTSQ thinking out loud. This step was aimed at collecting observational data regarding the usability of the DTTSQ. The data collected consisted of 2 kinds: (1) observations of participant’s behavior and (2) think-aloud data. The data were recorded on videotapes as well as audiotapes. In addition, the researchers took real-time notes for use during the following steps of the interviews as well as for later analysis. The researchers wrote their notes down on

hardcopies of print screens of the DTTSQ. Researchers IT and JS noted problems with operating the tablet computer, including using the touch screen, navigating through the questionnaire, understanding the task given in each screen, selecting response items, and using the correction function. They also wrote down when the stop button was used. The researchers did not interfere in the completion process by asking any questions or providing help.

Step 2

Researcher IT conducted an in-depth interview after the participant finished completing the DTTSQ. Data collection during this step was exclusively focused on filling possible gaps and checking the observational data collected during step 1.

Step 3

During step 3 of the TSTI, researcher IT conducted a semistructured interview aimed at eliciting experiences and opinions of the participant. During the interview, each screen was operated in the same way the participant did during step 1 and the same answers were entered. This was done to help the participant to clearly remember all his thoughts and actions during the completion of the questionnaire. Participants were stimulated to report feelings and express opinions, preferences, and recommendations. If they encountered problems in operating the DTTSQ, they were asked what they thought the exact nature and possible cause of each type of problem was and how they tried to overcome the problem. Then, the participants were questioned about their satisfaction regarding the ease of use of the user interface, technical operation, layout and content, and overall usability of the DTTSQ. Researcher JS was allowed to ask complementary questions, if she felt it was necessary, to get complete and enriched data. Researcher IT finished the interview by collecting demographic data and data on self-reported experience with mobile technology (see Tables 1 and 2).

Analyses

Data were analyzed using a thematic content analysis approach [40]. Overall, 4 types of data were analyzed: (1) video recordings of the completion of the questionnaire, (2) field notes of the observed participant behavior, (3) transcriptions of the audio recordings of the semistructured interviews, and (4) background information regarding the educational level, age, gender, and self-reported experience with using mobile technology.

To get more familiar with the data and to create an overview, researcher MW made a descriptive summary of each case on the basis of all 4 types of generated data. Each summary contained information on whether or not the questionnaire was fully completed, if, when, and why the stop function was used, the kind of problems that occurred with the operation, the completion time, and all emerging themes regarding satisfaction or dissatisfaction with the ease of use of the questionnaire. The summaries were supplemented with information regarding educational level, age, gender, and experience in using mobile technology.

Subsequently, researcher MW derived the observed problems from the summaries. She clustered the problems. For every new problem, a new category was made. MW analyzed the video recordings to see how many times each problem was made in total, per participant and per question/screen of the questionnaire. After a full overview of problems had emerged, she scored the level of severity of each problem, as described by Nielsen and Loranger [41]: low, medium, serious, or critical. To score severity, she used the method of Hattink et al [42]. The severity was scored by answering the 3 questions of Nielsen and Loranger [41] with *yes* (=one point) or *no* (=0 points):

1. Frequency: Do a substantial number of users encounter the problem? Within this study, this question was answered with yes if one-third or more participants had encountered the problem.
2. Impact: Does the problem cause much trouble to those users who encounter it? Within this study, this question was answered with yes if the problem had led at least one participant to stop completing the questionnaire.
3. Persistence: Does the problem cause trouble repeatedly? Within this study, this question was answered with yes if the problem had occurred with an average of more than one time per participant.

This resulted in a 0- to 3-point score per problem. Each score was related to a level of severity: 0=low, 1=medium, 2=serious, and 3=critical.

These severity ratings give an indication of which problems lead to disastrous usability problems and which problems are more cosmetic in nature [43]. This provides insight into whether or not the usability of the DTTSQ needs to be improved before it can be released. Nielsen and Loranger recommend tackling only serious and critical severe problems during the development process of a digital tool. Low and medium severe problems do not have priority according to Nielsen and Loranger because although they are bothersome, they are not likely to directly influence the usage of a tool. This makes it uninteresting to tackle them from a cost-benefit perspective. Serious and critical severe problems on the contrary can be so disrupting that they can make users stop using a tool or prevent them from even starting to use it at all. Therefore, they should not be ignored during the development process of a digital tool [41].

As a next step, researcher MW started open coding of all fragments in the transcripts of the semistructured interviews that were related to (dis)satisfaction about the ease of use of the questionnaire using MAXQDA 10 (VERBI Software). After she finished open coding, she organized and structured the codes until a coding scheme emerged on the basis of which the part of the research question that was related to satisfaction of the participants could be answered sufficiently.

As a last step, researcher MW ordered the analyzed data into 3 groups: data of participants who had (1) no, (2) little, and (3) average/high experience in using mobile technology. This was done to see whether or not data differed within and between these groups.

During the whole course of the study procedures, coding, analysis steps, and interpretation decisions were discussed with researchers HW, MJW, and WD.

Ethics

No external funding was received by the Utrecht University of Applied Sciences to conduct this study. This study was submitted to the medical ethics committee of the Academic Medical Centre of Amsterdam which declared that it does not fall under the scope of the *Medical Research Involving Human Subjects Act*. The study was conducted according to the principles of the Declaration of Helsinki. All participants provided written informed consent. The participants' names used in this article are all fictitious to protect their privacy.

Results

Effectiveness

Overall, 9 out of the 24 participants in this study did not complete the DTTSQ fully (see Table 3). Michelle (56 years), Bill (72 years), and Helga (54 years), who were all inexperienced in using mobile technology stopped completing the questionnaire by using the stop button. Inexperienced Ida (66 years), Ilene (79 years), Dora (77 years), and Mia (73 years) and little-experienced Peter (18 years) and Rose (60 years) went through the whole questionnaire but unintentionally left one or more parts open.

Table 3. Experience with mobile technology and completion of the Dutch Talking Touch Screen Questionnaire.

(Sub)Population	Not fully completed	Fully completed
No experience using mobile technology (n=9)	7	2
Little experience using mobile technology (n=11)	2	9
Average/high experience using mobile technology (n=4)	—	4
Total population (N=24)	9	15

Unanswered (Parts of) Questions

Inexperienced Michelle (56 years), Ida (66 years), Ilene (79 years), Dora (77 years), and Mia (73 years) and little-experienced Peter (18 years) and Rose (60 years) failed to fully complete the DTTSQ because they failed to select answering options and/or unintentionally skipped questions by double-tapping on the next button (see problems 1-5 in Table 4). All participants, except for Michelle, additionally failed to notice that they had not effectively selected an answer because the difference between activated and nonactivated answers was not accentuated enough (see problem 6 in Table 4).

Use of the Stop Button

When inexperienced Michelle (56 years) noticed most of her answers were missing from the summary in question 6, she got confused. In question 6, she was asked to choose the 3 most important activities in which she was limited. The screen contained only 1 activity photo whereas, in her mind, she had selected a lot of photo's earlier. Except for the 1 photo that she had managed to select, she had tapped on the text beneath the photos, in which case, the item was not activated (see problem 5 in Table 4). The activity on the 1 photo that she had managed to select was of no priority to her. Therefore, she decided to use the stop button and ended the questionnaire.

Inexperienced Bill (72 years) had a lot of trouble operating the questionnaire. He commented on the introduction clip:

> *I do not think that what she is saying is difficult, but I just am not able to remember it. I have no experience with these kind of devices. So I forgot what she said right away.*

Bill managed to get to question 4 by activating the help function on each screen he entered. When he touched the navigation button to see all the activity photos in question 4, the photo gallery moved in a different direction then he had presumed. This startled him somewhat and made him forget that he had to push the next button to go to the next screen (see problem 7 in Table 4). He activated the help function again, but that was of no use anymore. After trying a few buttons without succeeding to go to the next screen, he gave up and tapped on the stop button.

Inexperienced Helga (54 years) operated the digital questionnaire fluently until she had to choose the 3 activities that were most important to her in question 5. She did not use the navigation function of the photo gallery and as a result she did not see all her earlier selected activities (see problem 4 in Table 4). She chose the 3 most important activities out of the 5 photos that were immediately visible. When she realized what happened, she wanted to pause for a moment to find out how she could change her answer. She interpreted the stop button as a *time-out function* and was a bit shocked when she found out that she had stopped the questionnaire altogether.

A complete overview of frequency and severity of all problems encountered can be found in Table 4.

Table 4. Frequency and severity of encountered problems during the completion processes of all participants.

Problem	Number of participants	Frequency	Severity rating
1. Accidently skipping a screen by double tapping on the next button	8	16	Serious
2. Double-tap on answering option causing activation and deactivation of the answer of choice	1	1	Low
3. Skipping a screen by accidently touching the next button with the palm of the hand	1	1	Low
4. Not using the navigation function of the photo gallery in question 4 causing the participant not seeing all presented response items	2	2	Medium
5. Touching the text underneath a photo in question 4 to select an activity instead of touching the photo itself causing the activity not to be selected	3	30	Serious
6. Not able to see whether or not a selected answer is activated (not accentuated enough)	8	8	Medium
7. Not knowing how to get to the next screen	1	1	Medium
8. Pushing too hard or tapping too soft on the touch screen causing the touch screen not to respond	11	40	Serious
9. Not able to correct a wrong answer	8	13	Serious
10. Not reading the text above the photos of question 5 causing the participant to keep on performing the task given with question 4	4	8	Medium
11. Not noticing that the multiple numerical rating scale-effort scores in question 8 are related to different activities, which by mistake results in identical scores for different activities	1	1	Low
12. Scoring the body chart in question 2 mirrored	2	2	Low
13. Scoring (serial) questions that do not apply to the participants' situation (forced by the software)	1	4	Medium

Number of Problems

Average-/high-experienced Ellen (32 years), Sandra (39 years), and Joline (19 years) and little-experienced Jill (55 years), Lydia (56 years), and Christine (39 years) were able to complete the questionnaire without any problems. The other 18 participants were not able to operate the questionnaire fluently. In an absolute as well as relative sense, more participants with no experience in using mobile technology encountered problems during the completion of the DTTSQ than little-experienced participants did (see Table 5). Inexperienced participants encountered an average of 3 problems per person, whereas participants with little experience encountered an average of 2 problems per person. Within the subgroup of average-/high-experience participants, only 1 person encountered ` problem during completion (see Table 5). A total of 11 participants encountered problem 8, "Pushing too hard or tapping too soft on the touch screen causing the touch screen not to respond" multiple times (see Table 4). In some case, participants looked startled after problem 8 occurred. In these cases, researcher IT encouraged the participant to go on by kindly saying *try again*.

Table 5. Number of participants encountering each problem per level of experience with using mobile technology (N=24).

Problem	No experience (n=9)	Little experience (n=11)	Average/high experience (n=4)	Total population
1	5	3	—[a]	8
2	1	—	—	1
3	—	1	—	1
4	1	1	—	2
5	2	1	—	3
6	4	4	—	8
7	1	—	—	1
8	6	5	—	11
9	3	4	1	8
10	2	2	—	4
11	1	—	—	1
12	1	1	—	2
13	—	1	—	1

[a]Not applicable.

Efficiency

The 21 participants who got to the end of the questionnaire had an average completion time of 10 min and 25 seconds. Inexperienced participants needed more time than little-experienced participants did, who in their turn needed more time than average-/high-experienced participants did (see Table 6).

Table 6. Completion time of all participants who did not end the questionnaire prematurely.

(Sub)Population	Mean completion time (min)	Median completion time (min)	Range of completion times (min)
No experience with mobile technology (n=6)	11.38	9.38	8.2 to 22.10
Little experience with mobile technology (n=11)	10.41	9.57	6.54 to 18.10
Average/high experience with mobile technology (n=4)	7. 55	7.42	5.50 to 10.26
Total population (n=21)	10.25	9.43	5.50 to 22.10

Satisfaction

All participants were satisfied with the ease of use of the questionnaire. The use of plain language, the way ICT was used, and the way the user interface was designed were greatly appreciated by the participants:

> *Everything was well described. I am not always able to understand everything, but this went well. I understood what was asked of me.* [Inexperienced Dora, 77 years]

> *I have trouble operating my mobile phone and I own a notebook but don't you ask me how that thing works! I am capable of a lot but I am not technical in that way. [...] This was the first time for me to use a tablet computer. I only had to follow the instructions. I did not have to start it up or open something, it just started working and it shut down by itself. I thought it was easy to work with. Better than when you have to write things down.* [Little-experienced Roger, 70 years]

> *I am a very visual person. And this thing is very visual. [...] Like green is 'no pain' and red is 'a lot of pain'.* [Average/high experienced Ellen, 32 years]

All participants were satisfied with the completion time of the DTTSQ.

Satisfied Despite Encountering Problems

Operation problems, regardless of the amount and severity of the problems encountered by each individual participant, did not influence satisfaction about the ease of use of the questionnaire. Little-experienced Francine (61 years), for instance, was asked how she felt about the fact that the app did not always respond to her touch right away (see problem 8 in Table 4). She encountered this problem 13 times in total. She lightheartedly answered as follows:

> *Oh these are things that happen. I experience the same things with my own computer. My computer refuses to sometimes, so... I think I was just pushing too hard on the tablet sometimes, that's all.*

When inexperienced Bill (72 years), who used the stop button, was asked if he would have preferred a paper-based questionnaire he said the following:

> *No. It took me some time to get used to it but it is easy to use actually.*

Expectations Exceeded

A total of 9 participants explicitly stated that operating the questionnaire was easier than they had expected beforehand. When inexperienced Ida (66 years) was confronted with the questionnaire she agitatedly said the following:

> *Never in a million years I believe I can do this. That I can tell you right away.*

Noticeably reluctant and nervous, she started to complete the questionnaire. When she finished, she seemed surprised and relieved. She smiled and said the following:

> *Okay? So this was the questionnaire? [...] Ooooh but this was doable! I thought I would have to look up things and operate it like my grandchildren do.*

And then she started laughing out loud and cheerfully asked if anyone would like to have some coffee.

Little-experienced Christine (39 years) was positively surprised too:

> *It responds really well. Normally I am not that good with screens, but this is easy. It almost feels like a game! It really responds nicely. Nothing disappears when I touch it. It reacts very calmly but at the same time it is very fast. I really like that it contains photo's instead of drawings. It is instantly clear: these are my activities and that is what they mean by "sitting down". You see it right away. I also like the regular summaries. It keeps you on track and enables you to check whether or not you forgot something.*

Participants' Recommendations for Improvement

The most mentioned recommendations for improvement of the usability of the DTTSQ by participants were: shorten the length of the instructions, accentuate the activated response items, and improve the user interface of question 4 by giving participants a complete overview of activities to choose from in one screen, without having to use complicated navigation functions.

Discussion

Principal Findings

All participants within this study were very satisfied with the ease of use of the DTTSQ. Overall, 9 participants stated that the usability of the app exceeded their expectations. The participants who had no experience with using mobile technology completed the prototype of the DTTSQ less effectively and efficiently than the little- and average-/high-experienced participants did. In the group of average-/high-experienced participants, only 1 problem was encountered in total, whereas the inexperienced participants encountered an average of 3 and the little-experienced participants an average of 2 problems per person. Overall, 13 different kind of problems were encountered during this study. From a cost-benefit perspective, 4 of these problems will need to be addressed during future development of the DTTSQ because they have the potential to influence the future usage of the tool negatively [41]. The 4 problems that need to be addressed are problem 1 "Accidently skipping a screen by double tapping on the next button," problem 5 "Touching the text underneath a photo in question 4 to select an activity instead of touching the photo itself causing the activity not to be selected," problem 8 "Pushing too hard or tapping too soft on the touch screen causing the touch screen not to respond," and problem 9 "Not able to correct a wrong answer." Participants also recommended to shorten the length of the instructions and improve the user interface of question 4 by giving participants a complete overview of activities to choose from in one screen, without having to use complicated navigation functions.

