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Original Paper

Lifestyle Interventions for Polycystic Ovary Syndrome: Cross-Sectional Survey to Assess Women's Treatment and Outcome Preferences

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Abstract

Background: Polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women of reproductive age. Diet and lifestyle programs improve health, but women’s preferences for these programs have not been formally explored.

Objective: The aim of our study was to examine diet and lifestyle program preferences among women with PCOS.

Methods: We conducted a cross-sectional online survey of women with PCOS.

Results: At least half of the 197 respondents expressed strong interest in programs addressing energy level, anxiety, depression, weight, diabetes prevention, menstrual period regulation, and hirsutism. Similarly, at least half reported willingness to modify their sleep, stress, and physical activity; and slightly less than half reported willingness to adopt a very low-carbohydrate, paleo, or low–glycemic index diet. At least half reported interest in online or mobile programs and email-based mentoring. Younger age was associated with interest in help with acne and fertility; higher body mass index was associated with wanting help with weight loss, energy, and anxiety; and greater stress eating was associated with wanting help with depression, anxiety, and menstrual period regulation.

Conclusions: To our knowledge, this is the first study to examine attitudes and preferences of women with PCOS toward such programs. Future online and mobile diet and lifestyle programs may be able to capitalize on this information to better target this population’s expressed preferences.

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KEYWORDS

polycystic ovary syndrome; lifestyle intervention; online and mobile; health psychology; nutrition

Introduction

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women of reproductive age. Women with it often experience obesity, insulin resistance, hyperinsulinemia, infertility, and clinical manifestations of hyperandrogenism (chronic anovulation, hirsutism, and acne) as well as have a higher risk for cardiovascular disease and type 2 diabetes [1,2].

Women with PCOS can face other challenges. On average, they experience higher levels of depressive [3] and anxiety symptoms [4], which, when elevated, may increase their use of maladaptive coping strategies such as escape–avoidance coping (wishful thinking or behavior to avoid a problem) and lower levels of adaptive coping such as planful problem solving and positive reappraisal (focusing on positive meaning and growth) [5]. They may feel abnormal and less feminine because many of their symptoms, such as hirsutism and infertility, are not traditionally emblematic of femininity [6] and because the popular press often depicts them as less able to fulfill their roles as wives and mothers [7]. On the other hand, online discussion boards and in-person support groups may be able to provide them socioemotional and informational social support [8,9].

The Androgen Excess and PCOS Society calls for the primary treatment of metabolic complications for women with PCOS to be through diet and lifestyle programs [10,11]. Similarly, the Endocrine Society encourages these interventions for overweight or obese women with PCOS [12]. Thus, diet and lifestyle programs should be playing a central role in treating women with PCOS. However, previous trials of PCOS diet and lifestyle interventions have had high dropout rates [13-15].

These high dropout rates [13-15] have been related to various factors. For example, participants who dropped out had higher baseline testosterone [16], insulin resistance [14], or weight [14] than those of participants who completed the intervention. Moreover, women with PCOS tend to be younger than participants in typical weight loss programs, and younger women tend to have higher dropout rates generally [17].

Therefore, we aimed to extend the impact and retention of future PCOS diet and lifestyle programs by surveying women with PCOS about their program preferences. Thus, a goal of this research was to provide valuable data that can be used to inform future intervention development for symptom management and disease prevention among women with PCOS.

Methods

Setting and Participants

We solicited feedback from women who had been diagnosed with PCOS using an online survey website—Amazon Mechanical Turk. This allowed us to survey women anonymously while still paying them for their participation. We described that, "this survey is for women with Polycystic Ovary Syndrome (PCOS) who might be interested in a diet and lifestyle program to help improve their health… If you don't have PCOS do not continue." Thus, this was a self-qualified convenience sample.

Participants provided informed consent online. The research was approved by the University of Michigan Institutional Review Board (HUM00127004).

Measures

Participants used a 7-point Likert scale (1=*not very interested* to 7=*very interested*) to rate their interest in a diet and lifestyle program to achieve each of 9 health outcomes [18] using each of 7 potential program format options [19,20]. They also rated their willingness to make 6 diet and lifestyle changes [21-25] using a 7-point scale (1=*not at all willing* to 7=*very willing*). We measured stress-related eating using the 4-item Eating to Cope subscale of the Palatable Eating Motives Scale (PEMS) [26], which asks people to consider what reasons people give for eating highly palatable foods such as sweets, salty snacks, fast foods, and sugary drinks, rated on a 5-point scale (almost never/never, some of the time, half of the time, most of the time, almost always/always). The 4 prompts include "to forget your worries," "because it helps you when you feel depressed or nervous," "to cheer up when you are in a bad mood," and "to forget about your problems." We also asked participants 2 open-ended questions about their PCOS and possible programs: "What health concerns do you have related to it?" and "What other aspects of a diet and lifestyle program might be useful?"

Statistical Analyses

Descriptive data are presented in means, standard deviations, and percentages. We dichotomously classified interest responses of at least 6 out of 7 as "interested" and willingness ratings of at least 6 out of 7 as "willing." We computed associations between selected predictors (body mass index or BMI, age, education, and PEMS) and continuous ratings of interest and willingness. Given the exploratory nature of the study, we tested Pearson correlations using a conservative criterion of $P<.01$.

Results

We recruited 197 women with self-identified PCOS. See Table 1 for sample characteristics.

Table 1. Baseline characteristics of women with PCOS (N=197).

Characteristics	Values
Age in years, mean (SD)	32.8 (8.1)
Race/ethnicity , n (%)	
Asian/Pacific Islander	8 (4.1)
Black	16 (8.1)
White	173 (87.8)
American Indian or Alaskan Native	10 (5.1)
Latino	22 (11.2)
Education level, n (%)	
Not a college graduate	79 (40.1)
College graduate	85 (43.1)
Post graduate education	33 (16.8)
Total household income, n (%)	
Up to US $35,000	63 (32.0)
US $35,001- US $75,000	99 (50.3)
Over US $75,000	35 (17.8)
Years since diagnosis of PCOS[a] years, mean (SD)	6.9 (6.6)
Weight in kg, mean (SD)	81.2 (26.1)
Body Mass Index in kg/m^2, mean (SD)	29.6 (9.7)
Stress eating,[b] mean (SD)	2.7 (1.2)

[a] PCOS: polycystic ovary syndrome.

[b] Scores on Eating to Cope subscale of the Palatable Eating Motives Scale (PEMS).

Potential Program Outcomes

Between 53% and 73% of respondents reported interest in a program that would help them to feel more energetic, feel less anxious and depressed, lose weight, prevent a diabetes onset, regulate menstrual periods, and reduce hirsutism (Table 2).

The older the women were, the more interested they were in increasing their energy and preventing diabetes, but the less they were interested in reducing acne and becoming pregnant. The more overweight the women were, the more interested they were in increasing their energy, reducing their anxiety, losing weight, preventing diabetes, and reducing hirsutism. Greater stress eating was associated with interest in reducing anxiety and depression as well as regulating menstrual periods.

We also asked respondents to report any other health concerns they had about PCOS using an open-ended question. These responses included pain, thinning hair, mood swings, and loss of libido.

Table 2. Associations between interest/willingness ratings in potential program features and selected respondent variables.

Variables	Interested[a] or Willing[b] participants n (%) N=197	Pearson correlation			
		Age	Education	Body mass index	Stress eating[c]
Potential psychological outcomes					
Feeling more energetic	144 (73.1)	.23*	.07	.27*	.10
Feeling less anxious	132 (67.0)	.04	.01	.28*	.21*
Feeling less depressed	124 (62.9)	−.02	−.06	.11	.26*
Potential physical outcomes					
Losing weight	124 (62.9)	.03	−.07	.45*	.16
Preventing diabetes	116 (58.9)	.17*	.00	.24*	.13
Regulating menstrual periods	104 (52.8)	−.07	-.09	.12	.23*
Reducing hirsutism	104 (52.8)	−.04	.04	.23*	.13
Reducing acne	87 (44.2)	−.27*	.14	.03	.18
Becoming pregnant	45 (22.8)	−.28*	.07	-.02	.11
Potential content					
Eating a very low-carbohydrate, ketogenic diet	87 (44.2)	.11	.09	.08	.12
Eating a paleo diet or diet with little processed foods, grains, or dairy	89 (45.2)	.15	.11	.10	.09
Eating a low–glycemic index diet	87 (44.2)	.21*	.14	.07	.13
Getting regular physical activity	128 (65.0)	.19*	.10	.04	−.08
Getting sufficient sleep	160 (81.2)	.09	.07	.14	.09
Practicing stress-reduction techniques	146 (74.1)	.18	.08	−.02	−.01
Potential mentoring format					
Email	100 (50.8)	.20*	.17	.16	−.01
In-person	49 (24.9)	−.20*	.09	−.07	−.03
Phone	37 (18.8)	−.12	.16	−.13	.10
Video chat	26 (13.2)	−.03	.16	−.16	.06
Potential lesson format					
Online	106 (53.8)	.19*	.13	.21*	.10
In a mobile application on phone	100 (50.8)	.07	.08	.08	.05
In-person	37 (18.8)	−.18	.06	−.06	.07

*P<.01.

[a] Response of at least 6 out of 7 on interest scale.

[b] Response of at least 6 out of 7 on willingness scale.

[c] Eating to Cope subscale of the Palatable Eating Motives Scale (PEMS).

Program Content (Behavior Change Targets)

Between 65% to 81% of respondents reported a willingness to get regular physical activity and sufficient sleep as well as a willingness to practice stress-reduction techniques (Table 2). Only 44%-45% were willing to try each of the 3 diets. Older age was correlated with a willingness to try a low–glycemic index diet and get regular physical activity. Weight, education, and stress eating were not correlated with a willingness to change any of the behaviors.

Program Format

Between 51% to 54% of respondents were interested in receiving help from a mentor via email, online lessons, or mobile lessons. In contrast, one-fourth or less were interested in receiving mentorship in person, by telephone, or via video chat; and less than one-fifth were interested in in-person lessons. Age was positively associated with interest in being mentored over email and receiving online lessons, and negatively associated with being mentored in person. BMI was positively associated with interest in receiving online lessons. Education and stress eating were not correlated with any program format preferences.

Using an open-ended question, we also asked participants what other aspects of a diet and lifestyle program might be useful. They described other possible features, including getting support from a coach (“just having a person who is there for you”); peers (“I think the support of others going through the same thing could be very meaningful”); or generally anyone supportive (“Constant reassurance would be the most useful tool”). They wanted this support to help keep them accountable to their goals. Participants suggested that the program provide reminders of their goals and rewards for reaching those goals. Some mentioned wanting mobile applications or online or text-based interactions (“Daily goals/reminders through push notifications on a mobile app,” and “I just like accountability without having to talk on the phone or in person. I'm an introvert so I like online message boards, text messages, etc.”) whereas others wanted in-person help (“I would rather just have a checklist of things to do, like a hard copy piece of paper that I can hang on my fridge to help guide my food choices and remind me why those choices are important” and “I like meeting a person in real life because you can see and feel the motivation from them”).

Discussion

This study aimed to determine which diet and lifestyle program features appeal to women with PCOS. Results suggest that the majority of women prefer programs targeting numerous outcomes, including increasing energy, reducing anxiety and depression, losing weight, lowering diabetes risk, regulating menstruation, and reducing hirsutism. A clear majority were interested in a topical coverage of sleep, stress reduction, and physical activity. There were lower rates of interest in various diets. Finally, about half of the survey respondents expressed interest in email-based mentoring and online or mobile delivery.

Findings could also inform efforts to maximize program appeal to various PCOS subgroups. For example, the younger the women were, the more interested they were in typical concerns of younger women, including reducing acne and increasing fertility. Further, the higher a woman’s BMI, the more she preferred a program to help with weight loss, improved energy, and reduced anxiety.

To our knowledge, this is the first study to examine program attitudes and preferences in this population. However, a primary study limitation is the online recruitment of a convenience sample. This may at least partially explain reported preferences for online or mobile programs and email-based mentoring. Additionally, self-report biases such as social desirability may have affected respondents’ ratings of interest and willingness. Nonetheless, future online and mobile diet and lifestyle programs may be able to capitalize on this information to better target this population’s expressed preferences.

Overall, we hope that this research can help inform future diet and lifestyle programs for women with PCOS. Ideally, this will enable the programs to have fewer participants who drop out of the programs and more satisfied and adherent participants.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index

PCOS: polycystic ovary syndrome
PEMS: Palatable Eating Motives Scale

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Original Paper

Guiding Glucose Management Discussions Among Adults With Type 2 Diabetes in General Practice: Development and Pretesting of a Clinical Decision Support Tool Prototype Embedded in an Electronic Medical Record

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Abstract

Background: Managing type 2 diabetes (T2D) requires progressive lifestyle changes and, sometimes, pharmacological treatment intensification. General practitioners (GPs) are integral to this process but can find pharmacological treatment intensification challenging because of the complexity of continually emerging treatment options.

Objective: This study aimed to use a co-design method to develop and pretest a clinical decision support (CDS) tool prototype (GlycASSIST) embedded within an electronic medical record, which uses evidence-based guidelines to provide GPs and people with T2D with recommendations for setting glycated hemoglobin (HbA1c) targets and intensifying treatment together in real time in consultations.

Methods: The literature on T2D-related CDS tools informed the initial GlycASSIST design. A two-part co-design method was then used. Initial feedback was sought via interviews and focus groups with clinicians (4 GPs, 5 endocrinologists, and 3 diabetes educators) and 6 people with T2D. Following refinements, 8 GPs participated in mock consultations in which they had access to GlycASSIST. Six people with T2D viewed a similar mock consultation. Participants provided feedback on the functionality of GlycASSIST and its role in supporting shared decision making (SDM) and treatment intensification.

Results: Clinicians and people with T2D believed that GlycASSIST could support SDM (although this was not always observed in the mock consultations) and individualized treatment intensification. They recommended that GlycASSIST includes less information while maintaining relevance and credibility and using graphs and colors to enhance visual appeal. Maintaining clinical autonomy was important to GPs, as they wanted the capacity to override GlycASSIST’s recommendations when appropriate. Clinicians requested easier screen navigation and greater prescribing guidance and capabilities.

Conclusions: GlycASSIST was perceived to achieve its purpose of facilitating treatment intensification and was acceptable to people with T2D and GPs. The GlycASSIST prototype is being refined based on these findings to prepare for quantitative evaluation.

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KEYWORDS

type 2 diabetes; shared decision making; clinical decision support; general practice; primary care

Introduction

Type 2 diabetes (T2D) affects more than 420 million people worldwide [1]. In Australia, T2D affects 1.2 million people, amounting to more than Aus $6 (US $4.3) billion annually in direct and indirect health care costs [2]. Early achievement and maintenance of glycated hemoglobin (HbA_{1c}) in an appropriate target range reduces downstream complications and all-cause mortality [3]. Although the general target is HbA_{1c} of ≤7% (53 mmol/mol), the Australian Diabetes Society and international guidelines suggest that targets need to be individualized based on several factors, including age, duration of diabetes, comorbidities, and risk of hypoglycemia [4-6].

In Australia, as in many countries, most clinical care of people with T2D is based on general practice or primary care [7]. Treatment intensification by general practitioners (GPs) can help people with diabetes achieve glycemic targets [8,9]. However, more than 40% of Australian adults with T2D have an HbA_{1c} level above the target range [10]. Treatment intensification is typically delayed for 8 to 10 years, while HbA_{1c} remains out of target [11]. Barriers to GPs delivering evidence-based treatment intensification include lack of familiarity with clinical diabetes guidelines and the complex and rapidly changing treatment options for optimizing blood glucose levels (BGLs) [12-14]. Health system factors (eg, competing priorities in busy, reactive primary care settings [15]) and patient-related factors (eg, psychological resistance to insulin initiation [16]) can also play a role.

Clinical decision support (CDS) tools used in real time can enable GPs and people with diabetes to navigate this complex environment and intensify treatment in an appropriate and timely manner to achieve personalized HbA_{1c} targets. CDS tools and evidence-based electronic support can improve the process of care measures [17-19], the use of guidelines by GPs [20,21], and outcomes such as HbA_{1c} [22-25], without substantially increasing health care expenditure [26]. They can also reduce consultation duration and increase screening (eg, lipids) for complications associated with T2D [27,28].

Using CDS tools in real time during the consultation may also encourage treatment-specific conversations between GPs and people with diabetes, supporting shared decision making (SDM), an important aspect of quality care. A CDS tool embedded within an electronic medical record (EMR) has the added benefit of automatically extracting and using information present in the EMR to guide personalized clinical care. Until recently, most CDS tools have focused on helping people with diabetes achieve a standardized set of diabetes goals (eg, HbA_{1c} target of <7%) that are not necessarily individualized or person-centered [29]. Recently, CDS tools that encourage individualized diabetes care and are integrated within the EMR have become available [30,31]. There is a plethora of self-management apps for people with T2D, many with a focus on displaying blood glucose data with the option to add data about medications, diet, and exercise. Many of them can be shared with health professionals. However, at the point of clinical care, CDS tool design and efficacy are often inconsistent [20,32-34]. Few CDS tools combine the capacity for automatic deployment within the EMR in real time in the consultation with the capacity to make management recommendations (beyond specialized closed-loop insulin systems).