Comparison With Previous Work

In earlier studies, talking touch screens were found to be easy to use for people with different levels of education, literacy, or digital skills. These conclusions were based on study participants' level of satisfaction with the ease of use of the tool [44,45] or on results on satisfaction combined with the efficiency with which the tool was completed [46-50]. Effectiveness was not, or in case of Vargas et al very slightly [45], tested. This is a debatable approach, because Frokjaer et al consider effectiveness, efficiency, and satisfaction as independent aspects of usability and state that it is risky to assume that there are correlations between these aspects [34]. Therefore, according to Frokjaer et al, satisfaction and efficiency outcomes should always be tested in combination with outcomes of effectiveness to give a complete and realistic overview of the usability of a tool. The results of this study confirm the necessity of combining all 3 aspects of usability during usability studies. All participants in this study, including participants who were not able to fully complete the questionnaire because of problems they had with operating the app, were satisfied with the usability of the DTTSQ. Looking solely at the results on satisfaction with the ease of use (which were also found in the comparable studies [44-50]) one could make the assumption that the DTTSQ is, usability wise, ready to be released. Looking at the data found on efficiency within this study, one can see that more-experienced participants need less time to complete the questionnaire. This seems logical and matches the results of comparable studies [46,49]. In addition, the completion time was acceptable to all participants of this study. On the basis of the efficiency results solely, one could also conclude that the DTTSQ was ready to be released. Looking at the results on effectiveness and specifically at the severity rates of the problems that occurred during the response process though, the researchers of this study concluded that the usability of the DTTSQ needs to be improved to prevent problem 1, 5, 8, and 9 from occurring before it can be released.

The results of this study show how difficult it is to strive for an *inclusive design*. A lot of effort was put into developing a tool that is easy to use for potential users at risk of exclusion from usage of mHealth tools [31]. By choosing a co-design strategy, development of a user-friendly tool for people with diverse levels of education, literacy, and digital skills was taken a step

further than what was done in earlier comparable projects [44-50]. In the other projects, users were involved in the evaluation process of the tools, but development was done by designers and health professionals. In spite of the user-centered development approach that was taken during the development process of the DTTSQ, the goal of inclusive design was not reached yet. Looking at the results of this study, the tool is ready to be released for average-/high-experienced users but not for less-experienced future users. To be able to evaluate the worth of including potential users at risk of exclusion, it would be interesting to be able to compare data on efficiency and effectiveness of talking touch screens that were developed earlier. Specifically, because the user interface and structure of the DTTSQ differs from comparable tools. For instance, the screen of the DTTSQ contains fewer buttons and operation functions, it does not have a back function, it provides summaries of given answers regularly to the respondent, and questions are not automatically read out loud. In addition, the design and format of the answering options in the earlier developed talking touch screen [44-50] does not match the recommendations given by the low-literate people that helped to design the DTTSQ [31]. If it would be possible to compare results on effectiveness from the tests of several different kind of talking touch screens, a lot of insight could be gained in what does and does not work in striving for an inclusive design for less-skilled users of such tools.

According to Frokjaer et al, relations between the 3 aspects of usability depend in complex ways on the app domain, use context, and user's experience [34]. User's experience may well have been of influence on the satisfaction outcomes of this study. Overall, 83% (20/24) of the total study population had no or little experience in using mobile technology (see Tables 1 and 2). Limited or no user experience may have caused a form of computer anxiety, resulting in low self-efficacy, which in turn led to low expectations toward the ease of use of the DTTSQ [51]. A total of 9 out of the 24 participants in this study explicitly stated that operating the DTTSQ was easier than they had expected beforehand. The other participants did not explicitly state this, but their statements on the ease of use could easily be interpreted as such. No participant stated or gave the impression that the ease of use of the DTTSQ was lower than they would have expected. According to the Expectation Confirmation Theory [52], actual performance exceeding the expectations of testers leads to satisfaction among these testers. The more their expectations are exceeded, the more satisfied testers will become. Owing to the limited user experience of most of the study participants, expectations toward the ease of use of the DTTSQ may have been low, which may have made it easier to exceed them. Especially considering that the DTTSQ was specifically designed to be easy to use for low-educated people who lack the necessary skills to use ICT [31]. Looking at the results of studies that evaluated the satisfaction about the ease of use of earlier developed talking touch screens, a similar picture of highly satisfied study participants emerges [44-50]. The qualitative results in 2 of these studies also show that participants' expectations regarding the ease of use of the tested tool were exceeded [44,47] and 2 other authors report that satisfaction among the study participants was *extremely* and *overwhelmingly* high [45,48]. In all of the comparable studies, a large proportion of the study participants had no or limited computer experience [44-50]. It is reasonable to assume that limited computer experience may have led to low expectations regarding the ease of use of the talking touch screens and, therefore, played a role in the high satisfaction outcomes.

Strengths and Limitations

It is a strength of this study that all 3 aspects of usability, instead of just satisfaction and efficiency, were thoroughly tested and that all of the results of the tests were differentiated for inexperienced and little- and average-/high-experienced users (which was not the case in the reports of the comparable studies [44-50]). To this date, this is the first study on usability of talking touch screens that has taken this approach. As a result, an insight was gained into what kind and amount of usability problems are encountered by the most vulnerable group of potential users.

It is a strength in itself that inexperienced as well as little and average-/high-experienced users of mobile technology were included in this study. Although recommended in the literature [12,53], to this date, there has been an insufficient number of empirical studies to prove the worth of involving future users at risk of exclusion in the development process of eHealth tools [54]. In a recent review, Latulippe et al found only 3 studies that involved future users at risk of exclusion in their design and evaluation processes [8]. This study contributes to the body of knowledge of inclusive mHealth design which involves active participation of vulnerable potential users in usability evaluation.

The qualitative TSTI method [32] was chosen for data collection in this study. This method was never used in a usability study before. The results of this study show that the TSTI method is suitable to gain insight into the usability of mHealth tools. It helped the researchers to understand not only what kind of usability problems occurred but also what caused these problems to occur and what effect encountering the problems had on participants. In addition, this method suited the needs of low-educated and low-literate participants by not demanding any reading or writing skills from them. A downside of the chosen method is the lack of generalizability of the data.

A limitation of this study was that participants were encouraged by the interviewer to try touching the screen again when they looked startled because it did not react to their initial touch. This may have influenced the results on effectiveness because it is unknown what would have happened if the interviewer would not have interfered. This may vary from no effect because the participant would have tried it again anyway, to a higher frequency of occurrence of problem 8, to more participants prematurely stopping to complete the DTTSQ because of being under the impression that the app had stopped working. Any kind of interference in the process of usability testing has a direct influence on the effectiveness results and possibly also on the efficiency and satisfaction results and should therefore be avoided.

Conclusions

The usability of the DTTSQ needs to be improved before it can be released. No problems were found with satisfaction or efficiency during the usability test. Effectiveness needs to be

enhanced by (1) making it easier to navigate through screens without the possibility of accidently skipping one, (2) enabling the possibility to insert an answer by tapping on the text underneath a photograph instead of just touching the photograph itself, and (3) making it easier to correct wrong answers. Participants additionally recommended to minimize the length of the instructions and present all the answering options of question 4 in one screen.

Directions for Future Research

During further development of the DTTSQ, both the results of this study and the study on response process of the DTTSQ [36] should be taken into account simultaneously. The usability and the response processes will have to be retested in exactly the same manner after adjustments in the DTTSQ have been made. This process will have to be repeated until an acceptable level of usability and face validity of the DTTSQ are reached. The next step in research should be quantitative usability, validity, and reliability testing producing generalizable data.

Considering the difference in the number of problems encountered by inexperienced and little-experienced participants versus average-/high-experienced participants within this study, it can be concluded that in striving for an inclusive design, it is vital to involve potential users at risk of exclusion during further development and testing of the DTTSQ. Selecting quantitative methods for this purpose may be quite challenging because the researchers will have to develop a quantitative study design that will enable people with low literacy skills and low educational levels to participate. Research designs that include reading and writing tasks for participants are ineligible because these tasks may lead to exclusion of these vulnerable and hard-to-reach populations [55].

Researchers who want to investigate the usability of mHealth tools in populations that include little-experienced or inexperienced participants should take into account that the expectations of these participants may easily be exceeded resulting in high participant satisfaction outcomes regardless of the effectiveness and efficiency with which the tool is used. Satisfaction outcomes are influenced by the expectations that participants have before the test. It could be interesting to measure and further investigate computer anxiety and self-efficacy toward the use of the tested tool before and after usability testing to be able to put satisfaction outcomes into perspective.

Further research is necessary to gain more insight into the needs, preferences, capacities, values, and goals in relation to mHealth technology of people with low literacy skills, low educational levels, and no or little experience with using mobile technology. Insight is also needed into what effects meeting these user requirements will have on actual future use of these tools by these specific populations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
An overview of the screenshots of the Dutch Talking Touch Screen Questionnaire.
[PDF File (Adobe PDF File)1288 KB - formative_v3i3e11617_app1.pdf]

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Abbreviations

DTTSQ: Dutch Talking Touch Screen Questionnaire
eHealth: electronic health
ICT: information and communication technology
mHealth: mobile health
TSTI: Three-Step Test-Interview

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Original Paper

Using a Mobile Diary App in the Treatment of Borderline Personality Disorder: Mixed Methods Feasibility Study

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Abstract

Background: Borderline personality disorder (BPD) is a disorder characterized by difficulties with regulating emotions and impulsive behavior. Long-term monitoring of progress during BPD psychotherapy constitutes a challenge using paper and pencil registration. Hence, a mobile app assessing emotions and progress in treatment may be useful.

Objective: The aim of this study was to examine the feasibility of using the mDiary app as an adjunct to dialectical behavior therapy (DBT) for the treatment of BPD.

Methods: A total of 9 focus group interviews were conducted and analyzed according to the grounded theory approach. Furthermore, the usability of the mDiary app was examined using the System Usability Scale (SUS). The app was implemented in a standard DBT program as an adjunct to DBT. In total, 16 patients (age range 19-41 years) and 23 therapists (age range 25-64 years) from 5 Danish public outpatient psychiatric treatment facilities participated in the study.

Results: Overall, patients were satisfied with the mDiary app, as it was “easy to use” and “always there.” Inside-out innovation, meaning new work tasks generated during implementation and communication of modifications needed in the app, was found to influence the perceived usability negatively among the interviewed therapists. The patients rated the usability as high (mean SUS score 81.2, SD 9.9), whereas therapists rated the mDiary app at an average level (mean 68.3, SD 14.3). Older age of the users correlated with lower usability ratings on the SUS score (Pearson r=−0.60).

Conclusions: The mDiary app was considered as an acceptable and relevant way of registering DBT diary data for both patients and therapists generating increased long-term overview. Older users were overall more reluctant to accept this new technology in clinical practice. Time to align expectations among involved parties needs to be set aside when implementing this new approach to patient monitoring. Here, the focus should be on the realistic use of resources and expected impact on present clinical work.

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KEYWORDS

borderline personality disorder; mHealth; implementation; focus groups; e-diary; mobile app

Introduction

Borderline personality disorder (BPD) is characterized by emotional instability across a number of domains: mood, interpersonal relationships, self-image, impulse, and behavioral control. Generally, these BPD manifestations are attributed to a lack of ability to regulate emotions. Norwegian female patients with a personality disorder have a 38-fold increased risk of death by suicide compared with the general population [1]. In Denmark, Sweden, and Finland, the mortality of patients, who at some point have been admitted to hospital because of a mental disorder, is shown to be 2 to 3 times higher than in the general population [2]. It is estimated that between 1% and 5% of the Scandinavian population and 1.5% of the population in the Western world meet the criteria for BPD [3-5]. Around 10% of BPD patients will die from suicide, with most of these deaths occurring before patients reach 40 years of age [6]. The prevalence of BPD in clinical populations is estimated to be around 28% (range 9.3%-46.3% of patients across studies) [6].

Dialectical behavior therapy (DBT) has shown good clinical efficacy and is regarded as 1 of the most well-researched evidence-based treatments for BPD [5,7-9]. The main focus of DBT treatment is the learning of a predefined set of behavioral skills that target lack of emotional, mental, interpersonal, and behavioral control [10]. In standard clinical practice, evaluation of a patient's progress in learning DBT skills is left to the clinician's subjective memory and the weekly evaluation of paper-based client diary cards [11]. Although it is possible to go back and review progress over time, this is very time consuming and outside the realistic use of resources when using weekly paper-based diary cards in psychotherapy. An advantage when comparing app-registration with paper diaries would seem to be the addition of a long-term overview of patients' scores and a better overview of patient-acquired DBT skills [12].

Self-monitoring would logically reduce patient burden, increase compliance in registration, and generate new opportunities for long-term overview of patient progress [13]. Digital health care practice, treatment supported by computers or mobile phone apps, and addressing self-monitoring for BPD have been successfully tried on a smaller scale on an ad-hoc basis [14] as an adjunct to trauma work [15]. *Priovi*, a computer program adjunct to Schema therapy for BPD, has recently showed a significant effect on BPD symptoms [16]. Internet-delivered DBT skills training for suicidal and heavy episodic drinkers have also shown feasibility and promise in a pilot randomized control trial (RCT) [17]. In total, 2 different apps targeting DBT skills training have been developed by researchers from University of Washington and Rutgers University, the *DBT coach* [18] and *Pocket skills* [19]. These apps showed promise and acceptability among users. The end users in the *Pocket skills* study voiced a preference for visualization of diary card scores and aggregated scores. The mDiary study seeks to fill this gap in research. The platform and app for the study was developed by the first author and Monsenso. Monsenso has previously developed an app solution aimed at self-monitoring symptoms in the treatment of patients with bipolar disorder [20-22] and has now developed a modified Monsenso platform called the mDiary app.

The objective of this study was to examine the feasibility of using the mDiary app as an adjunct to DBT in the treatment of BPD.

Methods

Study Design

Using a mixed-methods approach, the feasibility of the mDiary app was assessed with qualitative interviews in 9 focus groups, as well as evaluations through a questionnaire measuring perceived usability. A total of 5 focus groups were dedicated to therapists only, whereas 4 were dedicated to patients only. Interviews were conducted on-site. Data from the interviews were recorded on an MP3 recorder during the interviews and transcribed verbatim afterwards.

Patients and therapists participating in the focus group interviews were concurrently given the System Usability Scale (SUS) [23] to evaluate system usability. SUS is widely used and is a valid and reliable assessment tool for usability of digital interventions. The total SUS scores are ranked from 0 to 100, where 100 represents the highest usability and a score of 68 reflects an average level of usability [24].

The quantitative data were used to formulate a theory of barriers and facilitators. The grounded theory (GT) approaches [25] of open, axial, and selective coding as well as theoretical sampling, ongoing development, and internally relating of concepts were used in the analysis.

The trustworthiness of the findings, in the sense that a credible and true picture of the phenomenon under scrutiny was presented [26], was addressed by basing conclusions on the verbatim transcripts of the focus groups [26], by discussing the derived concepts among the participating researchers, and by applying a form of triangulation of data by interviewing both therapists and patients and doing this separately, as well as using the SUS scores in the initial formation of a theory of barriers and facilitators. Trustworthiness was increased further by making comparisons of the findings with other broader theories of implementation of technology in the field.

Participants

All participating patients were enrolled in active DBT treatment in Danish public outpatient psychiatric care from January 2016 to December 2016. Before entering the study, all patients were assessed by a psychiatrist with the International statistical classification of diseases and related health problems. - 10th revision, Fifth edition, 2016 diagnostic manual.

. Patients were eligible for inclusion if they met the criteria for emotionally unstable personality disorder (F60.3), were admitted for psychiatric outpatient treatment, had at least 1 suicide attempt or at least 1 episode of self-harm within the last year, and active problems with suicidal and self-harm urges. Patients were excluded if they had no access to or ability to use a mobile phone or had a comorbid disorder, such as substance abuse, bipolar disorder, or a schizophrenia spectrum disorder. The majority of patients had comorbid disorders, such as depression, anxiety, posttraumatic stress disorder, substance abuse, and obsessive-compulsive Disorder. Alcohol and substance abuse

were allowed if it was not the primary diagnosis. After admittance to DBT treatment, BPD symptoms and diagnoses were rechecked again in a separate individual session with an experienced therapist.

The patients' mean age was 28.0 years (SD 6.2). Half of the sample had completed primary school or less and the other half had secondary education or more. All patients were enrolled in a 12-month DBT program [27] but were at different stages in their treatment program: 10 patients were in the beginning (months 1-3) of their treatment, whereas 6 patients had attended treatment between 4 and 12 months. All study subjects had previously tried paper registration and had switched to app registration for at least 4 weeks.

A total of 23 DBT therapists participated in the study. Half of the therapists were psychiatrists or psychologists and the other half were nurses, occupational therapists, or psychotherapists.

They had DBT therapy experience in the range of 1 to 14 years (mean 6.8 years). Their mean age was 44 years (SD 12). The therapists had different levels of experience with using the mDiary app solution, ranging from 1 month to 1 year.

Description of the Platform

The mDiary app was customized for dialectical behavior therapy treating borderline personality disorder. This platform consists of 2 modes of data handling: mobile phone-based and Web-based. Patient data were entered by the patient on a mobile app.