Utilization of CDS tools by health care professionals (HCPs) is low [32,35,36]. One way to increase uptake and utilization is through co-design that includes end users (eg, GPs and people with diabetes) [37,38]. The co-design theory suggests that technologies, services, and systems should be designed *with* the intended users, giving them the opportunity to inform development [39]. The focus is on engaging with end users to "jointly articulate ideas ... [and engage] ... with mock-ups and prototypes" [40].

The aim of this study was to use co-design principles to develop an EMR-based CDS tool for real-time use in consultations to support GPs and people with diabetes to select individualized HbA_{1c} targets and appropriate medication options together. In this paper, we describe the co-design cycles of feedback and tool refinement, drawing on first- and second-stage interviews and focus groups.

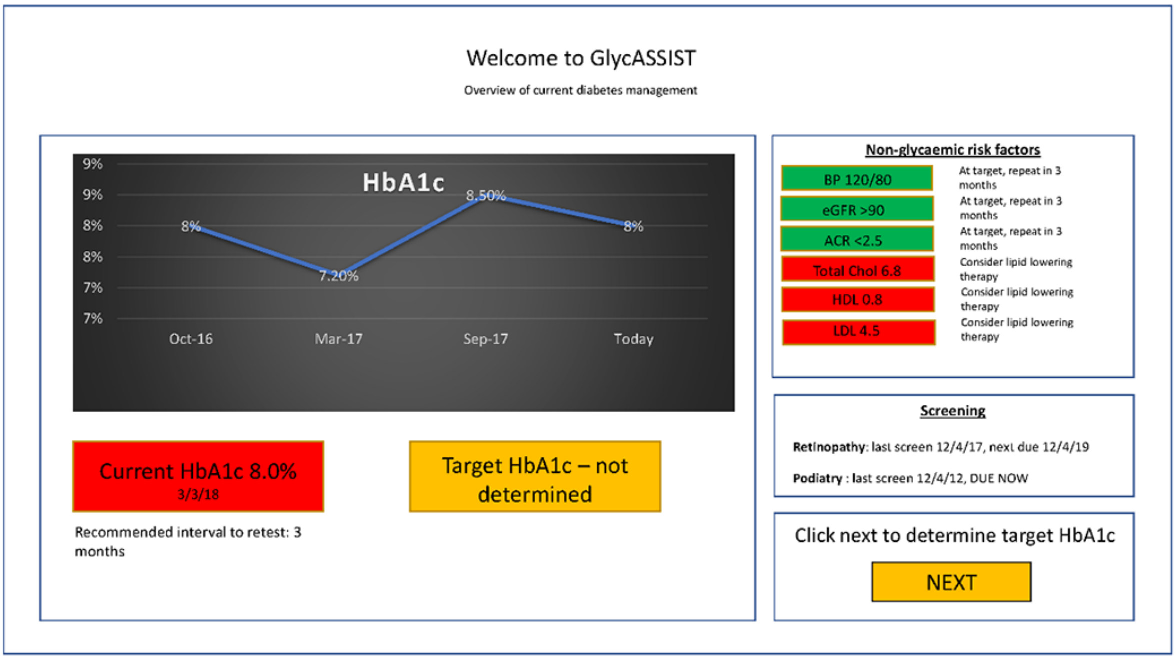
Methods

The University of Melbourne Human Research Ethics Committee provided ethical approval for both stages (stage 1: 1851169 and stage 2: 1851535).

Development of the GlycASSIST

We used an iterative two-stage co-design and refinement process to develop our CDS tool, GlycASSIST (Multimedia Appendix 1). This work was led by a multidisciplinary working group of academics and clinicians (with expertise in general practice, endocrinology, diabetes education, health psychology, behavioral science, and health informatics), who met monthly to critically review the design and refinement of GlycASSIST. A literature review identified T2D-related CDS tools currently available to GPs and summarized local guidelines [6,41] into evidence-based algorithms for personalizing HbA_{1c} targets (Multimedia Appendix 2), informing the design of the initial prototype before the first co-design stage (Figure 1). Algorithms also reflected cost to the patient via the Pharmaceutical Benefits Scheme (PBS). The PBS is a national system for providing medications at an affordable price to patients who meet specific prescribing criteria relating to current glycemic levels, previous medication use, intolerance, and contraindications to other medications. Given the number of medications available, it can be complex and time consuming for clinicians to navigate.

Figure 1. Initial prototype—page 1. ACR: albumin/creatinine ratio; BP: blood pressure; eGFR: estimated glomerular filtration rate; HbA1c: glycated hemoglobin; HDL: high-density lipoprotein; LDL: low-density lipoprotein; Total chol: total cholesterol.



Welcome to GlycASSIST

Overview of current diabetes management

Current HbA1c 8.0%
3/3/18

Recommended interval to retest: 3 months

Target HbA1c – not determined

Non-glycaemic risk factors

BP 120/80	At target, repeat in 3 months
eGFR >90	At target, repeat in 3 months
ACR <2.5	At target, repeat in 3 months
Total Chol 6.8	Consider lipid lowering therapy
HDL 0.8	Consider lipid lowering therapy
LDL 4.5	Consider lipid lowering therapy

Screening

Retinopathy: last screen 12/4/17, next due 12/4/19

Podiatry : last screen 12/4/12, DUE NOW

Click next to determine target HbA1c

We used interviews and focus groups to engage clinicians and people with diabetes in the co-design process. Although each data collection method has particular strengths, we used both to accommodate timing and venue preferences for participants. Stage 1 and 2 participants were recruited through networks of the working group, advertisements on social media (eg, Twitter), and professional association electronic communications. GPs and people with diabetes participated in both stages. Endocrinologists and diabetes educators were engaged in stage 1. The study was conducted in 2018.

Stage 1

Stage 1 interviews and focus groups were completed by trained facilitators (HM, ET, and BK) either in person or via web-based video chat. Clinicians were eligible to participate if they were a GP, an endocrinologist (with a case mix consisting of ≥50% people with T2D), or a diabetes educator. People with diabetes were eligible to participate in a separate focus group if they were aged 18 years or older, had T2D diagnosed for at least one year, and were taking glycemic medications. In-depth semistructured interviews and focus groups were designed, first, to identify the experiences and expectations of discussions about HbA_{1c} treatment targets and treatment decisions between clinicians and people with diabetes and, second, to gain feedback on the features and appearance of the initial GlycASSIST design (see Multimedia Appendices 3 and 4 for interview and focus group guides). Participants were shown the initial prototype (Figure 1 and Multimedia Appendix 5) as part of the interview and focus group and HCPs were also shown existing CDS tools [28,30,31]. The GlycASSIST prototype was further developed based on the feedback obtained.

Stage 2

GP-Simulated Consultations and Interviews

Stage 2 involved simulated clinical consultations and think-aloud interviews to understand how GPs and people with diabetes interacted with the second prototype of GlycASSIST (Multimedia Appendices 6-11) and how it could be used to facilitate SDM and treatment intensification and to gain further feedback on the design. The prototype consisted of 2 main elements: an HbA_{1c} calculator to inform personalized HbA_{1c} targets and a medication intensification tool.

Stage 2 sessions with GPs were all facilitated by a GP (HM) and software programmer (SL) in person in a mock/simulation clinical environment. GPs were eligible to participate if they had not participated in stage 1. The GPs used a desktop computer setup with EMR software that directly interacted with GlycASSIST, allowing GlycASSIST to automatically extract information from the EMR and use it to make recommendations. For GP participants in stage 2, an *initial briefing* on the features of GlycASSIST was followed by testing in a *simulated consultation*, with a diabetes educator playing the part of a person with diabetes (a *simulated patient* named Maureen). The GP was asked to interact with the simulated patient as they would any person with diabetes seeking care. The simulated patient had basic knowledge of T2D management and played *Maureen*, using a script (Textbox 1) to respond to the anticipated questions asked by the GP and to improvise in response to unexpected questions. The simulated patient's characteristics, contained within the script as well as additional clinical history, were uploaded to the EMR before the testing session to enable the GP to access clinical data as they might do routinely in a consultation and for GlycASSIST to extract and present Maureen's information to the GP. Following the simulated consultation, *a semistructured interview* was conducted (see Multimedia Appendix 12 for the guide) to follow up on comments made during the simulation and to identify feedback specific to the use of GlycASSIST and its role in treatment intensification and SDM. Clinicians were encouraged to verbalize their thoughts, including barriers and facilitators using GlycASSIST and overall usability issues [42]. GPs were asked to explain to the facilitator why and how they interacted with GlycASSIST if they decided to use it.

Textbox 1. Summary of Maureen, a person with diabetes profiled in the clinical vignette used during the simulation of a clinical consultation in stage 2.

- Maureen is a 55-year-old woman. She is seeing you/Dr Skari today to receive her most recent HbA_{1c} test results. She is reluctant to change her current medication plan but can be persuaded if the new medication is taken orally and is unlikely to result in weight gain. She does not want to check her blood sugar levels at home unless absolutely necessary
- Past medical history: No history of cardiovascular disease or stroke
- Social history: Lives alone. Carer for mother with dementia. Works part time as a receptionist. Her busy lifestyle can make it hard to manage her type 2 diabetes, but she reports that she takes her medication as prescribed
- Current medical history: type 2 diabetes for 5 years
- Current treatment: 2 g per day extended-release Metformin commenced 18 months ago. No complaints of dizziness or feeling faint
- Investigations: HbA_{1c} assessed 1 month ago=8%
- Lifestyle: Brisk walk 3 to 4 times per week for at least 30 min. Mediterranean diet but still occasionally has sweets
- Referrals: Currently seeing a dietitian. Last saw a podiatrist and an optometrist 3 months ago

Focus Groups With People With T2D

People with T2D were eligible to participate in 1 of the 2 *focus groups* based on the same criteria as stage 1 (some from stage 1 participated in stage 2). Each focus group (facilitated by HM and BK) involved participants *viewing a video of a simulated consultation* between a GP (HM) and *Maureen*, in which the GP used GlycASSIST with the person with diabetes to discuss an appropriate HbA_{1c} target and treatment plan. Participants were asked to comment on GlycASSIST and how it was used during the simulated consultation, including what they liked/disliked and suggest improvements (see Multimedia Appendix 13 for the guide).

Data Analysis

All sessions were audio-recorded, transcribed verbatim, and checked for accuracy before importing to NVivo 10 for analysis (version 2012, QSR International Pty Ltd). Two investigators (BK and JF) completed an inductive thematic analysis to identify emerging themes across participant groups. Disagreements were resolved by consensus. Themes and illustrative quotes were reviewed by the entire study team.

Results

Stage 1

In total, 12 clinicians (4 GPs, 5 endocrinologists, and 3 diabetes educators) and 6 people with diabetes (3 males and 3 females; 4 people aged <65 years, and 4 people with diabetes duration >10 years) participated in stage 1 focus groups (range 96-112 min) or interviews (range 39-92 min). Six themes were identified around key characteristics participants valued in such a tool or would like to see changed or enhanced in the next iteration of the prototype (Table 1).

Table 1. Themes identified in stage 1 with exemplar quotes from health professionals and people with diabetes.

Themes	Health care professionals	People with diabetes[a]
Balancing information needs: relevance is key	• "Too much information, and too much data entry, will just disengage people." (GP1[b]) • "I've got to go through it and I click things and it seems like that would take me longer..." (GP2) • "Is there somewhere to prompt specialist referral?...Because, sometimes they're referred years too late. Sometimes they're referred years too early. It's hard to strike a good balance. But, that may be relevant..." (Endocrinologist 2)	• "You need more information, whether it's linked to another page or something like that." • "Another thing they could add to the pop-up screen is asking 'has a...plan been set up?' because I find it so much easier." • "Its one case where I think information is not an information overload. [...]. I think information makes it acceptable and understandable."
Credibility	• "...whatever you do, you've got to be able to maintain this tool because it [the evidence] changes." (Endocrinologist 1)	• "I love hearing what is new around. I'm always interested in that."
Using GlycASSIST to reduce prescribing complexity	• "With all the changes [to the PBS schedule] I forget, off the top of my head, what you can and can't do..." (GP1)	• "...if you were having some of these side effects, the fact that there are other options is fabulous and the fact that they are listed up there [on GlycASSIST]."
The clinician, not GlycASSIST, retaining clinical autonomy	• "...it would be nice if you could have this tool open, but still look at the rest of their EMR at the same time, rather than be locked out of it." (GP1)	• "I guess it all depends on how the doctor...explains it."
Not just about medications	• "I'd double down on her diet and exercise habits, which are not really provided here [on the GlycASSIST screen], particularly in the light of her concern about weight." (Endocrinologist 3)	• "...[GlycASSIST needs] more information on the lifestyle of that person...because to come up with this number [HbA_{1c} target] is very complex."

[a] Focus group transcripts did not identify different individuals.

[b] GP: general practitioner.

Balancing Information Needs—Relevance Is Key

Clinicians wanted less information on the screen to avoid overcrowding and to reduce the number of clicks needed to progress to different GlycASSIST screens. Information retained on the screen needs to be relevant for T2D management. In contrast, people with diabetes wanted GlycASSIST to display a greater range of information (eg, weight, current medications, and comorbidities) to provide the GP with as much information as possible.

The presentation of all possible drug classes (n=8) was deemed important by clinicians and people with diabetes, but the inclusion of all side effects for each drug class was considered inappropriate by several clinicians, as some side effects are considered more common and/or serious than others. Instead, clinicians suggested listing only the most common and serious side effects. This was also supported by people with diabetes who felt it was important that medication information (both positive and negative) could be used by the GP during the discussion, where appropriate weighting could be given to each side effect.

Both clinicians and people with diabetes reported that prompts to establish a chronic disease management plan or refer to an appropriate specialist (eg, endocrinologist, dietician) would facilitate holistic and individualized care.

Credibility

Clinicians considered evidence-based recommendations critical to building trust in GlycASSIST. It was also important that the evidence was clear and updated as evidence changes. People with diabetes wanted updated information about new therapies.

Using GlycASSIST to Reduce Prescribing Complexity

Clinicians reported that GlycASSIST could be a useful tool to reduce the complexity associated with choosing diabetes glycemic medications for people with diabetes. Clinicians, especially GPs, indicated that GlycASSIST would be more useful if it included guidance on how to prescribe a medication that is subsidized by the Australian Government via the PBS. Having access to these complex subsidy regulations within GlycASSIST would make it easier to choose a medication affordable for the person with diabetes while also enabling the person with diabetes to choose a non–PBS-listed medication (ie, as a private nonsubsidized prescription) if they preferred. People with diabetes also saw the need for the tool to address complexity in the range of medication options available and in choosing based on side effects and cost.

The Clinician, Not GlycASSIST, Retaining Clinical Autonomy

It was important for GPs to make GlycASSIST work for them. For some, this meant having GlycASSIST directly generate a medication prescription, rather than only making recommendations. Others wanted GlycASSIST to perform time-saving tasks, such as entering clinical notes into the EMR, whereas for others, the autonomy to ignore or override HbA_{1c} targets or medications recommended by GlycASSIST was a priority. For people with diabetes, this was seen in how they wanted the tool to be something used by their doctor to personalize explanations and discussions, for example, in relation to medication contraindications or side effects. Several GPs indicated that it was important that GlycASSIST did not *pop up* on the screen, preferring a discrete icon that did not demand the GP's attention and could be minimized if desired.

Not Just About Medications

Both clinicians and people with diabetes reported that including lifestyle modifications (eg, regular exercise) is important for holistic care of T2D. Therefore, several participants suggested having a lifestyle assessment prompt in GlycASSIST.

GlycASSIST Prototype Refinement

Not all the findings from stage 1 could be accommodated in the second iteration of the tool. Several features were maintained and strengthened in the refined second prototype (Multimedia Appendices 6-11). Evidence-based recommendations and associated algorithms were enhanced by adding more text demonstrating the latest evidence in *hover over* boxes and including an additional algorithm related to PBS prescribing rules. Formatting features, such as color coding and not having GlycASSIST *pop up* and consume too much space on the screen, were also maintained.

Enabling clinicians to retain autonomy in their use of the tool was maintained by ensuring clinicians could continue to override recommendations, select medication classes as they deemed appropriate (ie, whether PBS is listed or not), and modify the auto-populated fields. However, it was not possible for GlycASSIST to have the capability to populate the EMR with clinical notes or generate prescriptions (rather than returning manually to the EMR and prescribing from there). These features would be possible through collaboration with EMR software vendors, but this depth of integration was not possible in this pretesting study.

The main changes made to the GlycASSIST prototype focused on information presentation and trading broadness for specificity. All changes led to a more specific focus purely on glycemia and medications (Multimedia Appendices 6-11), with removal of extraneous information, such as reference to other cardiovascular disease (CVD) risk factors, referrals, and patient preferences. For example, questions that focused on the acceptability of weight gain and injectable treatments for people with diabetes and lifestyle concerns (eg, smoking history) were removed. Yes/no responses to these issues potentially oversimplified important topics for clinical discussion. Information about medication effects, side effects, and administration were retained within the medication summary boxes (drawing on local evidence-based resources [43] to facilitate discussion). Focusing only on glycemic medications also simplified the tool, which was valued by both clinicians and people with diabetes. Finally, some changes were made to enhance the visual appeal of the tool. Clinicians appreciated the use of color coding to indicate contrasting results and to draw their attention to important information. However, the size of the font used on the screen was too small in some places.

GlycASSIST was given the ability to display the availability of PBS cost-subsidy for each recommended medication class and their associated medications. In addition, a link to the Australian Government's PBS webpage was provided [44].

Stage 2

Eight GPs (4 females, 5 trained in Australia and 5 in practice for >10 years) participated in the stage 2 computer simulations (range 35-56 min, including consultations and follow-up interviews, but not including the initial briefing). Six people with diabetes (4 women, 3 aged >65 years and 2 with T2D >10 years) participated in 1 of the 2 focus groups (range 78-83 min). Four themes were identified during the simulated consultations with GPs, debriefing interviews with GPs, and focus groups with people with diabetes (Table 2).

Table 2. Themes identified in stage 2 and exemplar quotes from general practitioners and people with diabetes.

Themes	General practitioners	People with diabetes[a]
Using GlycASSIST to support SDM[b]	• "This kind of decision making with patients, I'd normally say, 'This is what I recommend and what do you think?' I'd probably have this [SDM] conversation in my head." (GP2[c]) • "I thought it was quite handy actually, not just to me but I could talk through it with a patient." (GP3, registrar) • "...you can see all the medications and tick them off to say, 'This is what we've got'. It wouldn't be uncommon for those questions to come out, 'Do we add it? Do I stop it? Why am I taking this? Side effects?' It's a good prompt to say, 'Am I actually giving the right one here?'" (GP3)	• "She had full access to what he was looking at too, because generally you can't see the screen. The fact that they basically shared that screen [was good]." • "...it's almost too much information coming in. Its fine to have it all there in front of you but I just think...it's a bit overwhelming." • "...It allowed the doctor to stop and pause...[...]. not assume." • "...it gave him a starting point and then he went through quite systematic steps..[...].. the patient was curious, and then going through all the options."
GlycASSIST features	• "...usually I'll have to bring up diabetic guidelines and bring up therapeutic guidelines...Whereas, with the GlycASSIST, it was all there...I didn't need to move up and about, so it actually shortened the consultation time." (GP5)	• "They [GP and the person with diabetes in video] talked at length in the consultation about the exercise she was doing. There's nothing related to exercise [in GlycASSIST]...that's part of the treatment." • "There's a lot of people with diabetes who are on low income or pensions so it's a really good thing to include that [PBS information]."
Visibility and information presentation	• "...that was quite easy to use. That was very basic. It was clear and efficient, I could understand...and make a conscious decision. I thought that was good" (GP5) • "If it wasn't that easy to access...I'm unlikely to go to the desktop to find it." (GP6)	• "...that you're able to document it all and particularly get a printout of it..." • "..I don't think comes naturally to a lot of doctors to share what's on the screen...It makes it so much more easy to understand in the way its set out and everything. It's the same information but it's done in a different way..."
Workflow and navigation	• "I'm not familiar with them, so I went, well, we'll take that one [medication] out, we'll take that one out and then just pick the next one..." (GP6) • "If you could just minimize it, I think it would be simpler...Minimize, do it, pull it up. It would bring you back to the same place." (GP3) • "...So, this is the trouble with the software...you have to go back twice." (GP1)	• "... having a tool like this at the clinic I go to, there [are] probably 20 doctors […] they'll just log into it and have it all there in front of them..."

[a] Focus group transcripts did not identify different individuals.

[b] SDM: shared decision making.

[c] GP: general practitioner.

Using GlycASSIST to Support SDM

Clinicians reported that the second prototype of GlycASSIST could help them intensify treatment in collaboration with people with diabetes. They appreciated the advice about PBS availability for each recommended medication class and option. This helped GPs "comply with the [PBS] regulation" [GP1] while helping people with diabetes by ensuring that prescribed medications were affordable to them. It saved time by avoiding the need to read through the information-dense material on the government PBS website or within the EMR prescribing software.

Clinicians and people with diabetes perceived the HbA_{1c} calculator as useful for prompting collaborative conversations around appropriate HbA_{1c} targets, although several GPs were surprised by the lower recommended HbA_{1c} target of 6.5% and overrode it, independently suggesting that 7% was a more appropriate target. One GP cited concerns about hypoglycemia and clinician autonomy when overriding the target.

Some GPs appreciated how several individualized drug class recommendations were made by GlycASSIST, providing people with diabetes with a choice. However, some GPs wanted specific recommendations about the single most appropriate class for the person with diabetes, rather than being presented with a variety of clinically appropriate possibilities.

Several GPs suggested that although GlycASSIST could facilitate SDM around medication choice, they would be less inclined to discuss all options if they had already decided what medication they would prescribe. Rarely did the GP ask the simulated patient if they wanted to consider changes to their current medication management before presenting options using GlycASSIST. Furthermore, GPs rarely discussed all recommended medication classes with the person. Instead, most chose 1 or 2 classes that they deemed appropriate and presented these to the person to choose the final option based on their own preferences.

Experienced GPs suggested that GlycASSIST would be more useful for less-experienced GPs (eg, GP registrars) when choosing appropriate medication options for people with diabetes, despite stating that they themselves are not always aware of new medications and can forget existing ones.

People with diabetes mentioned that they would like to see and discuss the GP's screen as they used GlycASSIST, potentially facilitating SDM. However, in the computer simulation, several GPs did not turn their screen to show the recommendations or information provided by GlycASSIST to the simulated patient. Some GPs and people with diabetes reported that the information presented by GlycASSIST might overwhelm the person (eg, by using medical jargon), and 1 GP mentioned that it would be physically impossible for them to show their screen to the person because of their office layout. One GP suggested that SDM was not something that they routinely engaged in, preferring to make clinical decisions themselves, without involving the person with diabetes.

GlycASSIST Features

Overall, the second prototype of the tool was mostly well received. Clinicians often reported that GlycASSIST was easy to use, having the potential to shorten consultations and avoiding the need to seek out guidelines midconsultation. However, more features were requested.

Several GPs and people with diabetes suggested adding features to the screen presenting recommended medication classes. GPs liked the tabular display of medication classes, but they suggested that more information was needed, such as more detailed descriptions of each class (eg, listing both the generic and brand names for medications belonging to each class, their dose, frequency, and delivery mechanism). Some GPs requested side effects to be explicitly categorized into *rare* and *common*.

Clinicians often recommended to the simulated patient that they may benefit from seeing a diabetes educator and other allied health professionals as well as adopting and maintaining lifestyle changes. This suggests that using GlycASSIST did not dominate the consultation and still allowed the GP to address other important elements of T2D management. Some GPs requested additional features to further support them to deliver this care, for example, an integrated link to a *people with diabetes friendly* handout, including information appropriate for people with low health literacy. Several GPs suggested that GlycASSIST could present CVD risk factors (eg, lipid profile) and allow for CVD risk calculation. Finally, some GPs recommended having prompts to refer to allied health professionals. This was also suggested by people with diabetes as well as a prompt for the GP to talk with them about lifestyle modifications as part of their T2D management.

Visual Appeal and Information Presentation

Several GPs and people with diabetes reported that they liked how information was presented on the GlycASSIST screens. Most of the positive feedback was related to the graphical representation of HbA_{1c} results, enabling a trend to appear, and the tabular display of medication class choices. Overall, this layout made it easy to obtain and understand information. The use of color was also reported as appealing, with 1 GP and some people with diabetes also recommending the use of images, such as needles and syringes, when referring to injectable medications.

Clinicians and people with diabetes indicated that less information on the screen made it easier to interact with GlycASSIST. However, they were aware that a compromise must be met where relevant information remained accessible. Some GPs suggested that additional *hover over* boxes be used, enabling the GP to see important information (eg, updated evidence for suggestions and considerations for assessing the risk of hypoglycemia).

Some available information was not clear to some GPs. Some did not notice that the person's current medications and estimated glomerular filtration rate (a measure of renal function, extracted from the pathology results section of the EMR) were presented on the screen, so they sought that information manually from the EMR. Clinicians and people with diabetes also reported that the text size needed to be larger.

One GP mentioned that the subtle but obvious appearance of the GlycASSIST icon in the corner of the desktop increased the likelihood that she would click on it, suggesting that easy access and less dominating nature of the tool may be valued.

The presentation of relevant medication information, such as expected HbA_{1c} reduction, weight loss, and side effects such as nausea and genitourinary infections, was deemed important for SDM by GPs and appeared to be reflective of recommendations made in clinical guidelines.

Workflow and Navigation

Most GPs began the simulated consultation by asking the simulated patient general questions (eg, "How's work going?"), assessing lifestyle factors (eg, "Are you walking every day?"), and asking about their ability to manage their diabetes (eg, "Are you taking your tablets as prescribed?") before opening GlycASSIST.

GlycASSIST was usually opened once the GP wanted to talk about the simulated patient's HbA_{1c}, although several GPs accessed HbA_{1c} data from the investigation panel in the EMR first and then used GlycASSIST to demonstrate the trend in results over time. Clinicians progressed smoothly to the screen presenting the recommended medication classes once they had suggested to the person that their HbA_{1c} could be lowered. Once on this screen, some GPs discussed the classes with which they were most familiar and disregarded those that were unfamiliar.

Some clinicians progressed from the screen presenting the recommended medication classes to choose a specific medication to prescribe, but others found it difficult to identify a tab to facilitate this. Occasionally, GPs wanted to leave GlycASSIST to use the EMR (eg, to calculate CVD risk) or go back to the previous screen. Most GPs found these switching tasks difficult.

Discussion

Principal Findings

The aim of this study was to co-design and refine a prototype EMR-based CDS tool (*GlycASSIST*) for real time, in consultation use to support treatment intensification and SDM between GPs and people with diabetes when choosing HbA_{1c} targets and diabetes medications. The co-design process supported an iterative refinement of the tool based on early user experience. The findings from stage 1 interviews and focus groups with clinicians and people with diabetes indicated that GlycASSIST was perceived as useful for T2D management but required modifications to improve information clarity and functionality. Modifications were made to reduce the amount of information on the screens and to add recommendations regarding PBS availability, making the information presented more specific to glycemic medications. Stage 2 findings suggested that these changes were well received by GPs and people with diabetes, but more changes were required. Participants perceived GlycASSIST as useful for SDM and presented well. However, the participants recommended additional features. GPs wanted more information describing medications, added functionality (eg, being able to prescribe medications using GlycASSIST), and better navigation (eg, being able to return easily to a previous screen). People with diabetes wanted additional prompts for discussion of lifestyle, suggesting that such a feature in the tool may help overcome barriers that people with diabetes have raised on these topics.

Unlike existing CDS tools, GlycASSIST is unique in its specific focus on individualization of both HbA_{1c} targets and medication recommendations, resulting in recommendations tailored to the individual and based on both clinical and personal factors. Few existing CDS tools are EMR-integrated [28,30], and none calculate both an individualized HbA_{1c} target *and* make individualized medication recommendations on evidence-based, person-centered factors. Integration with the EMR is the strength of GlycASSIST, as it provides enough information and drug-specific advice to facilitate a conversation between the GP and person with diabetes about the most appropriate medication for them.

GlycASSIST was considered to make treatment intensification easier for both experienced GPs and registrars. This was based on the functionality of GlycASSIST (eg, using evidence-based algorithms to inform the presentation of appropriate medication classes and prescribing rules [45]) and its content (eg, including all T2D medication classes). Both clinicians and people with diabetes also felt that GlycASSIST has the potential to facilitate SDM, prompting discussion around medication side effects and outcome preferences. However, GPs in our study often overrode the HbA_{1c} target suggested by GlycASSIST and primarily discussed medication classes with which they were most familiar. Our findings suggest that although GlycASSIST might provide helpful recommendations, these recommendations do not necessarily inform clinical decisions or collaborative shared approaches to treatment choices. In a study in the United States, although >60% of physicians opened the Diabetes Wizard during a randomized controlled trial (RCT), few were still using it 1 year after incentives (and the intervention period) ended, despite most physicians being satisfied with the tool [30]. Some clinicians found it challenging to make explicit and share the conversation about medication choice that they would usually have *in their head*. Furthermore, the use of GlycASSIST in practice did not automatically lead to engagement of people with diabetes in SDM. Simply having the information and tools available to GPs may not necessarily lead to SDM if this is not the usual consulting style of a given practitioner. It was beyond the remit of our small pretesting study to include specific training or intervention to enhance SDM. Although GlycASSIST has the potential to save time in consultations and aid clinical recommendations, additional behavior change strategies may be required to facilitate uptake and reduce clinical inertia when GlycASSIST is tested experimentally [46,47].

GlycASSIST was designed specifically for (and explicitly limited to) 2 tasks: assisting GPs and people with diabetes to choose individualized HbA_{1c} targets and T2D medications. However, this explicit focus exists in tension with the ideal of holistic and integrated diabetes care. Holistic care for people with T2D includes the important role that lifestyle interventions can play in achieving glycemic targets. It also involves linking T2D to the broader clinical issue of CVD. GlycASSIST could, for example, have the capability for automated calculation and display of individualized CVD risk and highlight modifiable risk factors and lifestyle interventions for CVD. It has been recommended that T2D CDS tools include all domains of T2D care (eg, smoking frequency and other CVD risk factors) to facilitate increased and ongoing use [36]. This may generate a practical *one-stop shop* for GPs to access multimorbidity CDS. Thus, a targeted and focused tool such as GlycASSIST may benefit from integration into a more comprehensive chronic disease management tool, protecting its specificity while being embedded within a holistic approach to care by partnering GlycASSIST with related chronic disease management tools.

The evidence-based nature of recommendations generated by GlycASSIST was mentioned frequently as beneficial and necessary to facilitate treatment intensification, assuming that GlycASSIST remains up-to-date. The features that allow GlycASSIST to make treatment intensification easier are time, funding, and resource intensive [45]. A tool such as GlycASSIST needs continual updating as new evidence and clinical guidelines become available. Further development and testing of GlycASSIST in an RCT to establish efficacy at improving patient outcomes, SDM, and overcoming treatment inertia is necessary. At this stage, no plans exist for commercialization.

Strengths and Limitations

A strength of our study is that it is specific to the local context of the anticipated users (eg, by incorporating PBS rules and only medications approved for use in Australia) and provides person-centered individualized support for both establishing HbA_{1c} targets and choosing appropriate medications with people with diabetes, something not found in existing CDS tools specific to T2D management. With the multiplicity of EMR software providers in Australia and worldwide, integrated CDS tools must be developed locally to be clinically useful, incorporating their own prescribing rules. Co-design was used to enhance the design of GlycASSIST, ensuring that it met the needs of end users: both clinicians and people with diabetes. This process enabled the testing of GlycASSIST with end users to explore their interest in and interaction with GlycASSIST, which is critical for identifying both barriers to and enablers of adoption in real-world clinical settings [38,45].

One limitation, as discussed earlier, is that GlycASSIST focuses on HbA_{1c} only, although this was a compromise made explicitly and as part of our co-design process. Within that focus on glucose levels, GlycASSIST addressed pharmacological treatment intensification only, not lifestyle interventions. This limitation was a compromise, made consciously based on feedback about avoiding too much information in the tool. Another limitation of the tool is that it does not allow for uploading finger-prick BGL data. Many industry-based and other apps allow for the entry and display of individual BGL data, which could be used alongside GlycASSIST. Our tool focused on automated data extraction from the EMR for use in a consultation. Integration with the many BGL display apps could be an area for future development. Our tool did not include recommendations for deintensifying therapy. Again, this could be an area for future development. In this early formative study, GlycASSIST was developed to integrate with only 1 commercially available EMR software (Best Practice). There are multiple EMR vendors in Australia, and any future widespread implementation of GlycASSIST would require collaboration with the vendors. Our study was a formative evaluation and co-design of a prototype tool, so we did not test GlycASSIST in actual clinical practice. The GPs participating in the stage 2 computer simulations were provided with a comprehensive vignette of the simulated patient (*Maureen*). The details within the vignette might have inadvertently prompted the GP to make certain assessments, search for investigations, or make certain treatment suggestions (eg, based on CVD history). It is unclear if, and to what extent, this detail influenced the GPs' interactions with GlycASSIST or their comments about it, especially regarding suitability for clinical practice. Furthermore, the presence of the researcher and the simulated nature of the pilot testing likely impacted the way the GP interacted with the tool. Finally, GPs indicated that they participated because they were interested in GlycASSIST and clearly saw a clinical need for the tool, suggesting that their views may not be representative of the broader clinician community.

Conclusions

Our prototype has both face and content validity as well as acceptability and feasibility. Co-design incorporating local context and end user views led to a targeted tool that retained the capacity for integration with broader chronic disease management support. GlycASSIST requires additional refinement and evaluation, possibly as part of a suite of chronic disease management CDS tools, to establish its efficacy and broader acceptability for use in Australian general practice.