The Mobile Phone Sections

The mobile phone part of the system retrieves registered data, produces visualizations of that data, and delivers pre-entered psycho-educative material. This app replaces the previously used DBT paper-based diary card. It delivers descriptions of DBT skills in a short text format and in a 3-min sound clip format. Main variables collected by the app are prioritized as mandatory. Mandatory variables can only be modified by Monsenso. In our study, they were day score, dysregulation duration, dysregulation level, emotional numbness, and skill-use. The mandatory ratings were on a 0 to 5 scale. Skills was rated as *learning* or *learned* and could be switched on independently as they were learned. Other variables were optional, for instance: self-harm, drug use, specific basic emotions, and many more. These optional variables could be selected from a long list of typical BPD problem behaviors preprogrammed on the app. Finally, personal customizable variables could be constructed by the user.

Figure 1 shows mobile app screens. Screenshot A is of the daily input screen registering dysregulation level. Screenshot B is an example of a screen visualized after entering the data long term. Screenshot C is a screenshot of the text section and sound clip control buttons for generalizing the skill named *Stop*.

Many other subscreens were available on the mobile phone: daily notes, dedicated questionnaires, medication, triggered notifications, and a large library of psychoeducative material regarding the diagnosis.

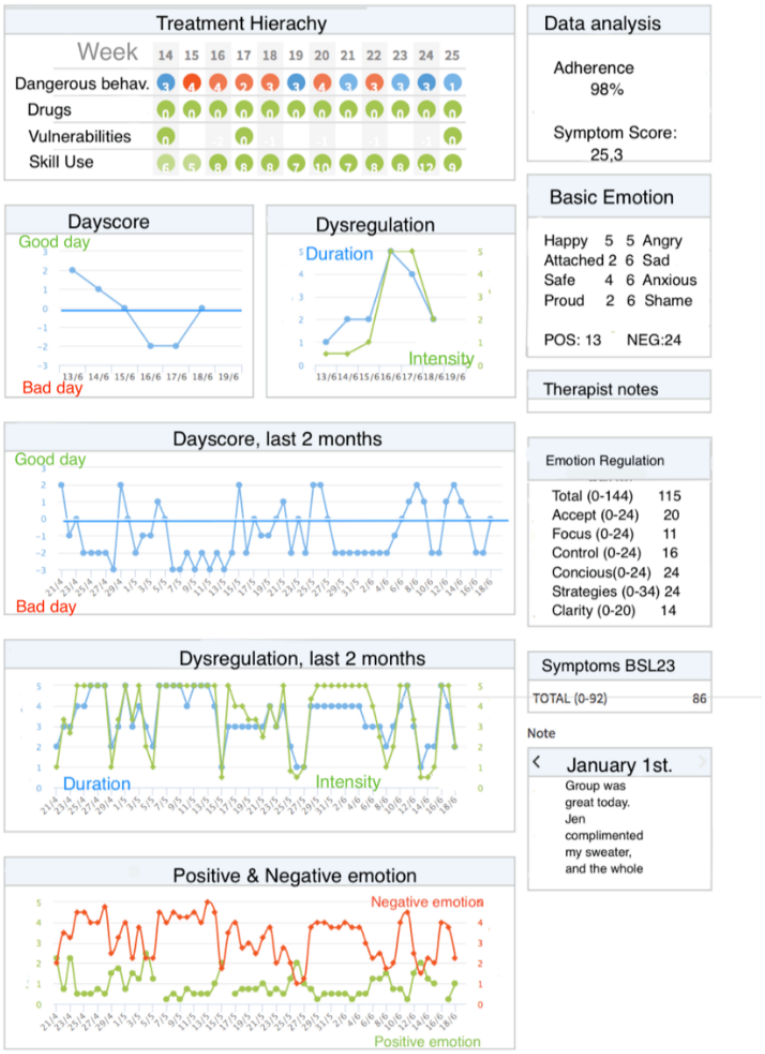
Figure 1. Mobile app screenshots.

The Web-Based Overview Screen

The Web-based section of the system has an overview screen intended for a tablet or desktop. This is primarily used in the therapy session to monitor the present state and progress of the patient in treatment. Here, the patient and therapist can explore the entered data together. The same screen can be accessed by patients from home via their computer. The Web-based interface gives a far more detailed current and long-term overview of the treatment progress than what is possible on a mobile phone screen. Submenus of the Web solution part include the following: a time series format overview, diary text overview, and skill utilization overview. For therapists, there is an extra protected section for creation and administration of new patients in the system and the ability to access the data of all the patients the therapist is treating.

Figure 2 provides an example of the main therapist overview screen. Here is an example of ratings from a patient who has started previous week out with good days, but then has had higher levels of dysregulated emotion later in the week. It is possible to follow self-harm, drug use, and skill use for the past 12 weeks in the top of the screen. If suicidality or self-harm is present, a red dot marks that week. It can be seen that this patient has had an episode of self-harm or a suicide attempt in week 22, a month ago. At the bottom, total scores of positive and negative affects are displayed, also showing the past 2 months. The right side of the figure shows adherence to registration, symptom scores, results of questionnaire registrations collected by the app, and below that diary text for single days can be seen.

Figure 2. The therapist overview screen.



Procedure—Development of the App

The primary development site, Site 1, was contacted by the Danish electronic health company, Monsenso, to assist in developing a BPD-specific Web- and mobile phone–based monitoring system. They started developing and testing the basis of the modifications of the already developed platform [21]. As this platform was originally developed for bipolar disorder, adjustments and modifications had to be made. After 4 months, Site 2 was invited to consolidate the improvements made, by testing further in the clinic; 10 months later, 3 new sites were invited to try out the solution in the clinic and report problems back to the app development team.

Analysis of the Focus Group Interviews

The study followed a GT approach [28]. The duration of all focus group interviews was 1 hour. During the interviews, a whiteboard was divided into a matrix of 2 rows by 3 columns: 2 horizontal rows held *pros and cons*; 3 vertical columns held the themes *paper*, *app*, and *future scenarios*. The participants were given sticky notes and encouraged to place them on the whiteboard and discuss the reason(s) for placing the input as either a *pro* or a *con*. The discussion was moderated by the principal investigator (SHJ) and 1 of the cowriters (TS). Themes from earlier interviews were offered to the participants when statements differed from what was discussed in the focus group (theoretical sampling). The qualitative analysis of the focus groups was performed in different steps as discussed further.

In Group

The first part of the analysis was done in collaboration with the patients using sticky notes at the end of the focus group session. The sticky notes that related to each other were grouped into themes by the participants on a whiteboard. This can be seen as the first part of the open coding in the analysis, the identification, and labelling of discrete happenings.

After Group

The emerging themes and other input were collected for later analysis by the researchers. Questions arising from previous interviews were discussed with the next interview group. After data collection, open coding themes were compared among the different focus groups and after another round of open coding done by the researchers, the resulting categories were arranged into axial coding categories, making connections between the open code labels. These categories were condensed from broader concepts and eventually a core category that we settled on calling *inside-out innovation* (see Barriers and Facilitators in the Results section), arose from the data through selective coding [25]. Perceived usability (SUS) in development sites versus age can be seen in Figure 3. The results of relating the concepts to each other can be seen in Figures 4 and 5.

The research sites were 5 specialized BPD treatment units (Table 1). They were all Danish public outpatient psychiatric facilities treating BPD with DBT.

Figure 3. Perceived usability (SUS) in development sites versus age.

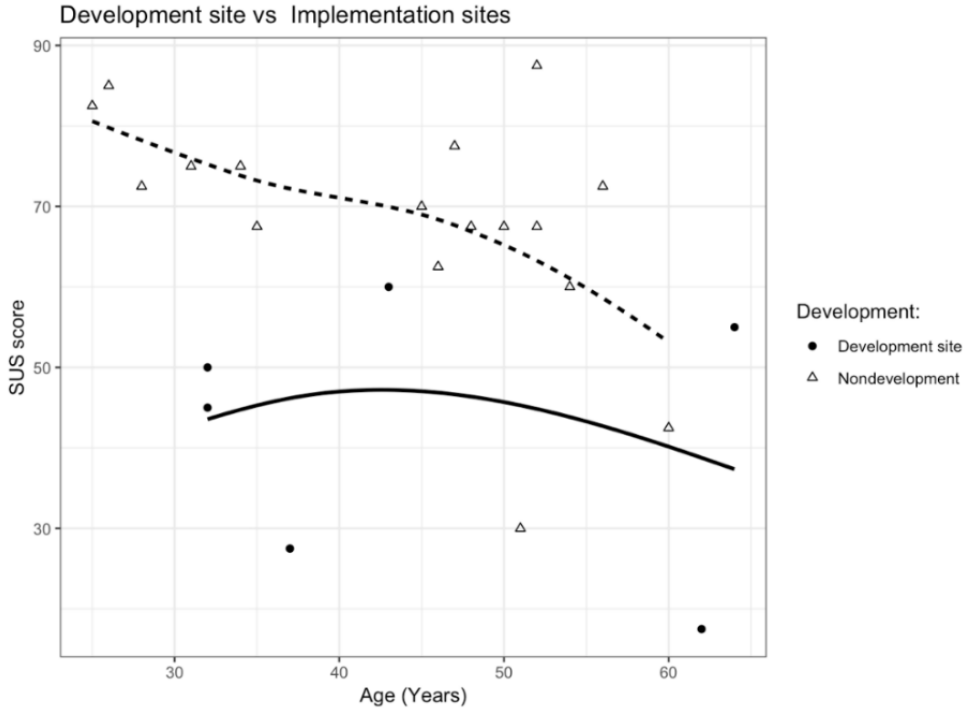


Figure 4. Inside-out and outside-in innovation.

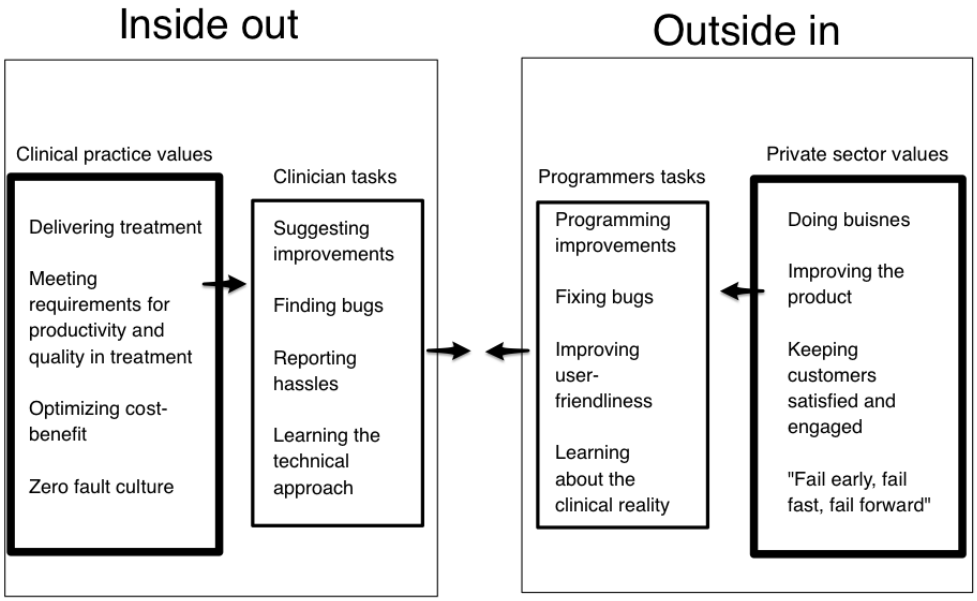


Figure 5. Balancing Inside-out hassles.

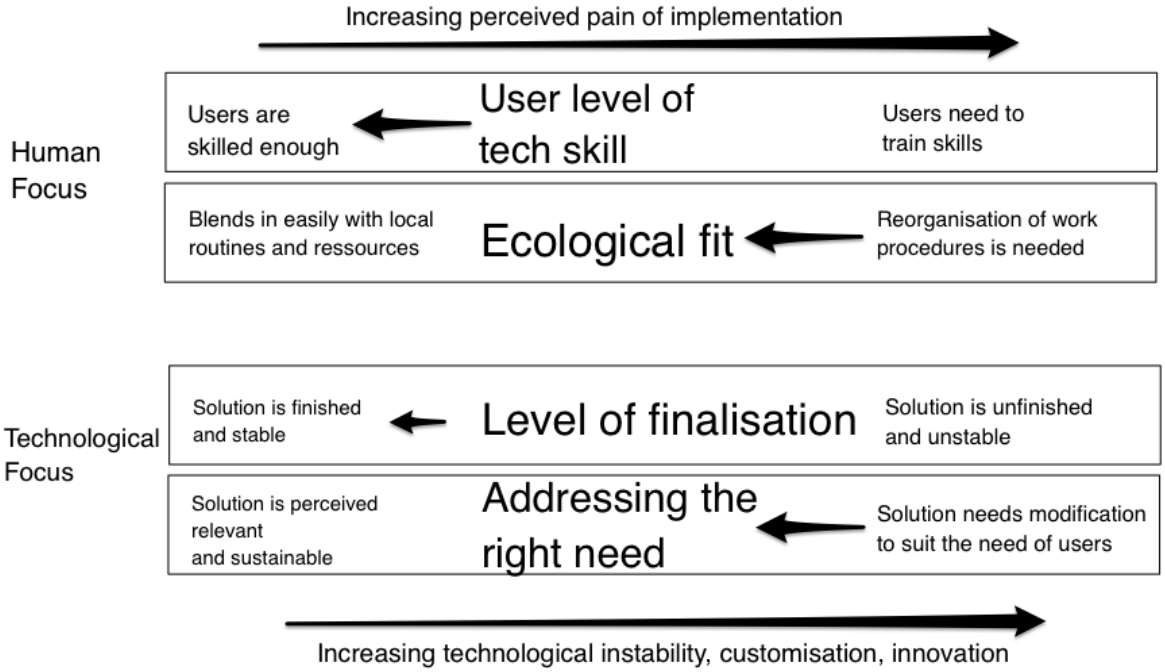


Table 1. Descriptions of participating dialectical behavior therapy sites.

Site number	Role	Duration of app use	Iterative feedback cycles[a]	Number of therapists	Number of patients
1	Primary development site	14 months	70	6	4
2	First testing and feedback	10 months	18	6	5
3	Recently involved	5 weeks	1	4	3
4	Recently involved	1 month	1	3	4
5	Recently involved	1 month	2	4	0

[a]Number of times a suggestion for improvement or a bug was acted upon by adjusting software.

Ethics

Patients signed an informed consent form before study participation. The study was approved by the Danish Ethics Committee in Region of Southern Denmark (S-20160085). The study protocol was approved by the Danish Data protection Agency (2008-58-0035). The approved database system used was Odense Patient Data Exploratory Network (OPEN) [29].

Results

Accepting New Technology

The SUS ratings showed that overall, patients were very satisfied with the solution (Table 2). Therapist SUS ratings were generally significantly lower compared with those of the patients (P<.001). Older users tended to rate lower usability than younger users (Pearson correlation coefficient: −0.60). At Site 1, the primary development site, therapists were significantly less satisfied than at the later development sites (P=.01), see Table 2 and Figure 3.

As shown in Table 2 and Figure 3, the first development site reported significantly lower usability than the rest of the sites, with scores falling below an SUS score of 60.

The therapists with the most influence on the development were the most critical of the solution. This is probably because they spent the most time dealing with bugs and problems. Our therapist SUS scores suggest that usability improved with every iteration of the development cycle, as more recent adopters had higher SUS scores and were generally more positive in the interviews than early adopters.

Table 2. System usability scores for subgroups of users.

Subgroup of users	n	Score, mean (SD)	P value[a]
Subgroup 1			**<.001**
Patients	16	81.2 (9.9)	
Therapists	23	61.6 (18.6)	
Subgroup 2			**.01**
Therapists (development sites)	6	42.5 (16.5)	
Therapists (nondevelopment sites)	17	68.4 (14.4)	

[a]*t* test, *nonpaired.*

Barriers and Facilitators

Implementation seen from the outside or from the inside is a matter of perspective. We define *inside-out innovation* as the instability introduced into the treatment context owing to introductions of new work tasks accompanying development and implementation. For instance: learning to use the app, adaptations needed in the context, getting the solution to work technically, and fitting the solution to the needs of the most important work tasks.

This can be seen as a complementary process to the *outside-in innovation*, which means new technology brought to the hospital from an external source. In the mDiary study, the outside-in innovation was the technical solution delivered from Monsenso. They delivered a starting point, a solution that had a general applicability, but were influenced by an outsider's perspective regarding the specific mental health context it was implemented in.