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Conflicts of Interest

ET and JS were supported by core funding from the Australian Centre for Behavioural Research in Diabetes (ACBRD), derived from the collaboration between Diabetes Victoria and Deakin University. JN reports grants and travel support from MSD, speaker fees and research support from Sanofi, nonfinancial support from Medtronic, nonfinancial support from Abbott, and research funding from Eli Lilly/Boehringer Ingelheim, outside the submitted work. JS has served on the advisory boards of Janssen, Medtronic, Roche Diabetes Care, and Sanofi Diabetes. Her research group (ACBRD) has received honoraria in respect of this and also received unrestricted educational grants/in-kind support from Abbott Diabetes Care, AstraZeneca, Medtronic, Roche Diabetes Care, and Sanofi Diabetes; sponsorship to attend educational meetings from Medtronic, Roche Diabetes Care, and Sanofi Diabetes; consultancy income and/or speaker fees from Abbott Diabetes Care, AstraZeneca, Medtronic, Novo Nordisk, Roche Diabetes Care, and Sanofi Diabetes. ET has undertaken research funded by an unrestricted educational grant from Abbott Diabetes Care, AstraZeneca, and Sanofi Diabetes; has received speaker fees from Novo Nordisk to ACBRD; and has served on an AstraZeneca advisory board. RA has served as a member of several advisory boards and has conducted paid presentations for pharmaceutical companies, such as AstraZeneca, Sanofi, and Novartis. JF has received unrestricted educational grants for research support from Roche, Sanofi, and Medtronic. DN is on advisory boards to Abbott Diabetes Care and Novo Nordisk and has had various financial relationships with pharmaceutical industries outside the submitted work, including consultancies, grants, lectures, educational activities, and travel. GK has served as a member of several advisory boards and has conducted paid presentations for pharmaceutical companies, including AstraZeneca, Sanofi, Lilly, and Novo Nordisk. DB, SL, and BK have no competing financial interests. The intellectual property in GlycASSIST is retained by the University of Melbourne.

Multimedia Appendix 1
Codesign phases.

[PNG File , 754 KB - formative_v4i9e17785_app1.png]

Multimedia Appendix 2
HbA1c algorithm.
[PNG File , 39 KB - formative_v4i9e17785_app2.png]

Multimedia Appendix 3
Stage 1 Interview guide.
[PDF File (Adobe PDF File), 92 KB - formative_v4i9e17785_app3.pdf]

Multimedia Appendix 4
Stage 1 focus group guide.
[PDF File (Adobe PDF File), 145 KB - formative_v4i9e17785_app4.pdf]

Multimedia Appendix 5
Initial prototype treatment intensification page.
[PNG File , 44 KB - formative_v4i9e17785_app5.png]

Multimedia Appendix 6
Second prototype - button within the EMR.
[PNG File , 241 KB - formative_v4i9e17785_app6.png]

Multimedia Appendix 7
Second prototype - opening page.
[PNG File , 976 KB - formative_v4i9e17785_app7.png]

Multimedia Appendix 8
Second prototype - treatment options page.
[PNG File , 1070 KB - formative_v4i9e17785_app8.png]

Multimedia Appendix 9
Second prototype - expanded treatment options.
[PNG File , 1276 KB - formative_v4i9e17785_app9.png]

Multimedia Appendix 10
Second prototype - prescribing page.
[PNG File , 177 KB - formative_v4i9e17785_app10.png]

Multimedia Appendix 11
Prototype 2 additional screens 6.
[PNG File , 198 KB - formative_v4i9e17785_app11.png]

Multimedia Appendix 12
Stage 2 GP Interview guide.
[PDF File (Adobe PDF File), 390 KB - formative_v4i9e17785_app12.pdf]

Multimedia Appendix 13
Stage 2 focus group guide.
[PDF File (Adobe PDF File), 110 KB - formative_v4i9e17785_app13.pdf]

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Abbreviations

ACBRD: Australian Centre for Behavioural Research in Diabetes
BGL: blood glucose level
CDS: clinical decision support
CVD: cardiovascular disease
EMR: electronic medical record
GP: general practitioner
HbA$_{1c}$: glycated hemoglobin
HCP: health care professional
PBS: Pharmaceutical Benefits Scheme
RCT: randomized controlled trial
SDM: shared decision making
T2D: type 2 diabetes

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Original Paper

Implementation of a Standardized Initial Assessment for Demand Management in Outpatient Emergency Care in Germany: Early Qualitative Process Evaluation

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Abstract

Background: Inadequate assessment of the severity and urgency of medical problems is one of the factors contributing to unnecessary emergency department (ED) visits. The implementation of a software-based instrument for standardized initial assessment—Standardisierte medizinische Ersteinschätzung in Deutschland (SmED) (*Standardized medical Initial Assessment in Germany* in English)—aims to support health care professionals and steer patients toward the right health care provider. This study aimed to explore the implementation process of SmED from a user perspective.

Objective: This study aims to evaluate the overall perception of SmED by health care professionals using the software, to examine to what extent SmED influences the workload and work routines of health care professionals, and to determine which factors are associated with the use of SmED.

Methods: An early qualitative process evaluation on the basis of interviews was carried out alongside the implementation of SmED in 26 outpatient emergency care services within 11 federal states in Germany. Participants were 30 health care professionals who work with SmED either at the joint central contact points of the outpatient emergency care service and the EDs of hospitals (ie, the Joint Counter; *Gemeinsamer Tresen* in German) or at the initial telephone contact points of the outpatient emergency care service (phone number 116117). Matrix-based framework analysis was applied to analyze the interview data.

Results: Health care professionals perceived that workload increased initially, due to additional time needed per patient. When using SmED more frequently and over a longer time period, its use became more routine and the time needed per call, per patient, decreased. SmED was perceived to support decision making regarding urgency for medical treatment, but not all types of patients were eligible. Technical problems, lack of integration with other software, and lack of practicability during peak times affected the implementation of SmED.

Conclusions: Initial experiences with SmED were positive, in general, but also highlighted organizational issues that need to be addressed to enhance sustainability.

Trial Registration: German Clinical Trials Register DRKS00017014; https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00017014

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KEYWORDS

emergency medical services; outpatient emergency care service; software; point-of-care systems; Germany

Introduction

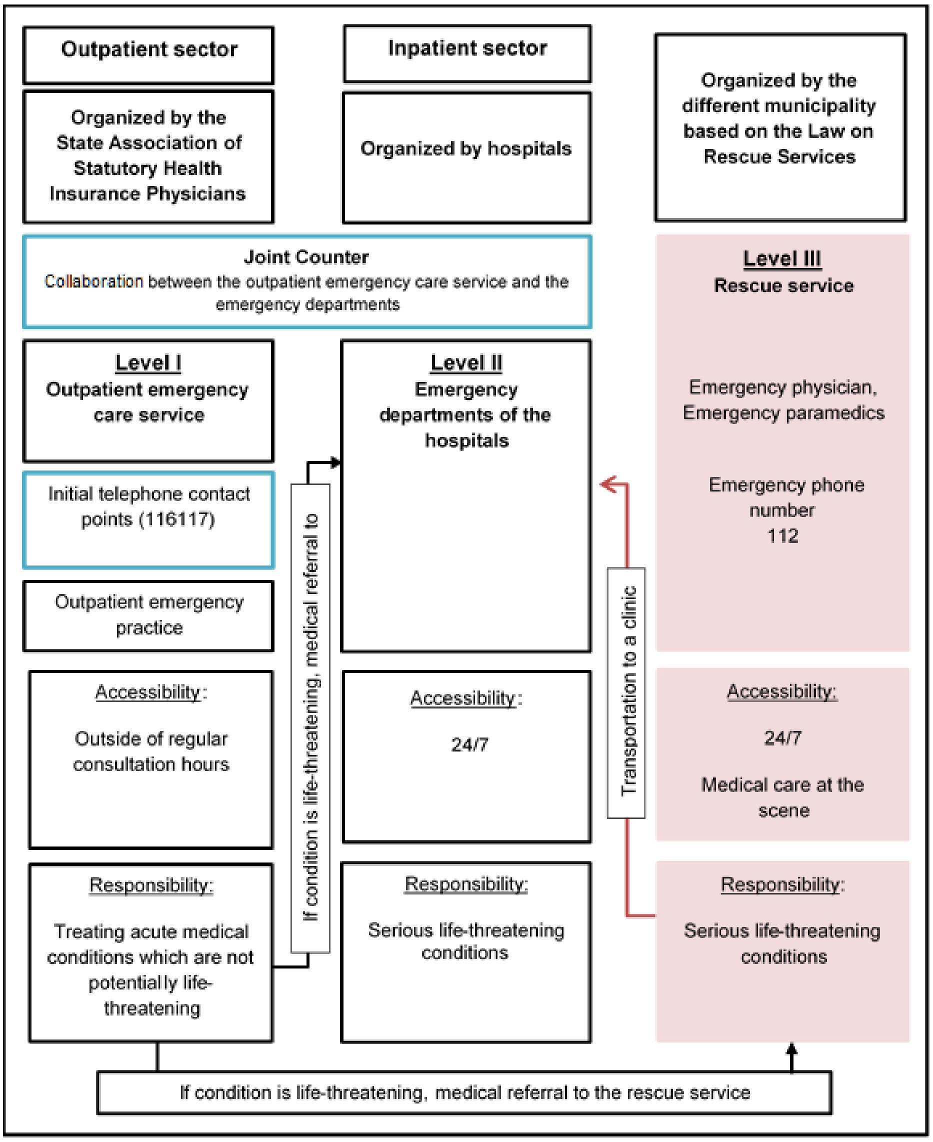
In recent years, steadily increasing utilization of emergency departments (EDs) has aroused public and political attention, not only in Germany but in many nations [1-7]. Different studies have examined factors that contribute to increased numbers of emergency admissions [5,8,9]. Factors that may explain high use of emergency resources include an aging population, increased number of chronically ill people, lack of cost awareness, lack of accessibility, unclear organization of outpatient emergency care service, and patients' personal assessments regarding severity and urgency of medical conditions [9-11]. The high use of EDs negatively affects not only patients (eg, long waiting times, reduced patient satisfaction, and higher mortality) but also health care professionals (eg, high workload, work-related stress, safety, and efficiency issues) working at the ED [2,4,9,12]. A range of strategies have been applied to address this issue by policy makers [6].

One category of strategies are programs and policies that aim to reduce the number of unnecessary ED visits. Unnecessary ED visits are defined as using the ED for health issues that do not require immediate medical treatment. Those visits could be classified as *inappropriate*, because ED resources are used for health issues that can be treated elsewhere (eg, in primary medical care or outpatient emergency care) [13]. The estimated prevalence of inappropriate visits at EDs is between 20% and 40% [13,14]. Factors associated with inappropriate use of EDs include patient age, education, and absence of family support [14]. In addition, inadequate assessment of severity and urgency of presented health problems determine inappropriate ED visits [4,14,15].

In Germany, the organization of emergency care service is complex [9]. The National Association of Statutory Health Insurance Physicians distinguish between three levels of emergency care services: the outpatient emergency care service (Level I), the emergency care service of hospitals (Level II), and the rescue services (Level III) [16]. The outpatient emergency care service is for acute medical conditions that are not potentially life-threatening that are presented outside of regular consultation hours. This service can be subdivided into the initial telephone contact points (ie, phone number 116117) or outpatient emergency practices. Outpatient emergency practices can be regular primary care physician practices or can be located at a hospital. The phone number 116117 is responsible for steering patients with medical conditions toward the right point of care. Patients calling this number have different options depending on their urgency for medical treatment. They can be advised regarding self-treatment at home, receipt of medical treatment by the primary care sector within the next few days depending on regular consultation hours, medical referral to an outpatient emergency practice, home visit by an outpatient physician, medical referral to the ED, or medical referral to the rescue service, based on their urgency for medical treatment. The Joint Counter (*Gemeinsamer Tresen* in German) is a cooperative arrangement between the outpatient emergency care service (Level I) and the EDs of the hospitals (Level II). Patients who visit the Joint Counter are either admitted to the ED or treated by the outpatient emergency care service (see Figure 1) [16].

Since the beginning of 2019, a computer-based software—Standardisierte medizinische Ersteinschätzung in Deutschland (SmED) (*Standardized medical Initial Assessment in Germany* in English)—has been implemented within the Joint Counter and the phone number 116117 to support health care professionals to steer patients toward the right point of care and, therefore, reduce inappropriate ED visits: both settings are highlighted in blue in Figure 1. Previous research showed that many complex interventions (eg, implementing a computer-based software like SmED) that have been shown to be effective failed to be implemented sustainably and widely in health care practice [17,18]. Many types of factors can act as barriers or facilitators of implementation of changes, including individual, organizational, and health system–related factors [19,20]. It is crucial to understand these factors in order to optimize the speed and comprehensiveness of implementation [17]. This study aimed to answer the following research questions: (1) What are health professionals' overall perceptions of SmED? (2) To what extent did SmED influence workload and work routines of health care professionals? and (3) Which factors were associated with the use of SmED?

Figure 1. Overview of the three different levels of emergency care in Germany.



Methods

Study Design, Ethics Approval, and Trial Registration

This early process evaluation aimed to investigate the following: Reach, Effectiveness and Efficacy, Adoption, Implementation, and Maintenance (RE-AIM), according to the RE-AIM framework [21]. A qualitative process evaluation on the basis of interviews with health care professionals was carried out alongside the implementation of SmED. Ethics approval was obtained from the Medical Ethics Committee of the Medical Faculty Heidelberg (S-640/2018) prior to the start of the study in October 2018. The study has been registered at the German Clinical Trial Register prior to the start of the study (registration No. DRKS00017014).

Study Setting

The overall aim of the DEMAND project is to improve medical care of patients who present with an urgent need for emergency treatment and/or medical advice on the basis of a more efficient use of emergency care resources. The implementation of a software-based instrument for standardized initial assessment (ie, SmED) aims to support health care professionals (eg, nurses, physician assistants, and paramedics) in emergency care and to steer patients with nonurgent medical needs toward the right point of care. The State Associations of Statutory Health Insurance Physicians have implemented SmED since March 2019 at the Joint Counter, as well as the phone number 116117, in 11 of the 16 federal states of Germany. Health care professionals within this setting were expected to change their service delivery by using the software and, therefore, influence individuals in the target population, which included patients who contact the Joint Counter or call 116117 regarding the need for medical treatment and/or advice.

Study Population

The Institute for Applied Quality Improvement and Research in Health Care (aQua Institute) invited all State Associations of Statutory Health Insurance Physicians from each federal state of Germany to take part in this project. Out of 16 federal states, 11 agreed to take part. No specific reasons for the nonparticipation of the other five federal states were identified. The State Associations of Statutory Health Insurance Physicians informed the research team at the University Hospital

Heidelberg about all health care professionals using SmED and were, therefore, potential participants. According to this number, information packages, including an invitation letter, an information leaflet, and an informed consent form for tape recording, were put together and sent to a contact person responsible for distributing. The information sheet included contact details of research team members who were available to participants to discuss the study or address additional concerns or questions. Participants who decided to take part in an interview were requested to contact the researchers directly. An informed consent form for tape recording was signed prior to the start of the interview by the participant and the interviewer. Different strategies, including email reminders, telephone calls, and the annual project coordination team meeting, were used to maximize response rate.

The Intervention

SmED is a computer-based software that requires an internet connection. The software can be used by health care professionals (eg, nurses, practice assistants, and paramedics) for initial assessment as a basis for demand management in outpatient emergency care services. The purpose of this software is to support health care professionals and to steer patients toward the right point of care based on their actual medical needs. SmED can be used in different outpatient emergency care services and applies a number of well-defined questions regarding different medical disorders and issues. SmED uses an algorithm based on the *red flag* approach to rate the urgency of patients. There are four different degrees of urgency: (I) emergency, (II) fastest possible medical treatment by a physician, (III) medical treatment by a primary care physician within 24 hours, and (VI) medical treatment within the next couple of days or telephone consulting. Patients are steered toward the right point of care based on this algorithm. In this project, SmED is used at the Joint Counter and during calls to the telephone number 116117. The software can be used immediately and at any time. However, in this project the sites decided individually when and how often they would use SmED. SmED was developed on the basis of an available system from Switzerland—the Swiss Medical Assessment System (SMASS)—and adapted to the German health care system before implementation. Regular software updates based on user feedback were performed to modify SmED during implementation.

Implementation Activities

The aQua Institute organized workshops prior to the implementation of SmED for all State Associations of Statutory Health Insurance Physicians from each participating federal state of Germany. A training concept for potential users and trainers was designed. Additionally, a data protection concept and an implementation plan for each project site was developed. Moreover, quality management and a support management program responsible for implementation sustainability were introduced.

Measures and Data Collection

Semistructured telephone interviews were conducted by the two first authors (AB and CR) with 30 health care professionals who used SmED between July and December 2019. The semistructured interview guideline (see Multimedia Appendix 1) was developed on the basis of the RE-AIM framework [22]. It covers the following themes: reach, effectiveness and efficacy, adoption and uptake, implementation, and maintenance and sustainability. These themes, as described in the original description of the RE-AIM framework [22], were translated into questions in the context of SmED. All interviews were audio recorded with the consent of all participants and ranged in length from 8 to 39 minutes. The interviews were pseudonymized and transcribed verbatim. Transcripts were not returned to participants for comment or correction. All interview quotes were translated into English by the first author (CR).

Data Analysis

The matrix-based method of framework analysis according to Ritchie and Spencer [23] and Gale et al [24] was conducted. This analysis is seen as an appropriate content analysis approach in a study where a conceptual framework is available at the start of the study [24]. As a first step, all interviews were transcribed verbatim (*Step 1: Transcription).* Additionally, all transcripts were reviewed by the two interviewers (AB and CR) for accuracy. After verbatim transcription of the interviews, the two first authors (AB and CR) became familiar with the whole dataset (*Step 2: Familiarization*). In step three, the first two interviews were deductively coded independently by the two first authors (AB and CR). Codes and themes of interest were defined based on the interview guide and on the RE-AIM framework. A few themes of interest were identified inductively from the data during the analysis (*Step 3: Coding*). The results were discussed and a final coding system based on the RE-AIM framework was developed for further analyses (*Step 4: Developing a working analytical framework*). The remaining interview transcripts were assigned to the existing codes by one researcher (CR or AB) and checked by a second researcher (AB or CR) (*Step 5: Applying the analytical framework*) [24]. The final step was to analyze whether there were any differences or connections between the codes. Interview data were analyzed using MAXQDA, version 2018.1.0, a computer-assisted qualitative data management software. Additionally, participant characteristics were analyzed descriptively using SPSS Statistics for Windows, version 25.0 (IBM Corp).

Availability of Data and Material

The dataset generated and analyzed during this study will not be made publicly available due to European Data Protection Law but may be available by the corresponding author upon reasonable request.

Results

Overview

At the beginning of the study, according to the project coordinator, 391 health care professionals used SmED. All 391 professionals were invited to take part in an interview and 30 decided to take part. Characteristics of the participants are described in Table 1.

Table 1. Characteristics of health care professionals.

Characteristic	Value (N=30)
Gender, n (%)	
Female	23 (77)
Male	7 (23)
Age (years), mean (SD)	43.3 (10.1)
Federal state of Germany, n (%)	
Baden-Wuerttemberg	1 (3)
Bavaria	3 (10)
Berlin	3 (10)
Bremen	6 (20)
Hesse	4 (13)
North-Rhine	2 (7)
Rhineland-Pfalz	5 (17)
Schleswig-Holstein	2 (7)
Thuringia	1 (3)
Westphalia-Lippe	3 (10)
Professional qualification, n (%)	
State-qualified nurse	3 (10)
Practice assistant	17 (57)
Emergency paramedic	7 (23)
Controller or dispatcher	1 (5)
Other	2 (7)
Work experience (years), mean (SD)	20.37 (9.62)
Period of time using SmED[a], n (%)	
1 month	1 (3)
Between 1 and 2 months	1 (3)
Between 2 and 3 months	4 (13)
Between 3 and 4 months	4 (13)
Between 4 and 5 months	1 (3)
Between 5 and 6 months	5 (17)
Over 6 months	14 (47)
Setting, n (%)	
Initial telephone contact point	18 (60)
Joint Counter	10 (33)
Both settings	2 (7)

[a] SmED: Standardisierte medizinische Ersteinschätzung in Deutschland (*Standardized medical Initial Assessment in Germany* in English).

Theme 1: Reach

Regarding the target population of SmED, the health care professionals explained that SmED is not applicable to patients with hearing impairment (1/30, 3%); elderly patients (2/30, 7%); terminally ill patients (2/30, 7%); patients who are incapable of answering questions due to, for example, neurological diseases (3/30, 10%); or patients suffering from alcohol or drug overdose (1/30, 3%). SmED is also not feasible for patients where someone else (eg, husband or wife) is calling on their behalf (3/30, 10%), patients with psychiatric disorders (5/30, 17%), or patients with language barriers (14/30, 47%). Moreover, SmED is not applicable if qualified health care professionals (eg, nurses working at a nursing home) call on the behalf of a patient (8/30, 27%). Health care professionals working at the initial telephone contact point (ie, phone number 116117) also reported that they do not use SmED for patients who want to order a prescription or for those seeking simple advice (3/30, 10%). Health care professionals working at the Joint Counter explained that, furthermore, SmED is not feasible for patients who are regular visitors to a long-term therapy service (1/30, 3%) or who are in poor medical condition (6/30, 20%). One health care professional stated that patients with chronic diseases or nursing diagnoses (eg, having a urinary catheter), for example, are not included.

> *80-year-old Turkish person who speaks very little German does not understand the questions and then there is no one to translate, and then SmED, it serves no purpose.* [Participant working at the Joint Counter]

Theme 2: Effectiveness and Efficacy

This theme concerns the impact of SmED on steering patients toward the right point of care and the impact of SmED on workload and working methods. A vast majority of health care professionals (21/30, 70%) stated that SmED rates the urgency for medical treatment higher than they themselves would rate the urgency. For instance, if patients report high blood pressure (4/30, 13%), infection of the gastrointestinal system (2/30, 7%), respiratory problems (3/30, 10%), fever and chills (3/30, 10%), severe pain (3/30, 10%), or uncontrolled falls (1/30, 3%), SmED immediately rates them as emergencies. Almost two-thirds of all participants (18/30, 60%) reported that if SmED rates the urgency for medical treatment higher than they expected, they changed the decision based on their professional experience or after consultation with a physician. If the health care professionals changed the category as rated by SmED, they documented and justified it on the final summary. Only 5 participants out of 30 (17%) said that they had to accept how SmED rated patients even though they disagreed with the software.

Handling of patients who are rated as nonurgent varied, depending on the setting. Patients who call the phone number 116117 and are classified as nonurgent are advised to visit an outpatient emergency practice (4/30, 13%), are forwarded to telephone counseling with a physician (9/30, 30%), receive a home visit by the emergency care physician (5/30, 17%), or are given advice (eg, going to the primary care physician within the next few days or treating themselves at home) (6/30, 20%). At some initial telephone contact points, patients are given the opportunity to call back if their medical condition is getting worse (3/30, 10%). Patients who contact the Joint Counter are treated by a physician within the next few hours but have to wait (9/30, 30%) or are referred to the outpatient emergency care sector (1/30, 3%). Due to legal requirements, all patients who contact the Joint Counter have to be treated or seen by a physician; thus, at three Joint Counters, waiting lists based on SmED categories are implemented to organize patients.

Theme 3: Adoption and Uptake

This theme concerns whether health care professionals are willing to use SmED. When asked about expectations or disappointments, one-third of the participants said they expected SmED to be an aid for decision making, especially for unexperienced colleagues (11/30, 37%). However, health care professionals stated that their professional experience influenced decisions concerning urgency of medical treatment independently of the software. In addition, their intuition, professional knowledge, and experience influenced how or if they used the software. Health care professionals stated that after working in the field of emergency care service for many years they are able to make safe decisions and rate the urgency for medical treatment of patients without a support system (18/30, 60%).

> *Well, meanwhile, I personally would say that especially for younger coworkers, it is a chance to ask structured questions. And it does not matter from where the patient is calling, we ask the same questions and eventually it is always the same result...* [Participant from telephone contact point (phone number 116117)]

Health care professionals stated that they assumed that SmED could function as a tool for quality assurance (eg, as a standard tool) (4/30, 13%). According to 7 out of 30 (23%) health care professionals, SmED provides support regarding decision making and helps to structure the assessment and, therefore, to correctly assess patients' needs for medical treatment. Nevertheless, one-third (11/30, 37%) of the participants reported that the tool is imprecise and unstructured. The order of the questions sometimes does not match a patient's symptoms. One advantage according to the health care professionals is that they do not forget questions and the system provides an opportunity for a structured assessment (8/30, 27%). In addition, questions asked after implementation have not been asked before (eg, whether the patient has been abroad lately) (1/30, 3%). Nevertheless, 4 health care professionals out of 30 (13%) mentioned that it is possible to skip questions if they are unnecessary or inappropriate, based on their professional judgment.

> *I think the main advantage is that the conversation is structured...And yes, that we identify people who dramatically report their symptoms even though they aren't that urgent. Yes, I think that we identify them.* [Participant from telephone contact point (phone number 116117)]

Although health care professionals expected SmED to be more patient oriented (8/30, 27%), some stated that it includes too many questions (3/30, 10%). Particular questions regarding medication or drugs are too complicated to answer for some patients. A small number of participants said SmED is too comprehensive (6/30, 20%). Moreover, almost one-third of interviewees (8/30, 27%) explained that they have the perception that a small group of patients are being rude and are annoyed due to busy lines, long waiting times at the Joint Counter, or being asked too many questions.

> *...the conversation definitely takes longer and, therefore, the lines are busy. Patients are sometimes annoyed if they have to wait 15 to 20 minutes instead of 10 minutes due to the additional time needed per call. Sometimes I have to ask comprehension questions like "What do you mean by that?" and that's definitely a disadvantage.* [Participant from telephone contact point (phone number 116117)]

In addition, if a patient is feeling really sick or if the situation is too challenging, answering all SmED questions puts an additional burden on the patient (2/30, 7%). Furthermore, if a patient is calling 116117 and the lines are busy, they may decide to hang up and call the rescue service.

> *I always think that if someone is really feeling sick, SmED might be a burden. I mean, I do not have feedback regarding that, no one told me that, but I have the feeling that SmED is too much for some patients.* [Participant from telephone contact point (phone number 116117)]

However, when asked about SmED's impact on patients, almost half of the participants (14/30, 47%) explained that they have the perception that patients, in general, feel like they are in good hands and that they are grateful for a more structured and comprehensive assessment. Thus, according to 6 professionals out of 30 (20%), using SmED increases patient safety.

> *...and a lot of patients like that we have to talk with them a little longer, they are like "It was very kind of you that you took that much time for me."* [Participant from telephone contact point (phone number 116117)]

The majority of health care professionals reported that one barrier was that using SmED increases their workload due to the additional time needed per call, per patient (21/30, 70%). However, through more frequent use of SmED, it became more routine and the additional time needed per call, per patient, decreased (9/30, 30%). A facilitator for implementation was motivation through colleagues, trainers, or leaders (3/30, 10%). If these persons are convinced by SmED, they were able to encourage other health care professionals. On the other hand, health care professionals who see only the negative effects of the new software can have a negative impact on successful implementation of SmED.

> *First of all, long-term employees have to be convinced because they are used to the old system. And yes, during work life, people are usually confronted with new things; however, Germans tend to only see the negative sides of new things at the beginning.* [Participant from telephone contact point (phone number 116117)]

Theme 4: Implementation

This theme concerns the consistency of the organization and adjustments made during and prior to the delivery of the intervention as well as implementation strategies. All interviewees (30/30, 100%) reported that they participated in a training session prior to implementation. The development and structure of SmED and its beginning in Switzerland were presented. During the training session, participants worked with exemplary patient cases. The success of the training sessions was monitored differently. However, nearly one-third of all health care professionals (8/30, 27%) stated that they used patient cases to learn how to use SmED. Those cases were discussed at the end of the training session. Out of 30 participants, 1 (3%) said that they used SmED once during their working hours with different patient cases to understand how the software works in real-life situations. Another participant (1/30, 3%) explained that they had to use SmED five times during their working hours and documented it. Out of 30 participants, 1 (3%) explained that they watched web-based videos and tested their knowledge afterward. A total of 5 out of 30 (17%) interviewees stated that they were able to ask experienced colleagues further questions at the start of the implementation of SmED to learn how to use the software correctly. The overall training was evaluated as completely positive by 20 out of 30 (67%) interviewees. Out of 30 participants, 1 (3%) brought up that it was too much input for one day. A total of 5 out of 30 (17%) participants mentioned that the theoretical part was too long and 4 (13%) said that more practical examples would have been beneficial.

> *We had a training session and after that SmED was installed by Medistar, which is the software provider. We then could use the test version to get familiar.* [Participant working at the Joint Counter]

Almost all participants (26/30, 87%) reported that they had not used an initial-assessment software prior to implementation of SmED. Health care professionals explained that they had internal standards and a guideline for conversations with patients but could ask questions individually. A total of 4 health care professionals out of 30 (13%) stated that they had access to another initial-assessment software, which prioritized and categorized patients.

Prior to the start of using SmED, 3 participants out of 30 (10%) from the Joint Counter stated that they introduced a system where patients first pull a number and are then transferred to a waiting area further away from the counter due to data protection law. Out of 30 interviewees, 2 (7%) mentioned that they increased their number of employees.

Theme 5: Maintenance

This theme concerns the extent to which SmED becomes institutionalized or part of the routine organizational practices and policies. Different facilitators and barriers influencing implementation of SmED were identified by the health care professionals. One barrier according to the interviewees (10/30, 33%) is that currently an integration with other software is not possible. Participants explained that a closer connection of SmED with the information system used in daily practice would increase acceptance and feasibility. At this time, health care professionals stated that they had to work with both software programs in parallel. This had a massive impact on workload. Implementing an interface between the two software programs would, therefore, enhance implementation sustainability.

> *One problem is that there is no link or interface between SmED and the software usually used.* [Participant from telephone contact point (phone number 116117)]
>
> *Nevertheless, I think if there is a link between SmED and our software, acceptance by the employees will increase and, with a higher acceptance, I will get more experienced and have a better understanding.* [Participant from telephone contact point (phone number 116117)]

Health care professionals stated that they were disappointed due to challenging technical problems they face during their daily working routines. Hence, SmED is not always practicable (5/30, 17%) due to, for example, a poor internet connection. A total of 2 professionals out of 30 (7%) said that SmED is a computer-based program that is error prone (2/30, 7%) and can be tricked; for example, patients who are frequent callers know how to answer in order to be rated as urgent (1/30, 3%). A total of 2 health care professionals out of 30 (7%) explained that another barrier for successful implementation could be lack of employees in the future. At this time, additional time needed per call, per patient, already increases the workload per employee.

> *We will definitely need more employees; this is crucial, since the number of incoming calls has increased gradually and also time needed per call rose due to using SmED...* [Participant working at the Joint Counter]

Moreover, using the software during peak times or at times with higher call volumes, such as during national holidays, is not feasible. Almost one-third of participants (9/30, 30%) reported that a large volume of incoming calls during the use of SmED increases pressure on employees and, thus, induces work-related stress. Health care professionals working at the Joint Counter stated that SmED is not practicable if the number of patients waiting is high (6/30, 20%).

> *At the moment, we use SmED only three days per week: Monday, Tuesday, and Thursday. I guess we are also supposed to use it on weekends and national holidays sometime soon. I think it is not feasible to use it then, due to the high number of patients visiting us.* [Participant working at the Joint Counter]

Another barrier described by 1 participant (3%) is that sharing information with the next point of care is currently not possible. On the other hand, 1 health care professional (3%) mentioned that information can be shared between the Joint Counter and the rescue service. Thus, patients calling 112—the emergency phone number—inappropriately can be steered to the right point of care easily. A total of 4 (13%) participants from the Joint Counter described problems regarding data security and privacy. According to the health care professionals, separate rooms are needed to use SmED to prevent invasion of privacy. At this time, patients usually wait in a queue and can hear what the person in front of them is being asked.

> *...the problem is data protection! Patients sit here or stand here and then we ask them questions and another person is standing behind them. Even though we say, "Could you keep a proper distance please..."* [Participant working at the Joint Counter]

A total of 2 (3%) health care professionals reported that, although they use SmED, a physician could be sitting next to them asking the patient the same questions and could rate the urgency based on her or his experiences and not based on SmED results. Nearly half of all health care professionals (14/30, 47%) described that, often, physicians do not read the summaries created by SmED. According to 11 participants (37%), summaries were only partly read. Thus, questions may be asked twice. This perhaps could give patients the impression that the professionals do not communicate effectively. Moreover, the health care professionals using SmED feel like their work is unnecessary.

> *Impact on the patient? I think...in general...patients like being questioned at first...it is not disadvantageous. However, sometimes the physician asks the same questions because they do not read the summary and then the patient thinks we do not communicate...* [Participant working at the Joint Counter]

A total of 1 (3%) interviewee stated that developing a simpler version of SmED that can be used at the Joint Counter while examining patients may positively influence implementation sustainability. Moreover, regular software updates including user feedback (eg, symptoms that are missing) were needed during implementation. More than one-third of all participants (11/30, 37%) described that they could collect suggestions for improvement and share this information with software engineers. If appropriate, those suggestions could be integrated into SmED within the next software update, which could facilitate implementation. A total of 2 (7%) participants stated that this will support implementation sustainability. Additional training will also improve maintenance. Another facilitator for maintenance mentioned by 4 (13%) interviewees is that SmED is a medical product and, therefore, assures legal certainty. The *red flag system* or the *priority list* (4/30, 13%), which helps to easily identify emergency patients, is another benefit.

More than half of the participants (16/30, 53%) explained that the medical responsibility lies with the health care professionals answering the call or admitting the patient to the ED. However, depending on the software ranking, responsibility stays with the professionals or is handed over to the next point of care. The other half (12/30, 40%) reported that the medical responsibility always lies with a physician. A total of 1 (3%) participant stated that after implementing SmED, liability is placed on the medical product, which enhances implementation sustainability. According to 4 (13%) participants, there are neither facilitators nor barriers influencing the implementation, since it will be binding for all State Associations of Statutory Health Insurance Physicians to use SmED for initial assessment from 2020 onward.

> *Our expectations have been met. We are legally protected, we do not forget to ask certain questions, and it is a support for decision making. It is perfect for us.* [Participant from telephone contact point (phone number 116117) and the Joint Counter]

Discussion

Principal Findings

This study focused on the perceptions of health care professionals at an early stage of the implementation of SmED. In general, health care professionals evaluated SmED positively. Workload increased initially, due to additional time needed per call, per patient. If SmED had been used more frequently and over a longer time period, its use by health care professionals would have become more routine, which would have a positive impact on time needed per call, per patient. SmED was perceived to support decision making regarding urgency for medical treatment, albeit not all patients were eligible. Technical problems, lack of integration with other software, and lack of practicability during peak times influenced the implementation process negatively. Eliminating given barriers may influence uptake and implementation sustainability.