A central barrier in the development process was found to be the inside-out innovation part.

A suggestion for reconfiguration would typically come from the involved users' perspective. Figure 4 shows what is seen as valuable from either an outside-in perspective or an inside-out perspective. The smaller squares in the figure show the concrete behavioral actions associated with the 2 perspectives.

When comparing in-clinic innovation with simply implementing a solution already developed and finalized, the effort needed is very different: Reporting hassles and giving suggestions for improvement back to the app developers, upgrading to new versions, reporting technically succinct accounts of bugs back to the app developers (eg, "The bug was on which version of the operating system? What type of phones had the problem? Under precisely what conditions?"), and maybe the clinician encounters trouble accessing data or meet unexpected needs for technological upgrades. All this is time consuming and requires focus and energy, leading to multiple small reductions in time for other tasks. Even if the mDiary study was a time-limited endeavor, this led to frustrations among the clinicians involved in the development. The same demands of productivity during the development phase was expected as within normal operation of the clinic. Mental health workers view delivery of psychosocial treatment as their primary goal. Without clear alignment of expectations and extra resource allocation, this generated frustrations:

> *I feel that I'm letting the project down. I do not have time to do it properly. I need more training and we have lots of other more important tasks to do, too. I'm not so fast with a smartphone and...It's a bit embarrassing, and I feel that I come out short, but the time is not there. It has been quite a burden.* [Nurse, site 1]

In the end, this came down to differences in values: In Figure 4, different views on finding faults in the mDiary app can be traced. The app developers' perspective finds exploration of faults in the system as a very worthwhile endeavor in accordance with the AGILE project management approach that finds value in *fail early, fail fast, fail forward* [30], whereas therapists

typically adhere to a value of minimizing faults at any cost owing to increased patient risk factors [31]. From one perspective, value might mean ability to fail often and fast thereby creating stability and profitability on the long term, whereas from another point of view, value might mean treating a specific patient, here and now, effectively without the delay of reporting bugs back.

Balancing Acceptance and Change During Inside-Out Innovation

The concept of *balancing acceptance and change* is borrowed from individual DBT psychotherapy [27]. We found this concept helpful to describe barriers and facilitators in the inside-out process. It seems that finding a balance between the status quo and changing old routines is essential and a culprit of many frustrations encountered during implementation.

When improvements were made, new procedures needed to be invented in the clinic, and uncertainty was added to known procedures. It was found that the introduction and development of new technology was a balancing act between *acceptance* and *change*. It could in other words be described as a search for the *optimal level of frustration of the users*. The central task was generating the largest amount of long-term positive change possible while keeping time use optimally focused on delivering therapy to the patients here and now. We have condensed the main acceptance-change dilemmas into 4 main sources of hassle, as shown in Figure 5.

The first 2 dilemmas were related to human factors.

User level of technical skills: The first dilemma was out-of-the-box intuitive usability versus training needed before the app was usable to the users. Note that here the term *user* relates to both staff and patients:

> *I'm not very good at computer stuff, I'm a slow learner.* [Therapist]

Ecological fit: The second dilemma was high versus low need for reorganizing known procedures and daily habits. The slight modification of therapy rules and procedures demanded new procedures at the organizational level:

> *What happens when the project stops...how can I access the data in 2 years if the patient is admitted again?...will we still have the app?* [Therapist]

This could imply new difficult-to-solve problems involving both developers and other layers of the hospital administration.

Another aspect of ecological fit could be seen from a patient perspective:

> *The smartphone is much easier than paper. Most of us bring it along all the time, it's always there!* [Patient]

The final two dilemmas were related to technological issues.

Level of finalization: The third dilemma was the paradox between having a stable technological product, that is, where the coding is consolidated, versus a more flexible solution where coding is a *work in progress*. Users want both specific tailored solutions suited to the context and at the same time they want the system to be stable. During the development of a new system, it is difficult to have both:

> *The app is really helpful, but I get really annoyed when things disappear. In the beginning something went wrong, my first 2 weeks of registrations were just lost.* [Patient]

Addressing the right need?: To what extent did the technological solution come across as relevant and sustainable here and now? To what extent does it need modification to effectively address the specific mental health problem the clinician is supposed to solve?:

> *Why does it need to track my phone calls and my emails? What is it for? I think it's creepy.* [Patient]

Monitoring activity by GPS coordinates and counting time spent on talking on the phone were quite easy to do in the solution. Sensors were present in the mobile phones and the coding was already in place as it was used in the bipolar solution. It was not possible to switch this off, and since it was collected passively, it seemed like it did not take extra effort from the patients. The specific task of monitoring mood and skill use, however, did not require this, as it was not a therapeutic necessity. The BPD patients saw this kind of activity monitoring as an unnecessary invasion of their privacy, so even if it was easily accessible and possibly interesting—it was not enough a part of the central task at hand, and thus did not have enough direct relevance to patients. Monsenso, on the other hand, was quite reluctant to let go of this feature. Here, different needs seen from the outside-in and inside-out perspectives stood out clearly. The inside-out perspective seemed to favor utility here and now. The outside-in perspective tended to favor the long-term potential creating big data from the same variables across different diagnosis.

Discussion

Principal Findings

The acceptance and usability of the mDiary app was generally high among patients. The SUS scores showed sufficient acceptability among most of the test site therapists. But the primary development site had significantly lower acceptance of the solution. The therapists most involved in the development process were surprisingly the most critical. We have attempted to explain this with a hypothetical concept of inside-out innovation. We found that the most important dilemmas within inside-out implementation were related to user levels of technology skills, ecological fit, finalization of the app, and addressing the right need.

Accepting New Technology

Resistance to implementing new technology in the health care setting is a well-known problem [32]. Since Davis' seminal paper in 1989, the Technology Acceptance Models has focused on *perceived usability* and *ease of use* as central variables for the successful implementation of new technology [33,34]. This theory targets implementability by reducing complexity to the individual adopter's viewpoint. The model has been replicated many times and specific data on health care found ease of use being less important than usability in health care settings

[34-36]. Realizing that a more multifaceted approach was needed, Venkatesh et al [37] tested several variables, such as gender, age, experience with performance expectancy, and effort expectancy that could impact the user's acceptability and satisfaction with technology. They also included the influence of attitude and social factors on behavioral intention to explain resistance more broadly using both background variables of users as well as attitudes. This extended model led to the formulation of the *Unified theory of acceptance and utilization of technology* [37]. In mDiary, usability scores followed this logic as it was found that user age influenced the SUS scores.

Inside-Out and Outside-In Innovation

Van Gemert-Pijnen et al [38] have pointed out that innovation in mental health is a "collaboratory participatory process of constantly changing cycles." *Values* in this cooperation are considered central. Values refer to what is considered meaningful in the context, not only economic value. Van Gemert-Pijnen described innovative change using 4 axes: *business model*, *value drivers*, *user requirements*, and *prototyping*. Value specification is considered important in obtaining desirable cooperation: *Value specification implies the recognition and quantification of the economic, medical, social, or behavioral values of the key stakeholders* [38]. Van Gemert-Pijnen's approach can be thought of as a broader theory looking at implementation from a systems perspective, focusing on different or shared values in the systems' interaction. Value specification was found to be important in our data. This is most clearly seen in the *addressing the right need* part of Figure 5 and the value sections in Figure 4.

Balancing Inside-Out Hassles

The hassles captured in the concepts *inside-out innovation* and *ecological fit* have been described in a study by Heeks when he was exploring what he called the design-reality gap [32]. Perspectives differ whether you are a programmer or a user. This is an analog to the *user level of technological skills* dilemma found in Figure 5. The gap in *technology* between design and reality in Heeks' theory can also be thought of as a case of poor *ecological fit* from our model.

Greenhalgh et al [39] have formulated a theory of "Nonadaptation, abandonment, scale-up, spread, and sustainability of new technology (NASSS)." The values described in Figure 4 fit very well as a theoretical clarification of Greenhalgh's description of different types of *value propositions*. One value is described by her as "knowledge needed to use the technology." She suggests that it is helpful to range this from simple to complex needs for knowledge. This is a similar concept to our *user level of technological skills* described in Figure 5. A concept similar to *level of finalization* in the same figure is also addressed by Greenhalgh, who found *dependability* to be a key value [39]. The dilemma of *addressing theright need* is covered in her theory as differences in *value propositions*.

This phenomenon of differences in inside-in and outside-in perspectives has also been addressed by Van Gemert-Pijnen et al [38], who also view explication of values of stakeholders as central to successful implementation. The Figure 5 elements of what we call *ecological fit* and *skills needed* are here conceptualized as differences in specification of what has value to whom. The following quote from Van Gemert-Pijnen (p. 10) sums up what we have encountered in developing and testing the mDiary app:

> *Implementation is often seen as a post design activity. In our view, the conditions for implementation must be considered right from the start (contextual inquiry and value specification). Potential implementation issues, such as limited resources (eg, time, staff, and money) or personal drawbacks (eg, skills, motivation, and anxieties), should be identified. These issues should also be accounted for in the subsequent stages (design and operationalization). In this way, the well-known pitfalls of stakeholder disregard can be avoided [38]*

This quote illustrates that the needs related to implementation depend on which perspective you take. The value of implementation is to some extent negotiable and different depending on which stakeholder perspective you take. Designing, implementation, and enhancing usability are all part of the same circular process. In the collaboration between Monsenso and public psychiatry wards, the needs of the patients, the needs of Monsenso, and the needs of therapists were all part of a continuous negotiation: a negotiation of whether to use the severely burdened patients' time on the long-term implementation of an—as yet untested—system; a negotiation of company resource utilization when improving the technical side of an app with an—as yet unknown ability to generate provenue; and finally, a negotiation with the therapists in getting them to allow for new procedures instead of established procedures of standard DBT treatment. The innovation in the mDiary app was this balancing act, eventually creating an app to the mutual benefit of all involved parties.

Limitations and Strengths

The study should be interpreted with the following limitations in mind. The number of participants and focus groups was small albeit adequate for a feasibility study. The sample was not randomly selected, but a select sample where patients were given a choice whether they wanted to test the mDiary app as a potential replacement for using paper and pen. Owing to the research method and sample size, the results can only be considered hypothesis-generating. In terms of trustworthiness, it must be noted that group polarization and mutual avoidance of discomfort could influence the results. The patient group is known to avoid difficult emotions [27] as well as being unstable in their baseline emotions [40], which might influence answers toward a more emotional direction. A large part of the sample of therapists were older and very well consolidated in the DBT procedures, which could lead to negative bias regarding approaches aimed at changing well-known procedures [41]. The study also has several strengths, including the involvement of the end users (both patients and therapists) in the development of the platform/app and a thorough and iterative process to optimize the platform/app.

Conclusions

The mDiary app is a useful and acceptable way of registering DBT diary cards, tracking emotion regulation, and skill acquisition and is now ready for implementation. Our data suggest adequate usability and feasibility in clinical departments with higher perceived usability from patients compared with therapists. At the present stage, the app is sufficiently ready to be used in further studies evaluating effectiveness. This will be done in the mDiary RCT study.

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Conflicts of Interest

None declared.

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Abbreviations

BPD: borderline personality disorder
DBT: dialectical behavior therapy
GT: grounded theory
RCT: randomized control trial
SUS: System Usability Scale

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Original Paper

Pedal-Assist Mountain Bikes: A Pilot Study Comparison of the Exercise Response, Perceptions, and Beliefs of Experienced Mountain Bikers

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Abstract

Background: Mountain biking is an aerobic physical activity that has experienced rapid growth. The emergence of the electric pedal-assist mountain bike (eMTB), while not without its critics, presents the potential for an even larger segment of the population to enjoy the health benefits of mountain biking. Although the research focused on the use of e-bikes generally is growing, there is limited research specifically targeting eMTB use. Research is needed exploring the potential exercise response of riding an eMTB, together with the beliefs and perceptions of mountain bikers who have and have not experienced eMTB riding.

Objective: This study aimed to compare conventional mountain bike and eMTB use. This was done by investigating 2 questions: (1) *What proportion of exercise response is retained for an experienced mountain biker while using an eMTB when compared with a conventional mountain bike?* and (2) *What are the perceptions and beliefs of experienced mountain bikers toward eMTBs both before and after riding an eMTB?*

Methods: A convergent mixed methods data collection approach was used in the study. Participants completed both a pre- and postride questionnaire, and data regarding heart rate were collected. Heart rates from each ride were compared against each other.

Results: The average heart rate during eMTB use was 94% (31/33) of the average heart rate during conventional mountain bike use. Therefore, eMTB use in this study achieved a majority of the exercise response and exceeded established biometric thresholds for cardiovascular fitness. Paired *t* test statistics were calculated to compare beliefs of conventional mountain bikes and eMTBs and to compare mean heart rate and speed between conventional mountain bike and eMTB use on the study loop. Participants overwhelmingly perceived the potential impact of eMTB use to be positive on both pre- and post-eMTB ride questionnaires.

Conclusions: Despite the measured benefit, participants' perceived exertion while riding the eMTB was low.

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KEYWORDS

public health; physical activity; heart rate

Introduction

Promoting physical activity is an international public health priority [1,2]. The United States Department of Health and Human Services (HHS) recommends that adults engage in moderate aerobic physical activity for at least 150 min each week or vigorous aerobic physical activity for 75 min each week or a combination of both [3]. In spite of the recommendation, the Centers for Disease Control and Prevention (CDC) estimate that only 20.9% of adults in the United States fulfill the recommendation [4]. There are many reasons attributed to the disregard, and potential solutions have been implemented and studied. This study investigated the physical activity of electric pedal-assist mountain biking as a viable solution to improve compliance with HHS recommendations.

Mountain biking is an aerobic physical activity that has experienced rapid growth in the United States [5]. However, mountain biking is often limited or perceived to be limited to those individuals who already enjoy a relatively high level of cardiovascular fitness and endurance. The emergence of electric pedal-assist bikes (e-bikes), and specifically electric pedal-assist mountain bikes (eMTB), presents an opportunity for a larger segment of the population to enjoy the health benefits of mountain biking [6]. A review of e-bike literature supports the hypothesis that e-bike use is a beneficial physical activity for a wide range of individuals with an added benefit of promoting health among individuals otherwise reluctant to engage in physical activity [7-12]. Recent studies suggest that e-bike commuting may be helpful in improving glucose tolerance [10], decreasing perceived exertion and improved enjoyment [11], and reducing barriers to conventional cycling, including commuting [13]. For example, results from a Web-based survey demonstrated that those using an e-bike to ride to work report an ability to ride greater distances while perspiring less, suggesting that e-bikes may reduce some of the personal barriers of conventional cycling as a form of active transport [14]. This combined body of research shows the potential physical health benefits of e-bikes.

A typical e-bike has an electric motor that functions as a pedal-assist, only engaging when the individual pedals. The motor's contribution allows a rider to cycle greater distances and up steeper terrain because of the decreased physical workload [14]. Though heart rate, energy expenditure, oxygen consumption, and intensity is generally lower compared with a conventional bike [7,13], e-bike use still produces moderate physical activity in comparable settings and between groups with differing fitness levels [8,9].

Although the research focused on the use of e-bikes is growing, there is limited research regarding eMTB use. There are 2 studies that investigated heart rate and energy expenditure between e-bike use with conventional bikes [7,13]. Each found that energy use was likely lower with e-bikes. Nevertheless, findings indicate that an e-bike rider still pedals and exerts energy, which may help them meet the physical activity guidelines and gain the associated health benefits. Part of our inquiry is to test this observation with eMTBs, which has not been done previously.

Although the popularity of e-bikes is growing and their benefits related to active transport and physical activity for a broad segment of the population are being established, the introduction of eMTBs to the mountain biking community has been met with much resistance. Concerns have been raised concerning eMTB use and increased trail damage, increased conflict between trail users, a potential for decreased trail access, and the perception that pedal-assist mountain bikes are akin to motorcycles and do not represent *real* mountain biking. These concerns have the potential to limit the adoption of eMTBs by individuals who may benefit from them or otherwise enjoy their use. To date, researchers are yet to explore any aspect of eMTB use, including the potential exercise response of riding an eMTB, as well as the beliefs and perceptions of mountain bikers who have and have not experienced eMTB riding. The purpose of this pilot study was to compare conventional mountain bike and eMTB use. In particular, this study aimed to address 2 research questions: (1) *What proportion of exercise response is retained for an experienced mountain biker while using an eMTB when compared with a conventional mountain bike?* and (2) *What are the perceptions and beliefs of experienced mountain bikers toward eMTBs both before and after riding an eMTB?*

Methods

Participants

Experienced mountain bikers aged between 18 and 65 years were recruited to participate in this study. Exclusion criteria included non–mountain bikers and mountain bikers with the inability to engage in moderate to vigorous intensity mountain biking for 12 miles or those who have a medical condition that would prevent them from moderate to vigorous exercise.

Procedures

The institutional review board at Brigham Young University approved this study. A study announcement was posted to a regional Facebook page popular with local mountain bikers. Individuals wishing to participate were directed to contact the principal investigator via email and set up a time to meet at a local trail system. Upon arrival at the trail system, individuals completed the pre-eMTB ride questionnaire using Qualtrics, a Web-based survey software platform, on their personal phone or the principal investigator's laptop computer. The first pre-eMTB questionnaire item included obtaining the individual's informed consent to participate in the study. Consenting individuals then proceeded to the remainder of the questionnaire. Upon completing the pre-eMTB ride questionnaire, participants were fitted with a heart rate monitor and corresponding Apple Watch. Each Apple Watch was paired to the heart rate monitor and Strava app to record the participant's ride data, including global positioning system (GPS) tracking, total distance traveled, and speed traveled. Next, participants were randomly assigned to ride the 6-mile study loop on either a conventional mountain bike or an eMTB. The study loop included approximately 700 feet of elevation gain spread throughout the ride with the most intense climbing section averaging a 5% incline over a distance of 1 mile. Upon completing the study loop on their initially assigned bike, participants' heart rate and Strava data were saved. Participants then rode the loop again on the remaining

bike—whichever type of bike they did not ride while completing the first loop. After completing the study loop a second time, participant heart rate and Strava data were again saved and each participant then completed the post-eMTB ride questionnaire. The study was completed between May 24 and June 16, 2018.

Instruments/Measurements

Both conventional mountain bikes and eMTBs were used in this study to establish a comparison between participants' heart rate and speed while riding the study loop. The electric mountain bikes used were Class 1 pedal-assist 2017 Specialized Turbo Levo FSR Comp Carbon 6Fattie models with a maximum assistance speed of 20 mph (32 kph) [15]. Participants were given the option of either riding their own traditional mountain bike or a 2017 Specialized Stumpjumper FSR Comp 6Fattie model—the equivalent of the Turbo Levo model without pedal-assist—while completing the non-eMTB lap of the study loop.

Third-generation Apple brand watches (Apple Watch) were paired with Polar H10 heart rate monitors to record the participants' continuous heart-rate data while completing each lap of the study loop. Total distance, speed, and time while riding was recorded during study laps using Strava, a mobile app using GPS technology available via the App Store for iOS and Apple Watch platforms. A comparison of participants' heart rate was used as a proxy measure to estimate exercise response. Specifically, estimated maximum heart rate (MHR) was calculated by subtracting the age of the study participants from 220. The estimated MHR was then used to establish a target average heart rate range for moderate-intensity physical activity (50%-70% of MHR) and vigorous-intensity physical activity (70%-85% of MHR). These ranges were calculated based on target heart rate recommendations from the CDC and the American Heart Association [16,17].

A total of 2 survey instruments, developed using the Web-based survey software provided by Qualtrics, were used in this study. Survey 1—the pre-eMTB ride questionnaire administered before riding either of the study bikes or loops—was used to gather basic demographic information, mountain biking history and experience data, perceived impact of eMTB use, and beliefs about eMTBs. Survey 2—the post-eMTB ride questionnaire—was administered after participants had completed riding the study loop on both a conventional mountain bike and an eMTB. The questions in Survey 2 were identical to the final questions asked in Survey 1, targeting participants' perceptions and beliefs related to eMTB use.

Analysis

All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc). Descriptive statistics were used to summarize demographic data from Survey 1. Paired *t* test statistics were calculated to compare beliefs about conventional mountain bikes and eMTBs and to compare mean heart rate and speed between conventional mountain bike and eMTB use on the study loop.

Results

Demographics

The majority of participants were male (88%; 29/33), and all identified as non-Hispanic and white. The average age was just under 38 years. All participants had completed at least some college. Complete demographic and mountain biking experience information can be found in Tables 1 and 2. Approximately half (16/33) of participants had more than 10 years of mountain biking experience. The majority (24/33) reported mountain biking at least twice each week. All participants indicated they mountain bike to increase fitness, spend time outdoors, and recreate or have fun. Few participants (n=3) had previously ridden an eMTB before participating in this study.

Exercise Response

Table 3 provides a comparison of average distance, time, speed, and heart rate metrics between conventional mountain bike and eMTB use as well as paired *t* test results.

Participants traveled approximately 5.5 miles (8.85 km) while riding the study loop. A paired *t* test analysis (Table 3) revealed participants completed the course an average of 12 min and 40 seconds faster when riding the eMTB as opposed to the conventional mountain bike ($P<.001$). The average speed of travel on the eMTB was 4.1 mph (6.6 km/h) faster than on the conventional mountain bike ($P<.001$). Participants' average heart rate during the eMTB ride was 9.9 beats per minute (bpm) lower than during the conventional mountain bike ride ($P<.001$). With a mean age of 37.8 years, participants' estimated MHR was 182 bpm. The target heart rate zone for moderate-intensity exercise (50%-70% of MHR) and vigorous-intensity exercise (70%-85% of MHR) was then calculated to be 91 bpm to 127 bpm (0.5x182=91.12, 0.7x182=127.4) and 128 bpm to 155 bpm (0.7x182=127.4, 0.85x182=154.7), respectively [16]. Riding both the conventional mountain bike and the eMTB placed participants' in the upper half of the vigorous-intensity zone (Table 4).

Table 1. Demographics (N=33).

Demographics	Value, n (%)
Age (years)	
20-29	7 (21)
30-39	9 (27)
40-49	13 (39)
50 and older	4 (12)
Race	
White	33 (100)
Ethnicity	
Non-Hispanic or Latino	33 (100)
Sex	
Male	29 (88)
Female	4 (12)
Education level	
Some college (not graduated)	8 (24)
2-year college degree	6 (18)
4-year college degree	12 (36)
Master’s degree	5 (15)
Doctoral degree	2 (6)
Annual household income ($ US)	
Less than 30,000	3 (9)
40,000-49,999	2 (6)
50,000-59,999	3 (9)
60,000-69,999	2 (6)
70,000-79,999	3 (9)
80,000-89,999	3 (9)
90,000-99,999	1 (3)
100,000 or more	16 (48)

Table 2. Mountain biking experience (N=33).

Mountain biking experience	Value, n (%)
Mountain biking experience[a] (years)	
Less than 1	2 (6)
1-5	7 (23)
6-10	6 (19)
11 and more	16 (52)
During a typical riding season, how often do you mountain bike?	
1-2 days a month	3 (9)
Once a week	6 (18)
2-3 days a week	19 (58)
4-5 days a week	5 (15)
Daily	0 (0)
For which of the following reasons do you ride a mountain bike? (yes)	
Recreation or fun	33 (100)
To spend time with family	16 (48)
To increase fitness	33 (100)
Racing	3 (9)
To spend time with friends	29 (88)
To spend time outdoors	33 (100)
What best describes your bike?	
Cross-country	5 (15)
Trail	11 (33)
All mountain/Enduro	17 (52)
Has previously ridden a class 1 electric pedal-assist mountain bike	3 (9)

[a]N=31.

Table 3. Riding and exercise response results.

Comparison of distance, time, speed, and heart rate metrics (N=33)	Descriptive statistics		Paired *t* test: MTB[a] vs eMTB[b]	
	MTB, mean (SD)	eMTB, mean (SD)	Mean difference	*P* value
Time (min:seconds)	38:54 (7:48)	26:14 (3:45)	12:40	<.001
Average speed (miles per hour)	8.8 (1.4)	12.9 (1.7)	−4.1	<.001
Average heart rate (beats per minute)	154.8 (12.9)	144.9 (13.7)	9.9	<.001

[a]MTB: mountain bike

[b]eMTB: electric pedal-assist mountain bike

Table 4. Riding and exercise response results.

Comparison of distance, time, speed, and heart rate metrics (N=33)	MTB[a], n (%)	eMTB[b], n (%)	*P* value[c]
Moderate-intensity physical activity	2 (6.1)	4 (12.1)	.09
Vigorous-intensity physical activity	31 (93.9)	29 (87.9)	—[d]

[a]MTB: mountain bike

[b]eMTB: electric pedal-assist mountain bike

[c]Chi-Square: MTB vs eMTB.

[d]Not applicable.

Perceptions

Table 5 includes pre- and post-eMTB ride data related to perceptions of potential impacts of eMTB use. Participants overwhelmingly perceived the potential impact of eMTB use to be positive on both pre- and post-eMTB ride questionnaires. Only "Potentially allows riders to ascend or climb greater distances and elevations in less time on dirt trails" was significantly different on the post-eMTB ride questionnaire, with more participants in agreement that eMTB use would have such an impact.

Beliefs

Table 6 includes the results of 26 pre- and post-eMTB ride belief statements regarding eMTB use. A total of 4 belief statements were significantly different after riding the eMTB. Fewer participants agreed that *eMTB use will prove to be a passing fad* and that they *could get the same cardiovascular workout on an eMTB as a conventional mountain bike*, whereas more participants agreed that their *heart rate is considerably lower while riding an eMTB as compared with a conventional mountain bike* and *eMTB use allows riders greater and deeper access to backcountry dirt trails.* Table 7 includes results from the final questionnaire item asking *how beliefs and perceptions about eMTBs changed after riding one* showed that few participants (n=3) were less accepting of eMTBs, some experienced no change (n=8), and the majority (n=20) were more accepting of eMTBs after riding one.

Table 5. Perceptions of potential impact of electric pedal-assist mountain bike use (N=32).

Perceptions of potential impacts of electric pedal-assist mountain bike use	Preride (agreed), n (%)	Postride (agreed), n (%)	*P* value[a]
Potentially allows older riders to continue enjoying mountain biking on dirt trails	32 (100)	30 (94)	.16
Potentially allows less-fit riders to more fully enjoy mountain biking on dirt trails	27 (84)	27 (84)	>.99
Potentially allows injured or disabled riders to continue enjoying mountain biking on dirt trails	32 (100)	31 (97)	.33
Potentially allows riders of varying fitness levels to mountain bike together on dirt trails	25 (78)	26 (81)	.66
Potentially allows all riders to mountain bike longer distances on trails[b]	25 (81)	27 (87)	.33
Potentially allows riders greater and deeper access to the backcountry on dirt trails	25 (78)	28 (88)	.18
Potentially allows riders to ascend or climb greater distances and elevations in less time on dirt trails	23 (72)	29 (91)	*.03*
Potentially allows riders who may otherwise shuttle the ascent or drive to the top of the trail in a vehicle to ride up on dirt trails	27 (84)	27 (84)	>.99
Potentially increases the appeal of riding on dirt trails to more people	21 (66)	24 (75)	.33
Potentially improves public health outcomes by increasing rates of physical activity	27 (84)	27 (84)	>.99

[a]*P* values were derived from paired *t* tests of preride and postride values. Variables were coded using the following logic: 0=Negative (con), 1=Positive (pro). The significant *P* value (<.05) has been italicized.

[b]N=31.

Table 6. Beliefs regarding electric pedal-assist mountain bike use (N=33).

Beliefs regarding eMTB[a] use	Preride (agreed), n (%)[b]	Postride (agreed), n (%)[b]	*P* value [c]
I believe riding an eMTB is cheating	16 (48)	13 (39)	.11
I believe riding an eMTB is equivalent to riding a motorcycle	4 (12)	5 (15)	.38
I believe if eMTBs are allowed on existing dirt trails, then trail access for all mountain bikers will be compromised	15 (45)	10 (30)	.26
I believe eMTB riders perceive they are actually mountain biking, but they are not; eMTB use is not mountain biking	11 (33)	5 (15)	.23
I believe eMTBs should be banned from existing mountain bike trails and trail systems	6 (18)	6 (18)	.79
I believe eMTB use causes more trail damage compared with conventional mountain bikes	6 (18)	4 (12)	.70
I believe eMTB use should be limited to riders with physical handicaps or impairments	6 (18)	5 (15)	.08
I believe that in the future, eMTB use will replace conventional mountain biking[d]	2 (6)	4 (13)	.26
I believe eMTBs have the potential to help older riders continue to enjoy mountain biking	32 (97)	31 (94)	.60
I believe eMTBs have the potential to help less-fit riders increase their fitness levels and transition to conventional mountain biking	25 (76)	25 (76)	.71
I believe I could get the same cardiovascular workout on an eMTB as I do my conventional mountain bike	14 (42)	5 (15)	*.002*
I believe my heart rate is considerably lower while riding an eMTB as compared with my conventional mountain bike	18 (55)	28 (85)	*<.001*
I am opposed to eMTB use	6 (18)	4 (12)	.11
I believe eMTBs are primarily being pushed on cyclist by the industry to make money	5 (15)	7 (21)	.41
I believe eMTB use will have a negative impact on mountain biking	7 (21)	7 (21)	.25
I believe eMTB use will prove to be a passing fad	10 (30)	6 (18)	*.03*
I am opposed to eMTB use by healthy individuals	8 (24)	8 (24)	.45
I am opposed to eMTB use on the same trails as conventional mountain biking	7 (21)	7 (21)	.32
I am fine with pedal-assist bike use on the street, but I am opposed to their use on dirt trails	7 (21)	6 (18)	.14
I believe eMTB use allows riders of varying fitness levels to mountain bike together on dirt trails	30 (91)	26 (79)	.34
I believe eMTB use allows all riders to bike longer distances	32 (97)	33 (100)	.07
I believe that eMTB use allows riders greater and deeper access to backcountry dirt trails	30 (91)	32 (97)	*.03*
I believe that eMTB use allows riders to ascend or climb greater distances and elevations in less time on dirt trails	31 (94)	33 (100)	*.001*
I believe that eMTB use allows riders who may otherwise shuttle the ascent or drive to the top of the trail in a vehicle to ride up on dirt trails	31 (94)	31 (94)	.54
I am supportive of eMTB use[e]	26 (84)	26 (84)	.17

[a]eMTB: electric pedal-assist mountain bike.

[b]Agreed n (%) includes both *strongly agree* and *agree* responses.

[c]*P* values were derived from paired *t* tests of preride and postride values. Variables were coded using the following logic: 1=strongly disagree, 2=disagree, 3=agree, and 4=strongly agree. Significant *P* values (<.05) are italicized.

[d]N=32.

[e]N=31.

Table 7. Overall belief and perception surrounding the question: how have your beliefs and perceptions about eMTBs[a] changed after riding one? (N=33).

Overall belief and perception	Value, n (%)
I am less accepting of eMTBs after riding one	3 (9)
My beliefs and perceptions have not changed at all	8 (24)
I am more accepting of eMTBs after riding one	20 (61)
Other	2 (6)

[a]eMTB: electric pedal-assist mountain bike.

Discussion

Principal Findings

This study sought to address 2 research questions: (1) *What proportion of exercise response is retained for an experienced mountain biker when using an eMTB compared with a conventional mountain bike?* and (2) *What are the perceptions and beliefs of experienced mountain bikers toward eMTB both before and after riding an eMTB?* Although significant differences in heart rate were measured between conventional mountain bike use and eMTB use, riding the study loop on both types of mountain bikes placed the vast majority of participants in the vigorous-intensity heart rate zone. Using heart rate as a proxy measure for cardiovascular exercise intensity and related exercise response, eMTB use appears to be an excellent form of aerobic or cardiovascular exercise, even for experienced mountain bikers who regularly engage in this fitness activity. *Physical Activity Guidelines for Americans* established by the CDC indicate that for substantial health benefits, adults should engage in at least 150 min a week of moderate-intensity aerobic physical activity or 75 min a week of vigorous-intensity aerobic physical activity [3,16]. Average heart rate during eMTB use was 93.6% of average heart rate during conventional mountain bike use. Riding both types of bikes on the study loop caused the participants to exceed at least heart-rate levels for moderate-intensity fitness activities and placed the average heart rate for a majority of participants in the vigorous-intensity zone [16]. Therefore, eMTB use in this study retained the bulk of the exercise response and exceeded established biometric thresholds for cardiovascular fitness. These findings of eMTB use on soft-surface trails are comparable to recent findings using e-bikes on city bike paths in which it was estimated that 95.5% of the cardiovascular benefit of conventional bike use was retained [18]. Although findings from the extant literature indicate that e-bikes can generally satisfy requirements for moderate-intensity physical activity [7-11,13,19], this study is the first to explore the exercise response of eMTB use on soft-surface trails and the first to associate pedal-assist bikes with vigorous exercise.