Comparison With Previous Work

Reach

SmED is not applicable to all patients, neither at the Joint Counter or at the initial telephone contact points. This group seems small, but includes patients with complex needs who may frequently contact out-of-hours care. Particularly, patients with neurological diseases [25] or psychiatric disorders [26] need to be steered toward the right point of care based on their urgency due to the risk of sudden or unexpected deterioration. The same is true for patients with alcohol intoxication [26]. According to a study by Pajonk et al [27], the number of psychiatric emergencies has increased in recent decades. It, therefore, seems problematic that SmED does not depict those cases.

Effectiveness and Efficacy

The overall aim of SmED is to improve emergency care for patients with urgent conditions, steer patients with nonurgent medical needs toward the right point of care, and, therefore, disburden the EDs. The urgency for medical treatment rated by SmED was perceived to be higher than health care professionals' assessments. This may have an impact on the effectiveness of SmED to identify patients with nonurgent conditions and to steer them toward the right point of care. This finding is consistent with those by Jansen Van Eijndt et al [28]. They had more urgent patients after implementing a computer-based triage system. A more defensive algorithm identifying nonurgent patients may be needed to improve the effectiveness of SmED regarding steering nonurgent patients toward the right point of care. A systematic review by Huibers et al [29] concluded that, on average, patient safety is high if patients with nonurgent medical symptoms contact the out-of-hours service via telephone. However, there is room for enhancing patient safety for patients who present with highly urgent medical symptoms [29]. They found that an average of 10% of telephone triage contacts with patients reporting urgent symptoms resulted in different adverse events, such as medical errors or unplanned ED attendance. In our study, health care professionals stated that patient safety, in general, increased after implementation of SmED. This finding agrees with the results of a study by Van Ierland et al [30] evaluating the validity of the Netherlands Triage System (NTS). They detected an increasing tendency toward more ED referrals among high-urgency-level patients and an increased amount of self-care advice among lower-urgency-level patients for the computer-based telephone triage. The urgency levels ranked by the systems matched with the majority of those using the system; thus, NTS seems to be feasible. However, an independent standard identifying true undertriage and overtriage may be needed [30]. According to Scherer et al [9], the main reason for overcrowding EDs is patients who do not require urgent medical care. Hence, the objective to address this problem may not be achieved, due to lack of effectiveness described above. In addition, at the Joint Counter, patients rated as nonurgent are treated by a physician but have long waiting times, which contribute to the overcrowding. Nevertheless, due to legal regulations (§ 27 SGB V), employees of the Joint Counter are ordered to treat every patient. Patients rated as nonurgent at the initial telephone contact points (ie, phone number 116117) are admitted to the outpatient emergency practice, connected to telephone counseling, or given telephone advice. However, at this point in time it is not clear whether patients accepted this procedure or whether they still sought medical treatment at the ED after calling 116117.

Health care professionals stated that their workload increased due to more time needed per call, per patient, when using SmED. This has a negative impact on the efficacy of the professionals. This finding is supported by the results of Porter et al [31]. In their study, they evaluated the experiences of paramedics using a computerized clinical decision support (CCDS) system. The interviewed paramedics reported that they need more time at the scene when using the CCDS system. Nevertheless, this finding disagrees with those by Ong et al [32]. In their study, they investigated whether there is a difference in call duration and triage decisions in out-of-hours cooperatives when using or not using an expert system. Professionals interviewed in our study stated that their perceptions regarding additional time needed changed positively over time due to frequent use of SmED, which enhances routine and, in turn, has a positive impact on efficacy.

Adoption

SmED can function as a decision-making process regarding urgency for medical treatment support for unexperienced professionals. Nevertheless, many years of professional experience and knowledge were perceived as a basis for safe decision making. These findings correspond with those by Snooks et al [7], who investigated paper-based protocols to assess and triage patients, regarding their need for transportation to the ED. According to the findings by Snooks et al [7], decisions were influenced mainly by experience. Porter et al [31] concluded that paramedics would rather trust their clinical skills than the software [31]. Chang et al [33] described that professional experience and intuition plays an important role for nurses while using a triage system and improves decision making; these findings are consistent with those by Smits et al [34], Van der Linden et al [35], and O'Cathain et al [36]. Smits et al [34] investigated telephone triage in general practices in the Netherlands and concluded that triage accuracy is higher among practice assistants with more years of professional experience. Van der Linden et al [35] investigated whether ED crowding affects triage processes in the Netherlands. They found that more patients were redirected to general practice care when the nurses were more experienced. O'Cathain et al [36] evaluated whether different types of nurses differ regarding their triage decisions. They observed that length of clinical experience and type of software used influenced decision making. Nurses with more experience were more likely to give advice regarding self-treatment at home compared to less experienced nurses [36]. Nurses with more years of experience have more professional knowledge and clinical skills compared to professionals with fewer years of experience; therefore, decision making differs [37]. Although SmED supports decision making among younger professionals, professional experience is perceived as an important factor.

Health care professionals expected SmED to be a tool for legal protection and quality assurance. However, at this point in time it is not clear if SmED can provide legal certainty. Moreover, health care professionals are able to skip questions; therefore, the concept of using a software program as a nationwide standard for quality assurance may not be fulfilled. Porter et al [31] support this finding. According to their results, several paramedics used CCDS systems retrospectively to save time and not as a decision support. SmED uses an algorithm based on the *red flag* approach. It is not clear whether only relying on this algorithm is acceptable or if the experience of health care professionals regarding patient safety should be considered. Interestingly, the perception of the structure of SmED varied between imprecise and precise. The participants reported that they can skip questions and that the order of the questions is inappropriate. However, SmED provides a system for a structured initial assessment and functions as a reminder for crucial questions. These findings agree with those by Porter et al [31], who found that health professionals explained that CCDS systems reminded them to do all necessary checks. Patients' satisfaction increased due to more structured and comprehensive assessments. This finding is supported by Snooks et al [7], where patients' satisfaction with their care was higher due to more in-depth assessments.

Implementation and Maintenance

In general, the introduction of SmED and training prior to implementation was evaluated positively. However, implementation slightly differed among the project sites. Success of implementation was ensured differently, therefore, continuity was not given. This may have an impact on how health care providers evaluated and accepted SmED in general. The main barrier mentioned by the professionals is the lack of integration with the software that was used parallel to SmED. This finding is consistent with those of Porter et al [31], who detected a variety of technical problems (eg, difficulties keeping the PC charged or printing patient records). Health care professionals also assumed that SmED could be a tool for quality assurance but, contrary to expectations, SmED still has some technical limitations, such as a lack of practicability due to a poor internet connection. These results agree with those by Porter et al [31], where paramedics reported having problems with the CCDS system, since it is web based and, thus, not practicable without an internet connection.

According to regulation § 75 SGB V, the outpatient emergency care sector is the first contact point for patients outside of regular consultation hours (eg, during national holidays or on the weekend). However, use of SmED is not feasible during peak times or at times with higher call volumes (eg, national holidays and weekends). Using SmED will be binding for all State Associations of Statutory Health Insurance Physicians at the initial telephone contact points (ie, phone number 116117) [38]. In addition, advertisements for the phone number 116117 have increased, with more marketing planned in 2020. Thus, the number of patients calling 116117 may rise further. More employees may be needed to ensure that all calls can be answered within an appropriate time period. High incoming call volumes have already increased work-related pressure. Additional time needed per call may exacerbate this issue. Nevertheless, it is not clear whether SmED is the only related factor.

Limitations and Strengths

This study was carried out in only 11 federal states of Germany; including the missing states could have identified new aspects. Although respondents were mostly outspoken about their perceptions, social desirability cannot be precluded. It is possible that comparability may not occur, due to the long time period for conducting the interviews. Moreover, health care professionals started to use SmED at different time points, which may have influenced their perceptions as well. Although different reminders to increase the response rate were used, only a low number of participants were reached. This may be due to not having contacted the health care professionals personally. This analysis was guided by an appropriate methodological strategy to minimize research bias and reduce the risk of losing relevant content. In addition, the analysis was done by the two first authors individually and was compared during several meetings to ensure consistent coding.

Conclusions

This study is probably the first study to investigate perceptions of health care professionals regarding a computer-based instrument for standardized initial assessment in Germany. Despite the limitations, this study shows that using a software-based instrument for standardized initial assessment supports health care professionals' decision making. Nevertheless, SmED rates patients' urgencies as higher than do the professionals; it is, therefore, not clear whether SmED steers patients with nonurgent medical needs toward the right point of care, thereby disburdening the EDs. The findings of this study could help to implement SmED in additional federal states of Germany, as well as to implement similar computer-based initial-assessment software systems in other European countries.

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Authors' Contributions

MW and JP conceived the study. CR and JP elaborated the study protocol. MW is principal investigator of the study and provided critical input at every stage of the development of the study protocol. AB, CR, and JP organized data collection. AB and CR conducted and analyzed the interviews. CR and AB wrote the manuscript. All authors provided substantial comments and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Translated interview guide used to conduct the qualitative interviews with health care professionals.
[DOCX File , 14 KB - formative_v4i9e18456_app1.docx]

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Abbreviations

aQua Institute: Institute for Applied Quality Improvement and Research in Health Care
CCDS: computerized clinical decision support
ED: emergency department
NTS: Netherlands Triage System
RE-AIM: Reach, Effectiveness and Efficacy, Adoption, Implementation, and Maintenance
SMASS: Swiss Medical Assessment System
SmED: Standardisierte medizinische Ersteinschätzung in Deutschland (*Standardized medical Initial Assessment in Germany* in English)

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Original Paper

eHealth Communication With Clients at Community-Based HIV/AIDS Service Organizations in the Southern United States: Cross-Sectional Survey

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Abstract

Background: Providing HIV/STD testing and prevention education, medical and nonmedical case management, housing assistance, transportation services, and patient navigation are just a few examples of how community-based HIV/AIDS service organizations will help the United States realize the goals of the updated National HIV/AIDS Strategy.

Objective: In this study, the aim was to assess electronic data security confidence level, electronic communication behaviors, and interest in using eHealth communication tools with clients of staff at community-based HIV/AIDS service organizations.

Methods: Staff were recruited from 7 community-based HIV/AIDS service organizations in the southern United States (3 in South Carolina and 4 in Texas). The principal investigator used state department of health websites to identify community-based HIV/AIDS service organizations. Staff were included if they provided HIV/STD prevention education to clients. A recruitment letter was sent to community-based HIV/AIDS service organization leaders who then used snowball sampling to recruit eligible staff. Chi-square tests were used.

Results: Among staff (n=59) who participated in the study, 66% (39/59) were very or completely confident that safeguards are in place to keep electronically shared information from being seen by other people; 68% (40/59) used email, 58% (34/59) used text messages, 25% (15/59) used social media, 15% (9/59) used a mobile app, 8% (5/59) used web-enabled videoconferencing, and 3% (2/59) used other tools (eg, electronic medical record, healthnavigator.com website) to communicate electronically with their clients. More than half were very interested in using eHealth communication tools in the future for sharing appointment reminders (67%, 38/59) and general health tips (61%, 34/59) with their clients. Half were very interested in using eHealth communication tools in the future to share HIV medication reminders with their clients (50%, 29/59). Forty percent (23/59) were very interested in using eHealth communication tools to share vaccination reminders with their clients.

Conclusions: Community-based HIV/AIDS service organization staff had some level of confidence that safeguards were in place to keep electronically shared information from being seen by other people. This is critically important given the sensitivity of the information shared between community-based HIV/AIDS service organization staff and their clients, and because many staff were very interested in using eHealth communication tools with their clients in the future. It is very likely that eHealth communication tools can be used in community settings to improve health outcomes across the HIV care continuum; in the interim, more research is needed to better understand factors that may facilitate or impede community-based HIV/AIDS service organization staff use and client acceptability.

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KEYWORDS

eHealth; communication; HIV; disparities; inequalities

Introduction

Background

The 4 main goals of the updated National HIV/AIDS Strategy [1] are reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV, reducing HIV-related disparities and health inequities, and achieving a more coordinated national response to the HIV epidemic. Providing HIV/STD testing and prevention education, medical and nonmedical case management, housing assistance, transportation services, and patient navigation are just a few examples of how community-based HIV/AIDS service organizations will help the United States realize its vision to

> *become a place where new HIV infections are rare, and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity, or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination* [1]

Electronic health (eHealth) is a field in which health service delivery and information sharing are enhanced through the use of the internet and related technologies [2]. A recent study provides the following 3 clearly defined domains of eHealth: (1) health in our hands (using eHealth technologies to monitor, track, and inform health), (2) interacting for health (using digital technologies to enable health communication among practitioners and between health professionals and clients or patients), and (3) data enabling health (collecting, managing, and using health data) [3].

In the field of HIV/AIDS prevention, eHealth communication tools improve health outcomes across the HIV care continuum, which include diagnosis of HIV infection; linkage, engagement, retention in HIV care; and achieving viral suppression [4,5]. Recent studies [6-14] have shown how social media and technologies such as avatar-led and smartphone games can be leveraged to prevent the spread of HIV infection and sexually transmitted diseases, as well as improve HIV-related health outcomes such as diagnosis of HIV infection; linkage, engagement, retention in HIV care; and medication adherence.

Unfortunately, some community-based HIV/AIDS service organization clients will encounter barriers using eHealth communication tools to access health services such as HIV/STD testing and HIV care. While some researchers have studied eHealth literacy, acceptability, adoption, and attitudes among individuals such as people living with HIV and men who have sex with men, the target audience is usually the client and not staff [15-19], though some have studied eHealth adoption and attitudes among health care providers in clinical settings [15].

Objective

While eHealth communication tools have been studied from the perspective of community-based HIV/AIDS service organization clients, little is known about electronic communication beliefs, behaviors, and attitudes of community-based HIV/AIDS service organization staff. This is unfortunate because researchers have shown that community-based HIV/AIDS service organization staff are a trusted source of information about health or medical topics, in addition to their primary role aimed at improving health outcomes along the HIV care continuum [20]. In this study, the principal investigator assessed staff confidence in electronic communication data security, electronic communication behaviors with clients, and attitudes toward using eHealth communication tools with their clients in the future among community-based HIV/AIDS service organization staff. The long-term goal is to build the capacity of community-based organizations to leverage their ability to reach marginalized vulnerable populations with eHealth communication tools that can improve their overall health and well-being, especially among people living with HIV who are underrepresented (compared to men who have sex with men) such as women, transgender persons, and older adults.

Methods

Data Collection

The principal investigator (LTW) used state department of health websites to identify community-based HIV/AIDS service organizations. A recruitment email was sent to community-based HIV/AIDS service organization leaders who were asked to invite their eligible staff to participate in the survey. Staff were included if they provided HIV/STD prevention education to clients. No other inclusion or exclusion criteria were used. Positions that were commonly held by participants were case manager, counselor, patient navigator (including linkage specialist or care coordinator), social worker, program coordinator or manager, prevention coordinator, and outreach specialist.

Staff were recruited from 7 community-based HIV/AIDS service organizations in nonclinical urban settings located in the southern United States. In May 2016 and June 2016, the principal investigator (LTW) conducted a paper and pencil survey with from staff at 3 community-based HIV/AIDS service organizations located in South Carolina. Approximately two-and-a-half to three years later (October 2018 to December 2018 and May 2019) when the principal investigator relocated to Texas, the survey was converted to an online format (Qualtrics XM) and distributed to staff at 4 community-based HIV/AIDS service organizations located in Texas. These study details have been previously published [20-22].

Measures

Sociodemographic Characteristics

To describe the sociodemographic characteristics of community-based HIV/AIDS service organization staff, age, sex, sexual orientation, marital status, race/ethnicity, and education were assessed. See Multimedia Appendix 1 for more details.

Electronic Data Security Confidence Level

To assess electronic data security confidence level, community-based HIV/AIDS service organization staff were asked, “How confident are you that safeguards are in place to keep electronically shared information from being seen by other people?” This question was adapted from the following Health

Information National Trends Survey validated question [23]: "How confident are you that safeguards (including the use of technology) are in place to protect your medical record from being seen by people who aren't permitted to see them?" Participants responded using a 5-point Likert scale. Response options were coded as 0 (not at all confident) to 4 (completely confident). For analysis, this item was recoded into a dichotomous variable where 1 (completely or very confident) and 0 (somewhat or a little confident). See Multimedia Appendix 2 for more details.

Electronic Communication With Clients

A dichotomous (yes or no) variable was used to assess the following modes that community-based HIV/AIDS service organization staff used to communicate electronically with their clients: email, text message, social media, web-enabled videoconference, mobile app, or something else. See Multimedia Appendix 2 for more details. A composite score was calculated so that a higher value represented the modes of electronic communication that staff used more.

Future eHealth Communication Tools With Clients

To assess interest in using eHealth communication tools with clients in the future, community-based HIV/AIDS service organization staff were asked, "How interested are you in electronically sharing the following types of health-related information with your clients: appointment reminders, HIV medication reminders, vaccination reminders, and general health tips?" Response options ranged from 1 (not at all interested) to 4 (very interested). See Multimedia Appendix 2 for more details. For analysis, this item was recoded into a dichotomous variable, 1 (very interested) or 0 (somewhat, a little, or not all interested). A composite score was calculated so that a higher value represented more modes of eHealth communication that staff were interested in using to communicate with their clients in the future.