Although eMTB use provided an intense cardiovascular workout in this study, average riding speed on the eMTB was approximately 4 mph (approximately 6.5 kph) faster than speeds on the conventional mountain bike, resulting in less time needed to complete the study loop. If a conventional mountain bike was to be replaced by an eMTB as part of a cardiovascular fitness program, then total ride time, not ride distance, would need to remain constant. In this study, speed was presented as an average across the entire study loop. It is possible that the higher speed for eMTBs is a factor in forming attitudes and beliefs both for and against their use. For example, higher eMTB speeds in high traffic areas or up hills may be a perceived source of trail conflict and slower eMTB speeds on downhill trail sections may result in trail congestion. These examples are only speculative and could be tested in future research on the adoption and uptake of eMTBs.

This study represents the first attempt to measure perceptions and beliefs of experienced mountain bikers before and after riding an eMTB. Relatively few significant attitudinal changes occurred from preride to postride, likely because of a sample of participants holding positive attitudes about eMTB at the onset. Only 18% of participants indicated they were opposed to eMTB on the preride survey. As there are many in the mountain biking community with strong negative opinions about eMTBs [6], this is likely a reflection of sampling bias, which is to say that those volunteering to participate in this study likely had more positive views of eMTBs and were excited for the opportunity to ride one. There were, however, several significant findings related to attitudes and beliefs along with several nonsignificant findings worthy of discussion.

After riding an eMTB, attitudes related to the future of eMTB use changed with fewer participants considering eMTBs to be a passing fad. This shift is consistent with industry trends and forecasts as eMTB sales climbed to US $77.1 million in 2017, a 91% increase in US sales from the previous year and an 8-fold increase since 2014 [20,21]. Market predictions are that eMTB sales will represent approximately 30% of the mountain biking market by 2020 [22].

Of particular note, participants in this study did not perceive riding an eMTB to be a workout or taxing on their cardiovascular system. Although mean heart-rate data indicated the eMTB study loop resulted in an approximate 10 bpm reduction when compared with the conventional mountain bike, all participants reached at least moderate levels of intensity and most reached vigorous levels while riding the eMTB. Despite this, participants' perceived exertion while riding the eMTB was low. This finding has potential implications for the utility of eMTBs in helping all users, including the experienced mountain bikers in this study as well as more sedentary individuals, to engage in regular physical activity and meet physical activity guidelines. As key constructs of the Health Belief Model (HBM), both *perceived benefits* and *perceived barriers* are predictive of adherence to health recommendations and behavior change [23]. *Perceived benefits* specifically refer to one's opinion of the efficacy of an advised action to reduce

health risks [23]. *Perceived barriers* refer to one's opinion of the cost, whether psychological, physiological, or financial, of engaging in a health-promoting behavior or practice [23]. The low perceived exertion of riding an eMTB, together with the cardiovascular benefit of continuous target heart rate zone activity, make the total perceived benefits of eMTB riding high and the perceived barriers low. This has been observed as it relates to physical activity in general, where perceptions of exertion significantly impact activity levels [24,25]. Utilizing pedal-assist technology to decrease the perceived exertion of physical activity may be a critical catalyst in helping individuals become more physically active. Specifically pertaining to the uptake of e-bikes, lower perceived exertion has been reported as impactful [26]. In relation to the HBM, this study examined the physiological barriers and benefits of eMTB use, but other barriers may exist that could delay the uptake of this technology. It is possible that on account of being an emerging technology and with the addition of an electric motor, potential users of eMTBs perceive the financial cost of purchasing an eMTB too high. Indeed, high performance eMTBs can be costly. The extent to which these perceptions exist and how they might impact potential riders was beyond the scope of this study but could be studied in the future.

Participants were more accepting of eMTBs after riding one. The adage "don't knock it until you try it" appears applicable with pedal-assist technology. A recent qualitative analysis of eMTB threads in mountain biking forums concluded that individuals could be divided into 2 groups when commenting on eMTBs: those who had personal experience with an eMTB and those who did not. The authors concluded that inexperience with an eMTB appears central to the conflict surrounding eMTB use and that many misconceptions about what an eMTB *is* and *can do* are resolved by riding one [6]. This study found that most participants either became more accepting (61%) of eMTBs after riding one or reported no change (24%) in their level of acceptance.

Of interest in this study are the perceptions and beliefs that were not significantly altered by the experience of riding an eMTB. Overwhelming agreement existed at both pre- and postride data collection related to eMTBs' ability to help older and less-fit riders find enjoyment in riding. Another stable perception is that eMTBs have the potential to improve public health outcomes through the encouragement or promotion of physical activity. Future research should explore this potential by including sedentary, less active, overweight or obese, and older individuals as participants. Such investigations could target behaviors, attitudes, and biometric indicators longitudinally.

Limitations

Findings from this study should be interpreted with consideration of several limitations. This study was limited by its small sample. Although the sample size in this study is equal to or greater than similar studies of pedal-assist bikes, it is not sufficiently large to generalize or draw conclusions beyond this specific sample. In addition, this study used heart-rate data as a proxy measure for exercise response and cardiovascular exercise intensity. Future studies examining similar variables would benefit from more sophisticated measures, such as maximal oxygen uptake, metabolic equivalents, and watts. Likewise, participants had only 1 trial on the eMTB and their heart-rate response might have changed after an extended observation period. Finally, the sampling procedure employed to recruit experienced mountain bikers in this study yielded participants who might have already been largely supportive of eMTB use. A more random sample may have produced different results, especially related to perceptions and beliefs before and after riding an eMTB.

Conclusions

This is the first study to compare the exercise response of conventional mountain bike and eMTB use on soft-surface trails and the first to associate pedal-assist bikes with vigorous-intensity aerobic or cardiovascular fitness. Findings indicate that riding an eMTB is moderate to vigorous physical activity, providing individuals with the opportunity to meet physical activity guidelines. Findings related to perceptions and beliefs before and after riding eMTBs were mixed yet support the use of pedal-assist technology in promoting physical activity.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

bpm: beats per minute
CDC: Centers for Disease Control and Prevention
e-bike: electric pedal-assist bike
eMTB: electric pedal-assist mountain bike
GPS: global positioning system

HBM: Health Belief Model
HHS: Health and Human Services
MHR: maximum heart rate

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Original Paper

Trends in Scientific Reports on Cartilage Bioprinting: Scoping Review

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Abstract

Background: Satisfactory therapeutic strategies for cartilaginous lesion repair do not yet exist. This creates a challenge for surgeons and biomedical engineers and leads them to investigate the role of bioprinting and tissue engineering as viable treatments through orthopedic surgery, plastic surgery, and otorhinolaryngology. Recent increases in related scientific literature suggest that bioprinted cartilage may develop into a viable solution.

Objective: The objectives of this review were to (1) synthesize the scientific advances published to date, (2) identify unresolved technical problems regarding human application, and (3) identify more effective ways for the scientific community to transfer their findings to clinicians.

Methods: This scoping review considered articles published between 2009 and 2019 that were identified through searching PubMed, Scopus, Web of Science, and Google Scholar. Arksey and O'Malley's five-step framework was used to delimit and direct the initial search results, from which we established the following research questions: (1) What do authors of current research say about human application? (2) What necessary technical improvements are identified in the research? (3) On which issues do the authors agree? and (4) What future research priorities emerge in the studies? We used the Cohen kappa statistic to validate the interrater reliability.

Results: The 13 articles included in the review demonstrated the feasibility of cartilage bioprinting in live animal studies. Some investigators are already considering short-term human experimentation, although technical limitations still need to be resolved. Both the use and manufacturing process of stem cells need to be standardized, and a consensus is needed regarding the composition of hydrogels. Using on-site printing strategies and predesigned implants may allow techniques to adapt to multiple situations. In addition, the predictive capacity of implant behavior may lead to optimal results.

Conclusions: Cartilage bioprinting for surgical applications is nearing its initial use in humans. Current research suggests that surgeons will soon be able to replace damaged tissue with bioprinted material.

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KEYWORDS

cartilage 3D printing; knowledge; tissue engineering; surgery; cartilage repair; chondrogenesis; cartilage biomaterials

Introduction

Cartilage is a specialized connective tissue devoid of nerves, blood, and lymph vessels. It has flexible characteristics and consists of an abundant extracellular matrix and chondrocytes. Articular cartilage lesions do not heal spontaneously and lead to impaired function, progressive disability, and decreased quality of life [1]. Traumatic and degenerative cartilage injuries represent one of the most challenging and frustrating clinical scenarios.

Medical specialties have a long history of adopting new solutions for patient problems, including new techniques to repair or replace damaged tissue, such as total joint replacement by orthopedic surgeons, cornea replacement in ophthalmology, and repairing malformations or congenital absence of the ear (ie, microtia) [2]. Repairing or replacing damaged or absent cartilage structures, such as the ear or nose, presents a significant challenge in reconstructive plastic surgery; in these cases, a clinically conceivable procedure needs to be created, because current procedures often involve multiple surgeries [3] and complications, such as infections, tissue necrosis, pain, and the risk of an undesirable result [4].

Bioprinting technology (ie, three-dimensional [3D]) is a new approach that allows the regeneration of cartilaginous structures using cartilaginous cells in a biocompatible environment. The 3D shape of the bioprinting product can be exact, which is very important in nasal septum or external ear reconstruction [5].

Tissue engineering and regenerative medicine are life science fields that use the principles of tissue engineering to regenerate damaged structures or create new ones [6]. Better understanding of how to optimize patient care can improve outcomes and quality of life, allowing more efficient use of health resources. Results of previous research [7,8] suggest that the most logical next step is to examine surgeons' responses to this new therapeutic possibility. Reviewing, analyzing, and categorizing the different research activities in this new field [9] will help define the scope and depth of future research and identify gaps in critical knowledge [10]. This review synthesizes published studies on bioprinted cartilage to accomplish the following: (1) identify the current state of cartilage bioprinting, (2) identify the technical issues associated with human application, and (3) highlight the need to extend the advanced knowledge to clinicians.

Methods

Overview

Previous literature in this field lacks specificity; therefore, a scoping study methodology was chosen to correctly identify information gaps and precisely illustrate future research needs. The scoping review system creates a map of the published literature to explore the methodological and empirical differences in various knowledge areas.

Study Design

Overview

A scoping review methodology was chosen because it is more exploratory and less methodological than systematic reviews; this was essential to meet the study objectives. The research strategy was modified according to Arksey and O'Malley's [11] methodological framework, which proposes a five-stage transparent process for replicating research strategies to increase the reliability of the results. The first stage clarifies and links the study purpose and the research questions; stage two balances feasibility with the breadth of the research process; stage three includes study selection; stage four involves mapping the data; and stage five summarizes the findings.

Clarifying and Linking the Purpose to Research Questions

This study aimed to identify the current status of cartilage bioprinting and the associated influence on clinical use, as well as to subsequently improve the information that reaches surgeons. The following research questions guided the search:

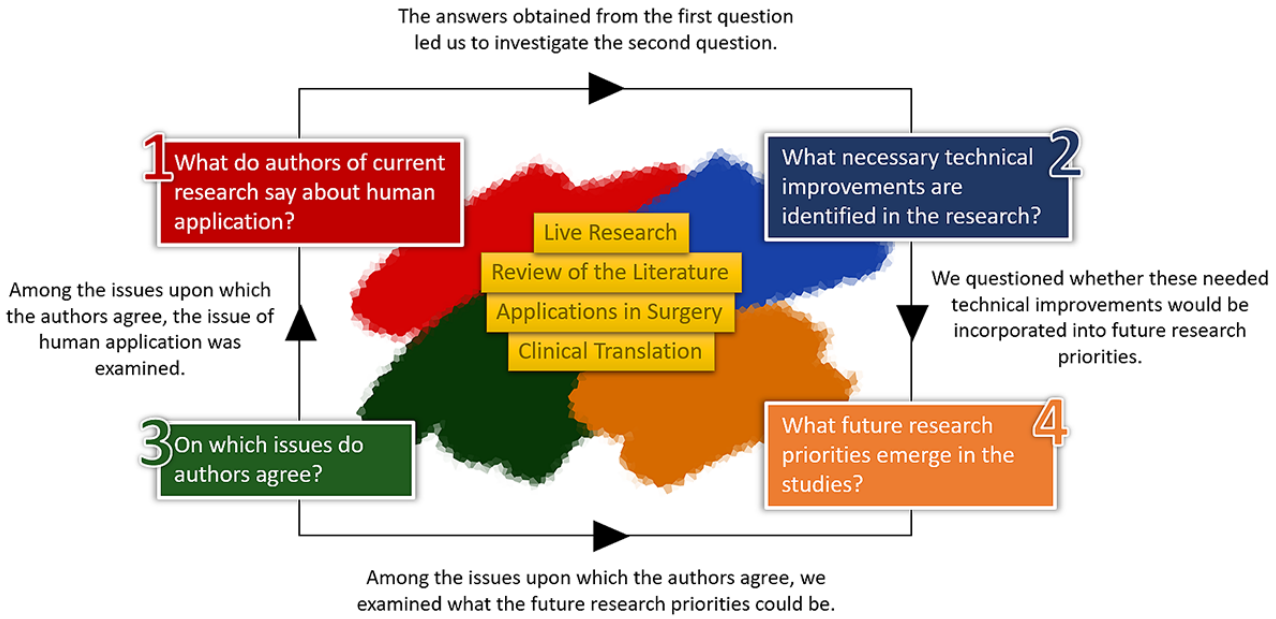
1. *What do authors of current research say about human application?*
2. *What necessary technical improvements are identified in the research?*
3. *On which issues do authors agree?*
4. *What future research priorities emerge in the studies?*

After determining the research questions, we developed a conceptual framework to define and map the key concepts of bioprinted cartilage and to identify research gaps that may hinder using bioprinting techniques in human applications (see Figure 1). The conceptual framework guided both the analysis and the systematic presentation of the summarized data. The four research questions comprised the main branches of the framework, and the extracted data were categorized into four blocks, which answer our research questions.

Balancing Viability With the Breadth of the Process

The bibliographic search was conducted between January and March 2019 and included Scopus, Web of Science, and PubMed databases. Choosing the correct key terms was critical to facilitating maximum coverage of the related research literature [12]. We used Medical Subject Headings (MeSH) terminology to increase search sensitivity: "bioprinting" AND "surgery" AND "cartilage" OR "surgical procedures." We also examined each article's reference list and conducted additional Google Scholar searches on research terms available in the gray literature. This expanded the search by adding the following terms: #bioprinting, #articular cartilage, #tissue engineering, #cartilage, #stem cells, #scaffolding, #biofabrication, #cartilage regeneration, #surgery, #transplantation, #cartilage tissue engineering, and #clinical translation.

Figure 1. Conceptual framework of the scoping review.



Study Selection

Bioprinted cartilage technology has changed in recent years; consequently, only a limited number of articles, some of which were already in the authors' bibliography archives, were included. Scoping reviews [13] are used to map underlying concepts; therefore, as in other types of knowledge synthesis [14], it is essential to define the methods. In 2015, the Joanna Briggs Institute published the methodological guidelines [15] for presenting a broad view of the evidence, regardless of study quality; clarifying key concepts; and identifying gaps [16]. This methodology involves incorporating a checklist to increase method transparency, judge validity and reliability, and adequately handle the search [17]. Among the existing forms of presentation, we focused on the revised and expanded Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Rapid Reviews (PRISMA-RR) [18]. Figure 2 illustrates the transparency of the article selection.

The electronic database search, the Internet hand search, and the archive database search identified 418 articles; 275 were excluded because the main concepts of our search were only cited in the context of this work. A total of 81 duplicates were also excluded as well as 31 articles due to exclusion criteria (see Table 1). Interrater agreement was analyzed for the remaining 31 articles using the Cohen kappa statistic [19-21], which indicated a moderate level of agreement among our evaluators and yielded a total of 13 articles for analysis.

Extracting and Charting the Results

Kok and Schuit [22] proposed a method to map research contributions to improve the impact of research on the population's health. The method focuses on producing anticipatory processes and extending, disseminating, and using knowledge. The articles selected for analysis through evaluator agreement were all published between 2016 and 2019.

The collected articles were organized by author, title, year, country, and type of article (see Table 2). The selected articles originated from the United States (4/13, 31%) [23-26], China (2/13, 15%) [27,28], Korea (2/13, 15%) [29,30], Sweden (2/13, 15%) [31,32], Australia (2/13, 15%) [33,34], and Canada (1/13, 8%) [35].

Reporting the Findings

The articles were classified by following types of study design:

1. Live research (ie, carried out on animals).
2. Literature reviews.
3. Surgical applications.
4. Clinical translation (ie, a review methodology focused on clinical application).

We also referenced the summarized information of each article for future interpretations.

Availability of Data and Materials

The data used and analyzed in this study are available from the primary author upon reasonable request.

Figure 2. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for the scoping review process.

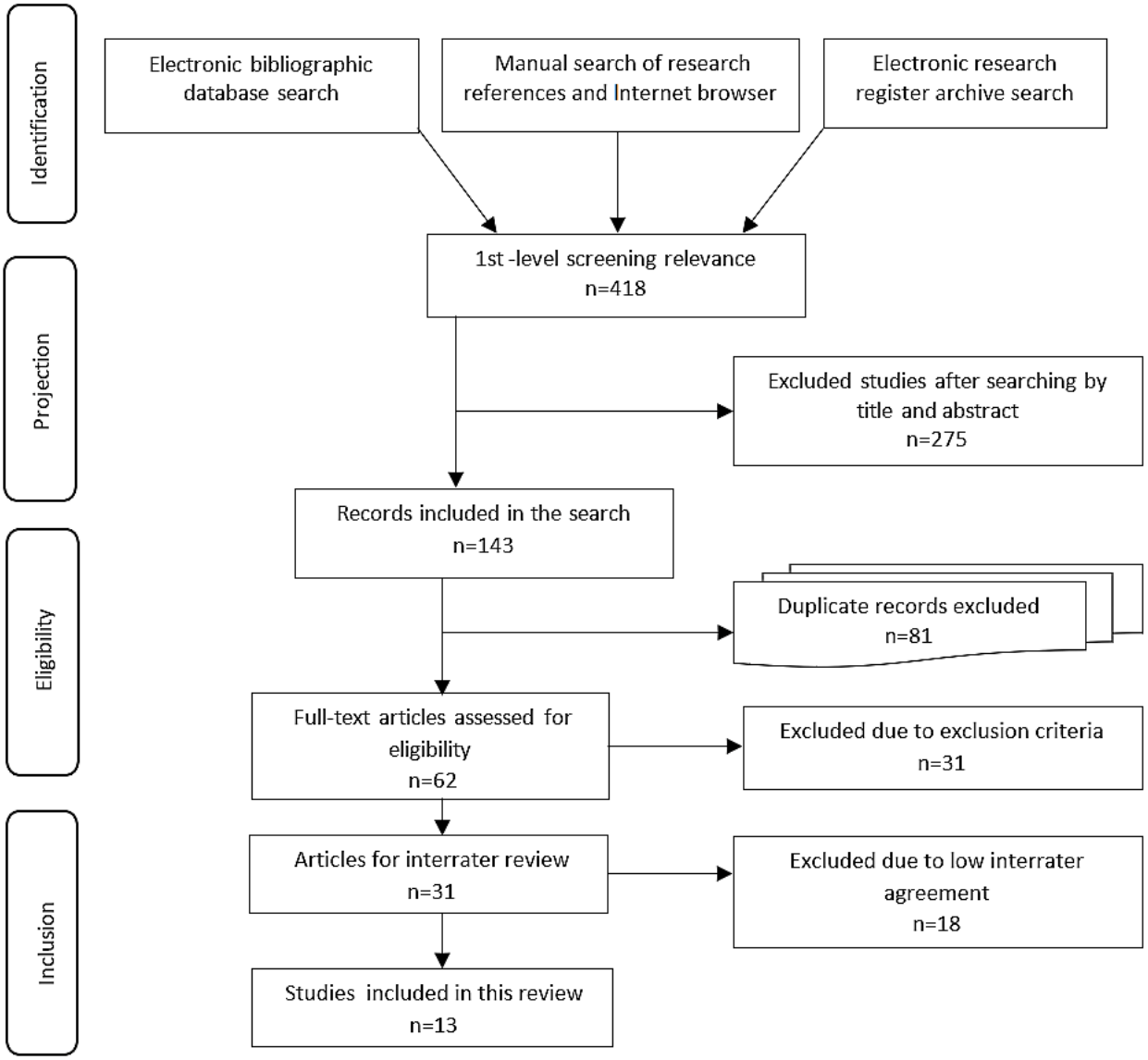


Table 1. Inclusion and exclusion criteria.

Criteria	Inclusion criteria	Exclusion criteria
Language	English	Non-English
Year of publication	2009-2019	Before 2009
Peer reviewed	Yes	No
Study design	• Original research • In vivo study • Literature revision • Description of surgical procedures	• Clinical trials in phase I/II • Studies conducted in the laboratory environment
Ethical permission	Obtained	Not obtained

Table 2. Selected articles.

Authors	Title	Year	Country	Type of article
Di Bella et al [34]	In situ handheld three-dimensional bioprinting for cartilage regeneration	2018	Australia	Live research
Onofrillo et al [33]	Biofabrication of human articular cartilage: A path towards the development of a clinical treatment	2018	Australia	Live research
You et al [35]	Homogeneous hydroxyapatite/alginate composite hydrogel promotes calcified cartilage matrix deposition with potential for three-dimensional bioprinting	2019	Canada	Live research
Apelgren et al [31]	Skin grafting on 3D bioprinted cartilage constructs in vivo	2018	Sweden	Live research
Wu et al [25]	Three-dimensional bioprinting of articular cartilage: A systematic review	2018	United States	Literature review
Dhawan et al [26]	Three-dimensional bioprinting for bone and cartilage restoration in orthopaedic surgery	2019	United States	Literature review
Leberfinger et al [24]	Concise review: Bioprinting of stem cells for transplantable tissue fabrication	2017	United States	Literature review
Apelgren et al [30]	Chondrocytes and stem cells in 3D-bioprinted structures create human cartilage in vivo	2017	Korea	Surgical application
Yi et al [29]	Three-dimensional printing of a patient- specific engineered nasal cartilage for augmentative rhinoplasty	2019	Korea	Surgical application
Kaye [32]	A 3-dimensional bioprinted tracheal segment implant pilot study: Rabbit tracheal resection with graft implantation	2019	Sweden	Surgical application
Li [27]	In situ repair of bone and cartilage defects using 3D scanning and 3D printing	2017	China	Surgical application
Boushell [23]	Current strategies for integrative cartilage repair	2017	United States	Surgical application
Liu et al [28]	Recent progress in cartilage tissue engineering: Our experience and future directions	2017	China	Clinical translation

Results

Overview

Table 2 lists the articles included in this review. All reviewed studies contributed to understanding the complexity of applying cartilage bioprinting in humans. Table 3 summarizes the authors' contributions regarding the first research question. This grouping allowed us to identify the approach according to the lines of research. The articles included in the group of in vivo studies emphasized the applied aspects of technology development, such as the elements that constituted the process (eg, bioink and its composition, replicability and cell viability, and the bioprinter), as well as bioprinting intervention strategies that included the use of a Biopen (ie, a manual bioprinter) with preclinical results in large animals. This is the strategy closest to human experimentation, according to the authors who used it.

Clinical Translation

Questions that arise from the studies cover a wide range of possibilities. Key elements for clinical translation included scalability and lesion characteristics, such as different lesion geometries and measurements. Insights from surgical application studies included problems specific to orthopedic, plastic, and otorhinolaryngology surgery. To progress toward human application, each surgical strategy must overcome these application-specific challenges. In addition, Boushell et al [23] opened debate on the scaffold versus cellular approaches. Li et al's [27] translational study provided specific reading aimed at clinical professionals to establish synergies with basic research. Its goal was to reach surgical professionals not directly involved in the research.

Table 4 details the technical improvements identified in the studies that were necessary to continue progressing toward human application. In general, they involve two concepts: cellular sources and biomaterials, including scaffolds and hydrogels. Onofrillo [33], Apelgren et al [31], and Leberfinger [24] prioritized the need to develop protocols for obtaining cells; they also recognized that, despite variable sources, all cells must maintain chondrogenic capacity, not cause morbidity at the donor site, expand easily in the culture without losing phenotype, and support the mechanical load in the joint case. Di Bella et al [34], You et al [35], and Wu et al [25] presented disparate technical aspects that should be improved, since they followed different research paths. However, they all identified necessary biomaterial and scaffolding improvements, although the types of recommended improvements did not coincide.

Table 3. Authors' perspectives about current research for human application.

Type of article, authors, year	Details and authors' perspectives
Live research	
Di Bella et al, 2018 [34]	Authors used the Biopen manual printing system in the operating room for implanting cartilage directly into the bed of a lesion. They suggested that this system would improve the possibility of use in humans because it facilitates in situ implant creation, and they have demonstrated clinical efficacy and safety in large animals. They have not detected intraoperative or perioperative complications. The preliminary data obtained on the safety and stability of the in vivo characteristics of the implanted cartilage suggest that use of the technique in humans may not be far off.
Onofrillo et al, 2018 [33]	Authors used the Biopen system and contributed to defining a possible clinical bioprinting protocol for application in humans. They studied the cell viability and characteristics of bioinks to ensure that the created cartilaginous tissue was similar to native tissue. They concluded that their discoveries allow customized repair of cartilaginous lesions in humans.
You et al, 2019 [35]	Authors studied hydrogel composition to improve the printing and dispersion of particles in situ. They reported that their investigations represent a step toward implantation in humans because they improved the mimesis with the osteochondral junction.
Apelgren et al, 2018 [31]	Authors in this mouse study investigated implanting skin-coated chondrocytes for application in auricular reconstructive surgeries. They suggested that for human surgery applications, it is necessary to show that the reconstruction procedure is clinically conceivable and replicable. The results increased the clinical potential in humans.
Literature reviews	
Wu et al, 2018 [25]	Authors demonstrated that articular cartilage bioprinting is a tissue engineering strategy that has potential translational value.
Dhawan et al, 2019 [26]	Authors reported scalability, geometric, and lesion measurement problems that may pose barriers to human application. They suggested the use of tomographic images for the design of the implant and its accuracy.
Leberfinger et al, 2017 [24]	Authors analyzed the essential elements of the bioprinting process, the different cellular sources, the bioink, and the implants with and without scaffolding. They conducted a cost-effectiveness study to evaluate the feasibility of clinical translation.
Surgical applications	
Apelgren et al, 2017 [30]	Authors studied the creation of cartilage with human chondrocytes in vivo; they also quantified the chondrogenic potential in combination with mesenchymal stem cells in bioprinting constructions implanted in mice for their application in plastic surgery.
Yi et al, 2019 [29]	Authors established a procedure based on a 3D computer-aided model to generate a customized nasal implant design. They reported that computer design is necessary for creating human implants.
Kaye et al, 2019 [32]	In their pilot study, authors investigated the feasibility of introducing a functional in vivo tracheal replacement in rabbits.
Li et al, 2017 [27]	Authors conducted a study to improve the cartilage defect imaging in orthopedic surgery for implementation in humans; they concluded that it is necessary to optimize the imaging process.
Boushell et al, 2016 [23]	Authors defended the use of scaffolding versus the cellular approach in human applications for orthopedic surgery. They noted that scaffolding requires fewer chondrocytes and that the functional mechanical properties of the tissue are more easily achieved by scaffolding.
Clinical translation	
Liu et al, 2017 [28]	Authors identified key aspects in clinical translation for human use in orthopedic surgery: (1) integration with subchondral bone for correct load distribution, (2) ensure the coincidence in the mechanical properties between the native cartilage and the implant to avoid the degradation caused by the tensional disparity, (3) guarantee resistance under deformations and movements, and (4) recapitulate different zonal architecture to achieve the structure-function relationship of the native cartilage.

Table 4. Needed improvements in the technical aspects.

Type of article, authors, year	Needed improvements
Live research	
Di Bella et al, 2018 [34]	The chemical characteristics of the biomaterial need to be improved to ensure adhesion of the implant in depth and thickness at the site of the injury.
Onofrillo et al, 2018 [33]	The ideal cell type for cartilage regeneration is still a matter of debate, as it has to be ensured that the cells obtained have a proven chondrogenic capacity, do not cause morbidity in the donor site, and are easily expandable in the culture without losing their phenotype.
You et al, 2019 [35]	The properties of hydrogels must be improved. The authors' findings show the promise of alginate/hydroxyapatite hydrogel printed on 3D scaffolds with a porous structure for calcified and bioprinted cartilage formation.
Apelgren et al, 2018 [31]	A model of bioprinted cartilage for an atrium has the potential to have a very elaborate form; however, authors state that they still need to obtain an adequate skin coverage that allows for highlighting of these high-resolution forms in the in vivo application.
Literature reviews	
Wu et al, 2018 [25]	The mechanical strength in bioprinting without scaffolding should be further investigated, along with the toxicity in the implanted cells. For the authors, bioprinting without scaffolding offers many possibilities for the future since it reaches a relatively high initial cell density without the inclusion of biomaterials; this translates into more space for extracellular matrix deposition as well as facilitating better cell-cell interaction, generating biomimetics, preserving cellular functionality, and eliminating tissue biodegradation.
Dhawan et al, 2019 [26]	The protocolization of technological manufacturing strategies of bioprinted cartilage needs improvement in order to allow its scalability. This technology would have the ability to manufacture tissues in clinically relevant volumes and address defects of different sizes and geometries.
Leberfinger et al, 2017 [24]	To ensure the clinical safety of obtained cells, necessary manufacturing facilities must be created for processing, including isolation facilities in hospitals, to facilitate the transition toward clinical use. Among the cellular sources that could be used, the authors point out embryonic stem cells, induced pluripotent cells, and adult stem cells from bone marrow and adipose tissue.
Surgical applications	
Apelgren et al, 2017 [30]	A significant challenge in reconstructive plastic surgery is the approach that allows the regeneration of cartilage structures using autologous cells dispersed in biocompatible scaffolds. Several problems associated with this method have not yet been investigated or resolved, including load-bearing capacities, shear strength, elastic characteristics, and resistance to degeneration.
Yi et al, 2019 [29]	In patients who require a nasal implant, the postoperative characteristics of the skin that will cover the implant must be improved to ensure that it is not affected by the external pressure generated later, nor by the degradation of the biomaterials in the long term. The authors propose a pre- and postoperative control algorithm that calculates all the variables.
Kaye et al, 2019 [32]	In their in vivo study of the implantation of a trachea seeded with cells, authors detected the need to cover the implant with a membrane to avoid inflammatory reactions and stenosis of the light when applied in humans. These findings are essential for the future of reconstruction and implantation of tracheal grafts.
Li et al, 2017 [27]	It is necessary to visualize the cartilaginous defect with computed tomography, synthesize suitable biomaterials, and print hydrogels in a personalized way in a short time. The use of a specific bioprinter to carry out this process is necessary to achieve the objective of personalized implants in situ through bioprinting.
Boushell et al, 2016 [23]	The characterization, optimization, and standardization of models in large animals will be critical for the next phase of the investigation for cartilage repair. In addition to the development of better culture models, more research is needed to fully understand the long-term maintenance and homeostasis interface of the integration strategies to ensure the success of the procedure.
Clinical translation	
Liu et al, 2017 [28]	Improving collaboration between materials scientists and experts from other fields related to tissue engineering is of vital importance to obtain hydrogels with balanced mechanical properties, electrical conductivity, degradation rate, biocompatibility, and chondro-inducing properties.

The surgical application studies focused on certain surgical approaches and identified specific technical improvements needed to obtain better results; improvements included an algorithm to ensure that the nasal implant is not degraded or subjected to excessive long-term pressure [29]; a process to guarantee the characteristics of the skin of the ear in plastic surgery [31]; and in otorhinolaryngology, the use of a membrane trachea coating and image processing to optimize surgical results [36].

Table 5 reflects those aspects that were identified as recurrent among the different groups. An elaborate synthesis of the elements shared across the studies was completed. Analyzing these recurring elements allowed us to understand the group positions and identify the main shared aspects.

Table 5. Issues upon which the authors agreed.