Data Analysis

Data for this cross-sectional study were analyzed using Stata/SE (version 16.1; StataCorp LLC). Median (range) or frequency (percentage) were calculated for sociodemographic characteristics, electronic data security confidence level, electronic communication with clients, and future eHealth communication with clients. Chi-square tests were performed to examine bivariate associations between electronic data security confidence level and the following: sociodemographic characteristics, electronic communication with clients, and future eHealth communication with clients. $P<.05$ was used to determine statistical significance.

Ethics

This study was reviewed and approved by the institutional review boards at the University of South Carolina and Texas A&M University.

Results

Participants

Table 1 shows the sociodemographic characteristics and median (range) values of the key measures for staff (n=59) at community-based HIV/AIDS service organizations located in the southern United States. The median age for staff was 44 years old (range: 21-70, n=56). Most were younger than 50 years old (36/59, 64%). More than half were female (35/59, 59%), and 41% (24/59) were a sexual minority. Only 10% (6/59) were Hispanic; the majority were non-Hispanic Black or African American (44/59, 74%). All had at least a high school diploma or GED, with 46% (27/59) having earned an undergraduate degree and 25% (15/59) having earned a master's degree.

Table 1. Sociodemographic and eHealth communication characteristics of staff at community-based HIV/AIDS service organizations located in the southern United States (n=59).

Characteristic	Value
Age in years (n=56), median (range)	44 (21-70)
Sex (n=59), n (%)	
Male	24 (41)
Female	35 (59)
Sexual orientation (n=59), n (%)	
Straight, that is, not lesbian or gay	35 (59)
Lesbian or gay	20 (34)
Bisexual	3 (5)
Preferred not to say	1 (2)
Marital status (n=59), n(%)	
Single, never been married	29 (49)
Married or living as married	24 (41)
Divorced	4 (7)
Separated	2 (3)
Race/ethnicity (n=59), n (%)	
Hispanic	6 (10)
Black or African American	44 (74)
White	7 (12)
Asian	1 (2)
Multiple	1 (2)
Education (n=59), n (%)	
High school diploma/GED/some college	17 (29)
Undergraduate degree	27 (46)
Postgraduate degree	15 (25)
Electronic data security confidence level (n=59), median (range)	3 (1-4)
Electronic communication with clients[a] (n=59), median (range)	2 (0-5)
Future eHealth communication with clients[b] (n=56), median (range)	2 (0-4)

[a] Email, text, social media, web-enabled videoconference, mobile app, something else (eg, electronic medical record, healthnavigator website).

[b] Appointment, medication, vaccination reminders, or general health tips.

Electronic Data Security Confidence Level

All were at least a little confident that safeguards are in place to keep electronically shared information from being seen by other people—Table 1 shows that the median confidence level was 3 (range 1-4) (ie, 3 indicates very confident). Among 59 staff, 66% (39/59) were very or completely confident and 34% (20/59) were somewhat or a little confident that safeguards are in place to keep electronically shared information from being seen by other people. Table 2 shows that there were no statistically significant differences in electronic data security confidence level between community-based HIV/AIDS service organization staff based on sociodemographic characteristics (age: *P*=.73, sex: *P*=.23, sexual orientation: *P*=.63, marital status: *P*=.53, race/ethnicity: *P*=.77, education: *P*=.82).

Table 2. Bivariate associations between sociodemographic characteristics and eHealth communication modes of staff at community-based HIV/AIDS service organizations by electronic data security confidence level (n=59).

Characteristic	All (n=59), n (%)	Electronic data security confidence level		*P* value
		Completely or very confident, (n=39), n (%)	Somewhat or a little confident (n=20), n (%)	
Sociodemographic				
Age in years[a], <50	36 (64)	25 (66)	11 (61)	.73
Sex, female	35 (59)	21 (54)	14 (70)	.23
Sexual orientation, sexual minority[b]	24 (41)	15 (38)	9 (45)	.63
Marital status, unmarried[c]	35 (59)	22 (56)	13 (65)	.53
Race/ethnicity				.77
Hispanic	6 (10)	3 (8)	3 (15)	
Black or African American	44 (74)	29 (74)	15 (75)	
White	7 (12)	5 (12)	2 (10)	
Asian	1 (2)	1 (3)	0	
Multiple	1 (2)	1 (3)	0	
Education				.82
High school/GED/some college	17 (29)	12 (31)	5 (25)	
Undergraduate degree	27 (46)	18 (46)	9 (45)	
Postgraduate degree	15 (25)	9 (23)	6 (30)	
eHealth Communication				
Electronic communication with clients, any mode[d]	52 (88)	33 (85)	19 (95)	.24
Future eHealth communication with clients, very interested				
Appointment reminders[e]	38 (67)	26 (68)	12 (63)	.69
Medication reminders[f]	29 (50)	21 (55)	8 (40)	.27
Vaccination reminders[e]	23 (40)	18 (47)	5 (26)	.13
General health tips[a]	34 (61)	21 (57)	13 (68)	.40

[a] Data were missing for 3 individuals.

[b] Lesbian or gay, bisexual, or preferred not to say.

[c] Divorced, separated, or single.

[d] Email, text, social media, web-enabled videoconference, mobile app, something else (eg, electronic medical record, healthnavigator website).

[e] Data were missing for 2 individuals.

[f] Data were missing for 1 individual.

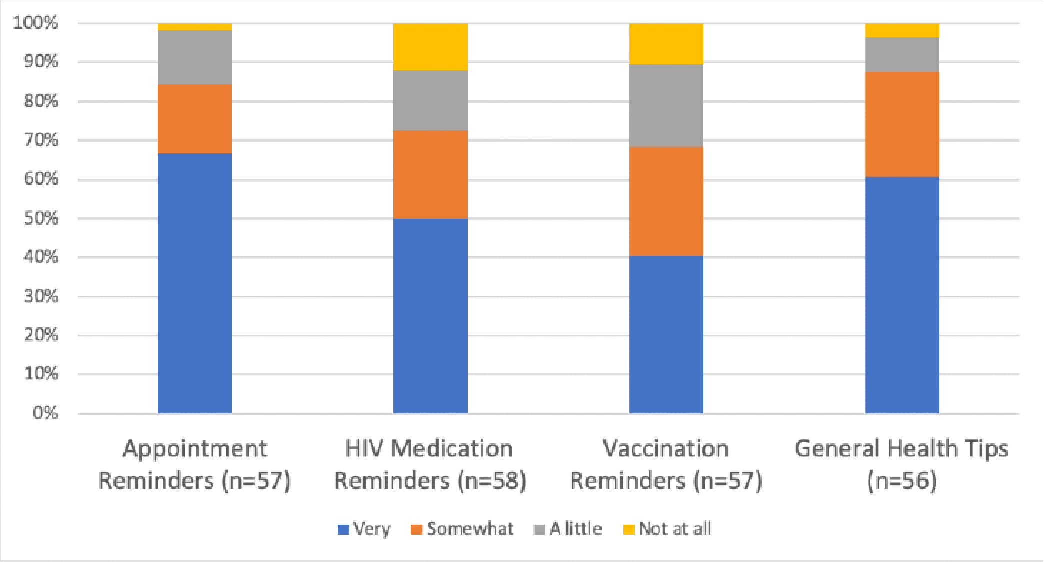
Electronic Communication With Clients

The majority of staff had used at least one form of electronic communication with their clients. Table 1 shows that the median number of electronic communication modes was 2 (range 0-5). More than half of staff had used email (40/59, 68%) and text messages (34/59, 58%) to communicate electronically with their clients. While 15 out of 59 staff at community-based HIV/AIDS service organizations (25%) who participated in our study had used social media (eg, Facebook, Twitter, Instagram, Snap Chat) to communicate electronically with their clients, very few had used a mobile app (eg, What's App; 9/59, 15%), web-enabled videoconference (eg, FaceTime, Skype; 5/59, 8%), or something else (ie, electronic medical record, healthnavigator website; 2/59, 3%). There were no statistically significant differences in the use of any mode of electronic communication with clients between staff who were completely or very confident that safeguards are in place to keep electronically shared information from being seen by other people when compared to those who were somewhat or a little confident (*P*=.24) (Table 2). Among the few (7/59, 12%) who did not communicate electronically with their clients, phone and mail were the preferred modes of communication.

Future eHealth Communication With Clients

Many staff were interested in using eHealth communication tools with their clients in the future. The median number of eHealth communication modes that community-based HIV/AIDS service organization staff were interested in using with their clients in the future was 2 (range 0-4) (Table 1). Figure 1 and Table 2 show that more than half of staff were very interested in using eHealth communication tools in the future for sharing appointment reminders (38/57, 67%) and general health tips (34/56, 61%) with their clients. Almost half were very interested in using eHealth communication tools in the future to share HIV medication reminders with their clients (29/58, 50%), and 40% (23/57) were interested in using eHealth communication tools in the future to share vaccination reminders with their clients. There were also no statistically significant differences in interest in using eHealth communication tools with clients in the future between staff who were completely or very confident that safeguards are in place to keep electronically shared information from being seen by other people compared to those who were somewhat or a little confident (appointment reminders: P=.69, HIV medication reminders: P=.27, vaccination reminders: P=.13, general health tip: P=.40) (Table 2).

Figure 1. Community-based HIV/AIDS service organizations staff interest in using eHealth communication tools with clients in the future.



Discussion

Principal Findings

The sample of community-based HIV/AIDS service organization staff had some level of confidence that safeguards were in place to keep electronically shared information from being seen by other people. In fact, the majority were completely or very confident about the security of electronically shared information. Having at least some level of confidence about data security could probably be attributed to the fact that many of the community-based HIV/AIDS service organization staff in the sample had used multiple modes of electronic communication with their clients. Only a few preferred to use phone or mail to communicate with their clients. Additionally, many community-based HIV/AIDS service organization staff were very interested in using eHealth communication tools to remind their clients about appointments, medications, and vaccinations, as well as to share general health tips with them.

According to recent data from the Pew Research Center, 90% of adults are online, which includes 81% who are online daily [24]. Of the adults who are online daily, 45% go online several times a day, and 28% are almost constantly online [24]. Although most adults are online, disparities exist among offline adults despite efforts to close the digital divide. Offline adults are more likely to be Hispanic or Black, older (ie, aged ≥65 years), lower socioeconomic status (ie, annual household income less than US $30,000; less than a high school diploma), and from rural communities [25]. People living with HIV share similar sociodemographic characteristics of offline adults such as racial or ethnic minority and lower socioeconomic status [26]. Unfortunately, these are the same characteristics of individuals who have been experiencing the digital divide in HIV/AIDS care for decades [27]. Chiasson and colleagues [28] concluded from their research study that

> *HIV prevention and care programs using digital media have great potential to cost-effectively meet the complex needs of diverse and often underserved populations living with or at high risk of HIV* [28]

In this study, among the staff recruited from community-based HIV/AIDS service organizations located in South Carolina and Texas, more than half used email and text message to communicate with their clients. In addition to the vast number of US adults who are online, another contributing factor to this study's findings is the fact that most people living with HIV are men who have sex with men who, studies have shown, go online for health information and social networking [10]. Additionally, the fact that most of the community-based HIV/AIDS service organization staff who participated in the study were completely or very confident that electronically shared information was protected and private is also a contributing factor to electronic communication with clients, and interest in eHealth communication with clients in the future.

Study Strengths and Limitations

This study adds to the scientific literature about eHealth communication among staff at community-based HIV/AIDS service organizations; however, there were some limitations. This cross-sectional study used self-reported data to describe eHealth communication attitudes, beliefs, and behaviors. The findings are not generalizable to community-based HIV/AIDS service organizations either across the southern United States or the entire United States since this study only included staff at organizations that were located in only 2 states in the southern US Census region. Additionally, the author was unable to determine the response rate because the total number of employees working at each organization was not obtained from all of the community-based HIV/AIDS service organization leaders.

Conclusion

Staff at community-based HIV/AIDS service organizations will play a critical role in moving us forward toward realizing the goals of the National HIV/AIDS Strategy, which are aimed at improving health outcomes across the HIV care continuum. Many of the staff at community-based HIV/AIDS service organizations who participated in this study were either already using electronic communication or were very interested in using eHealth communication tools with their clients in the future. In fact, only 12% of staff had not used any form of electronic communication. More research is needed to better understand how to build the capacity of community-based HIV/AIDS service organizations and their staff to help their clients overcome communication inequalities that have the potential to negatively affect HIV/AIDS-related outcomes in these vulnerable populations.

Public Health Implications

The current pandemic is a prime example of how eHealth communication tools can be used to improve health outcomes along the HIV care continuum. Although many organizations were forced to close during shelter-in-place orders that were issued in response to rising coronavirus disease 2019 (COVID-19) rates, as with all individuals, the health needs of people living with HIV continued. For individuals for whom community-based HIV/AIDS service organization staff are the only trusted source of information about health or medical topics, electronic communication has become a necessity.

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Authors' Contributions

LTW conceptualized and designed the study, collected the data, conducted the data analysis, interpreted the results, and drafted the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sociodemographic characteristics questionnaire.
[PDF File (Adobe PDF File), 84 KB - formative_v4i9e17154_app1.pdf]

Multimedia Appendix 2
eHealth communication questionnaire.
[PDF File (Adobe PDF File), 220 KB - formative_v4i9e17154_app2.pdf]

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Abbreviations

AIDS: acquired immunodeficiency syndrome
HIV: human immunodeficiency virus
STD: sexually transmitted disease

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Original Paper

Design and Implementation of a Multilevel Intervention to Reduce Hepatitis C Transmission Among Men Who Have Sex With Men in Amsterdam: Co-Creation and Usability Study

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Abstract

Background: In the Netherlands, transmission of hepatitis C virus (HCV) occurs primarily among men who have sex with men (MSM). Early HCV testing of at-risk MSM and immediate initiation of treatment will prevent onward transmission, but this may not be sufficient to eliminate HCV in a population with ongoing risk behaviors. Therefore, targeted socioculturally acceptable preventive measures, including behavioral interventions, are urgently needed. Currently, little contextually appropriate information about HCV or risk reduction interventions is available.

Objective: The objective of this project was to develop an intervention to reduce HCV transmission among MSM in Amsterdam through a co-creation process, with the input of men from the targeted community directly impacting intervention content, design, and implementation.

Methods: We developed a multilevel intervention targeting 6 levels: individual, community, professional, context, patient, and network. The intervention was developed in close cooperation between health professionals, gay community members, commercial stakeholders, and stakeholders from within the gay community. The co-creation process had 4 phases: a needs assessment, stakeholder engagement, co-creation, and implementation. The co-creation phase continued until consensus was reached between the researchers and community members on the intervention content and design. The final intervention, NoMoreC, was completed within 2 years, and implementation started in February 2018.

Results: NoMoreC includes web-based and face-to-face components as well as an anonymous HCV testing service. The NoMoreC website provides information about hepatitis C, HCV transmission routes, risk reduction strategies, testing and treatment options, and partner notification. The face-to-face component comprises a risk reduction toolbox, training for health professionals, and providing tailored advice to sex on premises venues. NoMoreC is promoted by an active voluntary campaign team.

Conclusions: Involving the community and stakeholders in the creation of NoMoreC has been the main strength of this project. It has resulted in an intervention with various components that resonates with the gay community at risk of HCV infection. The uptake and acceptability of the described intervention will be evaluated in the future. The description of the co-creation process and implementation of the project may serve as a rich and useful source for others who want to develop culturally and context appropriate HCV interventions.

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KEYWORDS

co-creation; mHealth; intervention; hepatitis C; prevention; risk reduction; MSM; HCV

Introduction

Hepatitis C virus (HCV) infection is a major public health problem: An estimated 71 million people worldwide are living with chronic HCV infection, which, if left untreated, may progress to serious liver disease [1]. In 2016, approximately 399,000 people died from HCV-related cirrhosis and liver cancer, and the number of deaths increases each year [2]. In the Netherlands, HCV transmission occurs primarily among HIV-positive men who have sex with men (MSM), as HCV incidence dropped to nearly zero among people who inject drugs [3-5]. Since 2000, there has been an unexpected and substantial increase in HCV incidence among HIV- positive MSM globally [6,7]. Data from the international CASCADE collaboration demonstrated a significant overall increase in HCV incidence among HIV-positive MSM — from 0.07/100 person-years in 1990 to 1.8/100 person-years in 2017 [8]. The incidence of HCV reinfection among HIV-positive MSM is 3-10 times higher than the primary infection incidence, and more recent data show ongoing HCV transmission among HIV-negative MSM using pre-exposure prophylaxis [9-14].

Recent improvements in HCV therapy have resulted in multiple highly tolerable direct-acting antiviral (DAA) regimens with cure rates of over 95%. [15] In many countries, DAA therapy is available for patients with chronic HCV [16]. In the Netherlands, unrestricted access to DAA for all chronically HCV-infected individuals has been available since 2015. The uptake of HCV treatment in HIV/HCV co-infected individuals in the Netherlands has been very rapid: 15 months after the introduction of DAA, 83% of HIV/HCV co-infected MSM were cured [17].