Type of article, authors, year	Issues
Live research	
Di Bella et al, 2018 [34]	Once tested on animals, it is necessary to design a strategy to detect whether the implant has been kept in situ in order to move on to human trials.
Onofrillo et al, 2018 [33]	To guarantee stability in situ, a gradient of osteogenic and chondrogenic growth factors should be added to the hydrogel to promote selective tissue differentiation that would allow the formation of bone and cartilage, acquiring the complete osteochondral unit.
You et al, 2019 [35]	To ensure that the skin regeneration characteristics obtained in mice can be extrapolated to humans, they will need to perform the same experiment on large animals with regenerative capacities more similar to humans.
Apelgren et al, 2018 [31]	To ensure cell viability and optimal measurement of the implant to preserve atrial features, large animals must be investigated.
All authors	Common opinion: the next steps are to expand the research on large animals and to prolong the monitoring time to confirm the preliminary results of cell viability, in situ conservation of the implanted tissue, maintenance of the mechanical characteristics, and long-term lateral integration.
Literature reviews	
Wu et al, 2018 [25]	Advances so far have allowed the replication of the anatomical structures, the biological function, and the mechanical properties of the implant; however, it is necessary to continue analyzing the viability and the autoimmune response of the implanted cells before the various stimuli to which they are subjected in the living organism are activated.
Dhawan et al, 2019 [26]	These specific designs for the patient must be protocolized, not only concerning the geometry of the implant but also at the anatomical level of defect.
Leberfinger et al, 2017 [24]	The authors have found that the lack of standardized and efficient differentiation protocols of stem cells leads to variable results among groups of researchers.
All authors	Common opinion: the authors consider it essential to protocolize cell differentiation and to ensure viability, chondrogenic differentiation, scalability, and control of autoimmune reactions for implantation in humans.
Surgical applications	
Apelgren et al, 2017 [30]	It is necessary to extend the control period in experimental animals to assess stability and long-term integration in order to ensure the absence of malignancy.
Yi et al, 2019 [29]	It is necessary to ensure the long-term maintenance of the implant shape in large constructions and to control the central hypoxia of the implant; this would avoid an insufficient supply of oxygen and nutrients to the cells through the hydrogel that allows its diffusion.
Kaye et al, 2019 [32]	When an ideal tracheal replacement graft is constructed, the ability to fully integrate in vivo depends on its immunogenicity and its ability to promote revascularization. Also, any tracheal replacement graft must be a mechanical and functional complement similar to the native trachea.
Li et al, 2017 [27]	It is necessary to establish a methodology for in situ printing mediated by images for personalized implants. The proportion of balanced hydrogel between the speed of printing and the maintenance of cell viability must be considered as an indispensable part of the bioprinting. The structural characteristics and zonal organization of normal articular cartilage should be considered.
Boushell et al, 2016 [23]	Further exploration of appropriate culture models is required to obtain tissue integrity and prevent ectopic calcifications. A long-term solution for the treatment of full-thickness cartilage defects must be developed.
All authors	Common opinion: long-term evaluation is essential to ensure the maintenance of the form, the mechanical and functional resistance of the implant, as well as vascularization. A clinically relevant methodology must be established.

Table 6 reflects the lines that suggest prioritizing diverse groups. These were derived from the specific research studies, and therefore there was no shared opinion. At a general level, however, more research on manufacturing strategies to establish the role of scaffolding and accelerate integration of native and newly formed cartilage is required. Finally, when the technology is available to humans, the results obtained from bioprinted cartilage should be compared to the traditional gold standard.

Table 6. Future research priorities proposed by the authors.

Type of article, authors, year	Future research priorities
Live research	
Di Bella et al, 2018 [34]	Authors propose the use of the Biopen for its ease of use, which does not require prior training by the surgeon. They highlight the need for more trials to evaluate the biomechanical characteristics of cartilage.
Onofrillo et al, 2018 [33]	Authors propose studying the phenotype, cell migration, matrix deposition, proteolytic activity, and the rate of degradation of the construct; they propose this in order to evaluate and correlate with the formation of new cartilage and to better understand the interaction between human adipose-derived stem cells and the gelatin methacrylate/hyaluronic methacrylate cross-linked hydrogel.
You et al, 2019 [35]	Authors propose that the combination of alginate/hydroxyapatite should be considered a critical component for the regeneration of the osteochondral interface of the skeletal joints.
Apelgren et al, 2018 [31]	Authors propose a methodology capable of evaluating the in vivo proliferation of chondrocytes, alone and in a combination with mesenchymal cells. They suggest that their technique is viable in that it maintains the proliferative capacity of cartilage over time.
Literature reviews	
Wu et al, 2018 [25]	Authors propose studying the mechanical forces that are applied to the knee and that a semiconfined compression is a good way to mimic the native mechanical environment in future studies. Thus, it will be possible to study how the mechanical stimuli regulate the cell activities in the bioprinted constructs.
Dhawan et al, 2019 [26]	Authors propose that when the technology is available for humans and once bioprinted cartilage implants are obtained, they can be compared with the traditional gold standard.
Leberfinger et al, 2017 [24]	Authors recommend carefully studying the growth factors that are part of the biomaterials before proceeding to standardize the bioprinting and implantation of the graft.
Surgical applications	
Apelgren et al, 2017 [30]	Authors propose exploring other cellular sources from in vivo studies to compare before standardizing the bioprinting process. Stem cells derived from adipose tissue that could support chondrogenesis are proposed. They propose lengthening the study time in vivo to confirm the stability of the cartilage shape, elastic characteristics, and integrity.
Yi et al, 2019 [29]	Authors propose investigating algorithms for implant applications in other types of tissues, since they argue for the high versatility of the technology; the availability of various extracellular matrix materials of the tissue; and the pluripotency of the human adipose-derived stem cells. This contributes to the structural accuracy of the nasal cartilage, and the hydrogel provides a favorable environment for chondrogenic differentiation and the formation of neocartilage.
Kaye et al, 2019 [32]	Authors propose that for uses of cartilage bioprinting where the implant should not be integrated (eg, the trachea), the study of separating membranes that allow the implanted organ to remain isolated is recommended.
Li et al, 2017 [27]	Authors propose the use of bioprinting with assistance from a scanned image for significant segmental defects of long bones and open chondral lesions. The technique allows a dual approach to cartilage and bone.
Boushell et al, 2016 [23]	Authors propose new strategies of clinical management based on research with personalized scaffolds combined with chemotactic factors; these would give rise to a stable, functional repair with good long-term results.
Clinical translation	
Liu et al, 2017 [28]	Authors propose elaboration of a guide of Good Manufacturing Practice that allows the complete production of cartilaginous grafts on a large scale. Most of the new developments in engineering of cartilage tissue have not yet translated into measurable improvements for clinicians.

Discussion

Principal Findings

In recent years, there has been an increase in the annual publication of articles on cartilage bioprinting, contributing to the knowledge and management of this process. The methodology adopted in this review allowed us to analyze 13 articles and present systematically summarized data. No clinical trials in humans have been identified to date. Tests with large animals presented some challenges and suggested possible strategies [37]. In this context, the reviewed articles provided polyhedral visions to the problem and proposed lines of research to progress toward human application. Identifying four groups based on research characteristics allowed us to establish synergies, understand confluences across studies, and highlight specific problems that surfaced as well as potential problems that may emerge as the field advances.

The Biopen [33,34] is the technique most likely to be applied in humans in the short term. The Biopen arose out of a collaboration between researchers at the University of Wollongong-based Australian Research Council Centre of Excellence for Electromaterials Science and orthopedic surgeons at St. Vincent's Hospital in Melbourne. The Biopen technique is based on a small bioprinter that is easy to handle and is loaded with biological inks composed of stem cells inside a biopolymer, which in turn is protected by a second layer of hydrogel. The

exchange of injectors allows different cells to be deposited at different concentrations on the surface to be repaired and, thus, recreates the zonal anatomy of native cartilage. It is then solidified by an ultraviolet light embedded in the pen. It is an attractive proposition for surgeons since its use does not require a long learning curve. The Biopen allows precise positioning of cells and biomaterials, rapid placement at the defect site, and minimal manipulation by the surgeon. Other authors advocate the predesign rather than in situ design of the implant: Yi et al [29], Apelgren et al [31], Li et al [36], Kaye et al [32], and Boushell et al [23]. These five studies focus on surgical applications in plastic surgery, otorhinolaryngology, and orthopedics.

The characteristics of these approaches make it difficult to use on-site technologies, while the preoperative design of the implants is necessary. In Kaye et al's study [32], tracheal substitution started from a decellularized extracellular matrix trachea and subsequently seeded cells. Currently, in situ application of the technique appears to be restricted to joint injuries, despite being in a more advanced state of research. The image-mediated design, with algorithms such as those proposed by Yi et al [29], allows an implant, as similar as possible, while allowing for preoperative assessment of pressure and skin growth effects in plastic surgery implants. For Li et al [36] and Yi et al [29], the use of images is a line that must be exploited to ensure functional transplants with preservation capacity in both nasal and orthopedic applications. The Biopen technique would make it possible to ignore image studies, which contain a certain margin of error. This is evident in both Li et al's [36] and Yi et al's [29] studies, where they recommended technical improvements for obtaining and processing previous images to guarantee the implant design and facilitate optimal implantation.

Both impression approaches face a series of challenges, including maintenance of the implant form, cell viability, and mechanical resistance. The interface between the implant and adjoining native tissues also needs to be addressed. Form maintenance encompasses different strategies, such as the use of desacralized structures, as described by Kaye et al [32] with tracheal implants.

Scaffolds can contribute rigidity and mechanical resistance to the implant. In scaffolding, a structure with synthetic biopolymers provides mechanical support to maintain shape and load, while hydrogel provides a biological environment for regeneration of bioprinted cartilage [5]. Boushell et al [23] advocated the use of scaffolds insofar as they require a lower cellular concentration and facilitate the mechanical properties of the implant, which seems to adopt better mechanical-functional behaviors. On the other hand, Biopen techniques do not require a classic scaffold; however, they should guarantee both peri- and postoperative safety, functionality, and nondegradation of the construct, while scaffolds must ensure lateral integration of the implant. There is debate about the usefulness of scaffolds in orthopedic surgery. To date, lateral integration of the implant has not been confirmed with enough clarity.

Implant integration and fixation are aspects that can affect all the analyzed proposals. Correct integration and fixation of the neocartilage requires geometric measures of the osteochondral lesion's total volume. Resistance to implanted cartilage degradation should be guaranteed in the long term, whether or not scaffolding is used. Wu et al [25] proposed semiconfined compression as an excellent way to mimic the native mechanical environment in future studies, facilitating research on how mechanical stimuli regulate cell activities in bioprinted constructs.

The risk of inflammation or the contraction or deformation of the implanted tissue, either with or without a scaffold, affecting the end result should not be overlooked. Kaye et al's [32] work highlighted this difficulty in tracheal surgery; Yi et al [29] advocated greater precision in the algorithm to ensure that there is no modification of the postoperative nasal implant related to external causes. Postoperative cellular viability, such as maintaining cellular replication over time, must be analyzed by methods such as those proposed by Apelgren et al [30]. To date, the Biopen technique has not provided long-term viability results in large animals.

The hydrogels used must respond to a variety of biological needs, ensuring balanced mechanical properties, electrical conductivity, degradation rate, biocompatibility, and chondro-inducing properties [27]. Specific equilibria can be found in the speed of printing and the maintenance of cell viability [36]. In plastic surgery and otorhinolaryngology, they must also allow the correct irrigation of the tissue to avoid situations of hypoxia. The combination of biomaterials, such as alginate/hydroxyapatite [35] or a cross-linked gelatin methacrylate/hyaluronic methacrylate [33], should be considered a critical component for regeneration of the osteochondral interface in orthopedic surgery.

The cellular source of the implants is the last element of debate. There are two issues: cellular origin and cell treatment. The cells can be obtained from adult tissue-derived stem cells (ie, fat cells, bone marrow, and others), mesenchymal stem cells, autologous chondrocytes, and induced pluripotent cells. Researchers used two types of cells in the reviewed works: mesenchymal stem cells and stem cells derived from adipocytes. Cells extracted from the patient encounter extraction problems, but the chondrogenic capacity facilitates cellular processing and regulatory requirements, which are much higher with stem cells. Standardizing all steps in the process (eg, cell differentiation, the composition of the hydrogels, and the speed of printing) is necessary to enable translation to humans [27].

Identified Gaps

Although approaches differ depending on the study type and the application, a series of gaps and challenges were identified that were shared across studies, although there are differences in the ease of resolution, functional technique, and surgical strategies:

1. Optimum integration with the host subchondral bone and cartilage must be achieved.
2. The biological, biomechanical, and degradation properties of the bioprinted cartilage must be ensured.

3. A systematic manufacturing process must be developed and implant preservation, cellular sources, and the role of scaffolds must be optimized.
4. Clinical safety related to the effects of implants on native tissues must be examined.

Challenges

Overview

Surgical challenges similar to allogeneic organ transplants, including cellular ischemia and size adjustment, will persist. According to Li et al [36], the size match can be planned before surgery with computed tomography and computer-aided design images [38]. The implanted tissue must be composed of biocompatible materials that are integrated into the native cells, allowing growth and preventing an immune response. Ethical dilemmas and regulatory problems are also likely to arise as this technology advances.

Ethical Dilemmas

To avoid an immune response in current transplants and lifelong treatment, adult stem cells offer the ability to produce autologous tissue that prevents the need for immunosuppressive therapy [24]. Support and biocompatible biological components must have a low inflammatory response to prevent the appearance of macrophages [39]. Even small changes in the chemical, physical (ie, structure and degradation), and mechanical properties of bioprinting materials can affect the integrity and biocompatibility of the structural component and, ultimately, the performance after it is implanted [40].

Two crucial nonclinical challenges will also affect implementation of this technology: regulation and costs. The reviewed studies focused primarily on specific technical aspects, except for the Leberfinger et al study [24], which investigated cost relationships. In addition, Liu et al [27] suggested a need for useful practice manuals to facilitate both the translation and regulation of the techniques.

Regulation

Currently, when cells are modified and combined with a scaffold that provides physical support for the growth of new tissue, they are regulated as biological products in the United States and as advanced therapy drugs in the European Union (EU) [41]. The regulatory aspects that align development of these combined products lack clarity, both in the EU and in the United States. There is also uncertainty regarding the potential impact of current proposals to amend the EU directive on medical products [42].

Costs

One concern associated with personalized regenerative medicine is the uncertainty regarding the cost of obtained tissues [40]. Costs associated with cell acquisition and processing, scaffold manufacturing, bioreactor maturation, surgical implantation, and postoperative care are also likely to be substantial, but it is not clear how they will compare with the current cost of transplants [43]. As with any new scientific advance, costs will probably decrease as technology evolves and becomes more efficient.

Implications for Future Research

Bioprinting technologies are unique in that they allow a certain pattern of multiple cell types and materials to recreate the native structure of cartilage [44]. Future studies should evaluate other sources of multipotent stem cells, such as stem cells derived from adipose tissue or from mesenchymal or other cells, to support chondrogenesis. These stem cells can be easy to collect, and some studies report that they have substantial proliferative potential [30].

Collectively, the analyzed studies demonstrate the feasibility of cartilage engineering and underscore the need for a continuous biological barrier between the neo-cartilage and the bone region. It is likely that the biphasic design alone is not sufficient to achieve consistent and functional cartilage, as well as formation and integration into the subchondral bone [30]. Peripheral distribution in the matrix formation, as well as correct orientation of the collagen fibers and mechanical resistance to tension, are vital elements in cartilage tissue engineering [33]. Although in vivo testing has been conducted in large animals, before progressing to human trials it is necessary to specify and resolve the detected gaps to establish the necessary physical and biomechanical characteristics, address potential implant degradation, and ensure transverse integration of the graft in the host.

Strengths and Limitations

One limitation is the heterogeneity of the selected articles. Evaluating the methodological quality of the included studies was not within the scope of this review, which aimed to identify and synthesize the key concepts in cartilage bioprinting research. There may be additional relevant works that were not identified by the search strategy used in this review.

This concise review presented the evolving technology of cartilage bioprinting and its main components, with a particular focus on clinical translation. This work contributes a summary and update of current research in this area, which can be made available to clinicians to facilitate a better understanding of this new technology.

Conclusions

Human applications for bioprinted cartilage are likely to emerge in the near future. Advanced research on bioprinted cartilage can become a spearhead for adapting the technology to bioprint other types of tissue. On-site printing strategies and predesigned models can adapt to different situations. In addition, as imaging technology advances, processing implants and identifying the predictive capacity of implant behavior will allow better results. Regulation of the technology across different countries and cost-effectiveness of the technique will also need to be addressed in future studies.

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Authors' Contributions

ASV conducted the study and data analysis with MY. BS and FGC contributed to the writing and editing of the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

3D: three-dimensional
EU: European Union
MeSH: Medical Subject Headings
PRISMA-RR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Rapid Reviews

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