Early testing of at-risk MSM and immediate initiation of treatment prevent onward transmission, but this may not be sufficient to eliminate HCV in a population with ongoing risk behavior [18-20]. Uptake of DAAs differs greatly between countries [21], and international HCV transmission in HIV-positive MSM persists [22,23]. Salazar-Vizcaya et al [18] showed that prevention of high-risk behavior alone could result in a considerable reduction of HCV transmission among HIV-infected MSM based on different modeled scenarios on hypothetical behavioral and treatment interventions [18]. In another modeling study, the potential impact of the Swiss HCVree Trial was assessed [24]. In this trial, a behavioral intervention that prevents HCV transmission through individual risk counseling was combined with early DAA treatment. The model suggested that treatment plus counseling can reduce HCV prevalence among HIV-positive MSM. These modeling studies indicate that early treatment in combination with the implementation of health promotion interventions that reduce high-risk behavior is an effective strategy to control the HCV epidemic in MSM. Targeted socioculturally acceptable preventive measures, including behavioral interventions for MSM at risk of HCV infection, are scarce and urgently needed.

In 2016, we established the Amsterdam MSM Hepatitis C Free (MC Free) consortium with the goal of stopping HCV transmission among MSM in Amsterdam. MC Free is the driving force behind the NoMoreC project, an innovative project co-created with the Amsterdam gay community. Actively involving the target group in the development and implementation of an intervention is a promising approach to increase engagement of the target population [25]. This asks for strong collaboration between health care professionals, researchers, and the target group. Using a co-creational approach ensures that the design is pragmatic, local, and tailored to the target group and the specific settings for which it is created. Consequently, co-creation results in contextually appropriate intervention strategies as well as creation of a platform for co-learning and enhancing ownership and empowerment among the target group [26,27].

For the NoMoreC project, a multilevel intervention was developed and implemented at the individual, community, health care professional, context, patient, and network levels. We believe that targeting these levels simultaneously will lead to a more substantial impact on risk reduction behavior, testing frequency, early diagnosis, early treatment, and partner notification than a single-level intervention would. In this paper, we describe the co-creation process including the development and implementation of the various components of the multilevel intervention.

Methods

MC Free Consortium

In January 2016, the Public Health Service of Amsterdam (PHSA), Amsterdam University Medical Centers, location Academic Medical Center, Soa Aids Nederland, and Amsterdam Institute of Global Health partnered to establish the Amsterdam MSM Hepatitis C (MC Free) consortium. Soa Aids Nederland is a nongovernmental organization specializing in sexual health and sexually transmitted infections (STIs) with strong links with the gay community. MC Free is advised by an international scientific advisory board and a local community advisory board. The consortium combines the knowledge and expertise of professionals from different backgrounds and members of the gay community to work towards a common goal: the elimination of HCV among MSM in Amsterdam.

Multilevel Intervention

MC Free developed the NoMoreC project, a multilevel intervention strategy targeting 6 levels: individual, community, professional, context, patient, and network. For each level, we formulated specific aims (Table 1).

Table 1. Levels and corresponding project aims and target groups of the NoMoreC project.

Level	Aims	Target group or context
Individual level	Increase HCV[a] knowledge and awareness, promote regular testing, and promote risk reduction behavior	MSM[b] at risk of contracting hepatitis C, including MSM with high-risk sexual behavior and MSM who have sex in networks where hepatitis C infections occur
Community level	Increase HCV knowledge and awareness, promote regular testing, promote risk reduction behavior, and create an atmosphere where men feel responsible for keeping their community HCV-free	Gay community
Professional level	Increase HCV knowledge and awareness, increase knowledge about the available HCV testing options, increase knowledge about risk-reduction strategies, and improve partner notification	Health care professionals who provide care for MSM at risk of hepatitis C, including professionals at the PHSA[c] STI[d] clinic, professionals at HIV treatment centers, and GPs[e] with a substantial number of MSM attending their practices
Context level	Create an enabling environment for risk reduction[f]	Sex on premises venues and organizers of sex parties
Patient level	Provide fast linkage to care and prevent reinfection	MSM who acquired HCV
Network level	Penetrate social and sexual networks where hepatitis C infections occur and enhance partner notification	Social and sexual networks where hepatitis C infections occur

[a] HCV: hepatitic C virus.

[b] MSM: men who have sex with men.

[c] PHSA: Public Health Service of Amsterdam.

[d] STI: sexually transmitted infection.

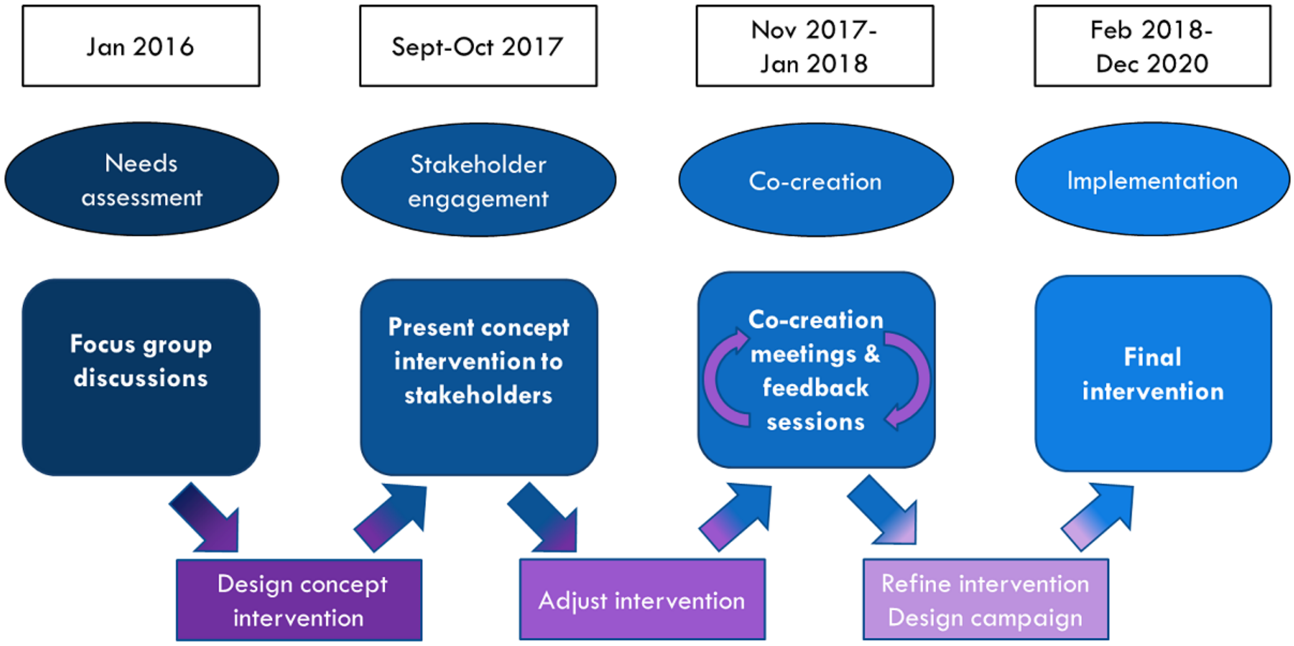
[e] GPs: general practitioners.

[f] An enabling environment is an environment where risk reduction is facilitated and products for risk reduction are available.

Co-Creation Process

The NoMoreC project was developed in close cooperation with health professionals and the gay community in Amsterdam. Commercial stakeholders and stakeholders from within the gay community were involved at an early stage. The process had 4 distinct phases: a needs assessment, stakeholder engagement, co-creation, and implementation phase (Figure 1).

Figure 1. Flow chart of the co-creation process leading to the implementation of the final intervention.



Needs Assessment

In January 2016, prior to development of the intervention, we conducted 2 focus group discussions to identify and discuss the needs regarding hepatitis C information and testing options. MSM at risk of HCV infection were recruited through MSM cohorts of the PHSA, 4 HIV treatment centers in Amsterdam, the Dutch HIV patient association, a magazine for people living with HIV, and a gay dating site. One focus group was held with 7 HIV-positive MSM who had been HCV-infected in the past and 1 HIV-positive MSM who was under HCV treatment at the time of the focus group discussion. The participants of the second focus group were HIV-positive MSM who had never been HCV-infected but had concerns about becoming infected. The following themes were discussed in both focus groups: hepatitis C information (need and current availability), hepatitis C risk, concerns of getting (re)infected, desired hepatitis C prevention tools, motivators and barriers for risk reduction strategies during sex, and different hepatitis C testing options. Structured questions were formulated and posed to the groups, touching upon all themes. The themes were expanded upon depending on the group dynamics. Responses were categorized and clustered per theme.

In addition, 3 intervention ideas were suggested by the researchers: (1) home-based HCV testing service, (2) checklist to estimate personal risk of contracting hepatitis C, and (3) toolbox containing items to assist in HCV risk reduction. The feedback and opinions of the participants regarding these suggestions were collected and processed later in the further development of these interventional aspects.

Stakeholder Engagement

Based on the needs assessment, a first concept of the NoMoreC multilevel intervention was designed and presented to a group of commercial and gay community stakeholders in September 2017. This group consisted of owners or managers of sex on premises venues (SOPV), gay chat and dating sites, fetish shops, (sex) party organizers, and representatives of HIV interest groups and organizations active in the gay or HIV community. In October 2017, we organized a second stakeholder meeting for professionals who either treat HCV-infected individuals or are involved in the prevention and control of HCV infections. The meeting was attended by nurses, nurse practitioners, and physicians from HIV treatment centers and STI clinics in Amsterdam; policy advisors and program managers from the National Institute for Public Health and Environment; and Soa Aids Nederland. A total of 9 commercial stakeholders, 4 gay community stakeholders, and 31 professionals attended the meetings. Furthermore, presentations were organized for the clinical staff of HIV treatment centers in Amsterdam. The goal of the stakeholder meetings and presentations was to introduce the NoMoreC intervention and ask for input on the development and implementation of the project as well as to strengthen relationships with stakeholders. Input given during the meetings was used to adjust the concept NoMoreC intervention.

Co-Creation Phase

The first co-creation meeting with members of the gay community (n=11) to shape the NoMoreC project was organized in July 2017 prior to the stakeholder meetings, where the first concept intervention was presented. An intensive co-creation phase followed from November 2017 until February 2018 with a group of men from the Amsterdam gay community at risk of HCV or men who had been HCV-infected. The co-creation phase was an iterative process with co-creation meetings and feedback sessions that were used to constantly refine the intervention. During this phase, the group brainstormed, and ideas were discussed and incorporated in the project. Feedback sessions were used to test if the ideas were translated correctly and adjusted where necessary. A total of 78 men contributed to the development of NoMoreC during one or more of the co-creation sessions. Co-creation meetings were held on the development of a hepatitis C prevention toolbox, the online campaign, and outreach activities. The starting point of the meeting about the prevention toolbox was the information collected during the needs assessment. The contents of the NoMoreC toolbox were discussed extensively and decided jointly by the community members and researchers. During the meetings about the campaign and outreach activities, calls-to-action, tone of voice, prevention messages, and different promotion strategies were discussed. Ideas on how to engage men during outreach were proposed and materialized by community members.

Results

Co-Creation Process

Needs Assessment

The needs and recommendations that were mentioned during the 2 focus group discussions with MSM at risk of HCV are summarized in Table 2.

From the discussions, it became evident that there was a need for clear information about HCV in general and information relevant to the target group and their sexual settings in particular. The participants mentioned that they found it difficult to find reliable information, including information about HCV testing, symptoms, and treatment options. It was mentioned that they felt a good information source was lacking and that a website containing as much information as possible was recommended. They stated that they had a great need for advice regarding their sex lives during the period from the time of infection to cure, including practical tips to limit the risk of transmission during sex. The following quotes illustrate the availability and need for information about HCV.

> *I use google….but the information is really very limited….there is some information, but it is not a lot.* [Participant who had been HCV-infected]
>
> *…I had questions about that (the risk of transmission during sex), but I now realize that I know little about that.* [Participant who had been HCV-infected]
>
> *I would want to know about the severity of treatment, the duration of the treatment, whether there are treatment choices, what are the prospects (for controlling HCV), what is the chance of a cure, what side effects does it (the treatment) have, what if it (the HCV infection) becomes chronic?* [Participant who had never been HCV-infected]
>
> *….I have had sex with a friend who had HCV. I want to know more about what risk reduction measures you can take to prevent HCV.* [Participant who had never been HCV-infected]

After discussing HCV information needs, the researchers proposed developing a toolbox containing items to assist in HCV risk reduction and asked the participants' opinions. The participants reported being interested in a prevention toolbox if it contained disinfectants that quickly kill HCV, clear explanation on its use, and possibly a list of other products that can assist in risk reduction. Furthermore, 2 other intervention ideas were proposed by the researchers: (1) a home-based hepatitis C testing service and (2) an online checklist to estimate personal risk of contracting HCV. We hypothesized that a home-based testing service could lower barriers to testing, increase testing frequency, and enable MSM to test shortly after potential exposure and thus prevent onward transmission. The rationale of the checklist is two-fold: (1) the proposed checklist would guide men in their decision to test for HCV based on their personal risk, and (2) providing tailored practical risk reduction advice may stimulate risk reduction behavior.

These 2 proposed intervention ideas were received positively and discussed by both focus groups and subsequently added as recommendations (Table 2). Offering easier HCV testing options based on measuring the virus within a short period was considered as important by most focus group members, and it was mentioned that this could assist them in taking control of their own health. Some participants were prepared to pay for such a testing service, while others were not and brought up their concern that men with a low income would be excluded from the service.

Table 2. Summary results of two focus group discussions determining the needs and recommendations regarding hepatitis C information and testing options.

Theme or topic	Needs	Recommendations
HCV[a] information	Better HCV information sources	Provide good and reliable online information about HCV, provide information specifically relevant to MSM[b], link websites visited by MSM to reliable online information about HCV, provide information about symptoms, and provide an online chatroom where men can ask questions to a professional
HCV risk	Information about which sexual techniques confer a transmission risk and personal advice on HCV risk factors	Provide information about which sexual techniques increase the transmission risk and which sexual techniques are safe as well as a risk checklist
HCV prevention	Information about disinfectants effective against HCV and information about sexual behavior that increases HCV risk	Provide information about disinfectants that quickly kill the virus, provide a list with products and how to use these for the prevention of an HCV infection, and create video instructions for risk reduction
HCV testing	Information about different types of tests, information about where you can be tested, and testing possibilities for HIV-negative men outside the general practice	Offer a test that detects the virus (instead of antibodies) that can be used by men who have been infected in the past, offer an HCV test as part of a comprehensive STI[c] screening package at the PHSA[d] STI clinic, communicate test results by a telephone call or face-to-face, and offer a home-testing service to take control over your own health (a convenient option and good option for MSM outside of Amsterdam)
A positive HCV test result	Information about disease progression, treatment (duration, side effects, regimens, cure rates), consequences of a chronic infection, safe sex while being infected, and partner notification as well as contact with a gay man who has been infected, treated, and cured	Provide information covering the information needs as mentioned under "needs" in the left adjacent column, offer DAA[e] treatment as soon as possible, and offer peer support by bringing a newly HCV diagnosed man in contact with a gay man who has had HCV in the past and was treated with DAAs, to share experiences about being infected and the treatment

[a] HCV: hepatitis C virus.

[b] MSM: men who have sex with men.

[c] STI: sexually transmitted infection.

[d] PHSA: public health service Amsterdam.

[e] DAA: direct-acting antiviral.

Stakeholder Involvement

Based on the needs and recommendations that were brought forward in the focus group discussions, a first concept of the NoMoreC project was designed and presented to the stakeholders. The project, containing a web-based component, hepatitis C testing service, and face-to-face component, was received with interest. The stakeholder meetings were successful in gathering input and discussing possible support for project implementation. Useful ideas were voiced, and cooperation was offered by various stakeholders: Fetish shop owners offered to distribute or sell potential NoMoreC products as well as assist in project promotion (hand out flyers/posters), and managers of gay sex venues requested to be informed about disinfection on location and made condoms and fisting gloves available for clients, to make their premises "hepatitis C proof."

Co-Creation Phase

During the co-creation phase, different components of the intervention were executed in collaboration with the gay community. These included the development of a prevention toolbox, making content for the project website (eg, explicit comics), filming of testimonials, shooting photos of volunteer models, organization of theme events, and forming a campaign team. The campaign team (the "NoMoreC Boy Scouts") was formed by a group of men at risk of HCV, including men from specific fetish scenes: leather, rubber, and sportswear [28]. All activities were performed on a voluntary basis. For the coordination of the campaign team, a community member was appointed who received a modest fee. The end result of the co-creation phase was the finalized NoMoreC project including web-based and face-to-face components, an anonymous hepatitis C testing service, and a (social) media campaign. The influence and challenges of the co-creation process are mentioned in the following descriptions of each intervention component.

Web-Based Intervention Components

NoMoreC Website

The project website [29] is available in Dutch and English and targets at-risk MSM (Figure 2). Part of the content was co-created with the community, such as the instructional videos, photos, testimonials, and graphic illustrations. The website was tested by 3 community members. Feedback on their user experience and suggestions for improvement were used to fine-tune the final product. The website was launched in February 2018.

The website provides information about hepatitis C, HCV transmission routes, risk reduction strategies, testing and treatment options, and partner notification. Video testimonials are presented in which men share their personal experiences with hepatitis C, being at risk, and what they do to reduce transmission risk (Figure 3).

Information about HCV transmission routes and risk reduction strategies are illustrated by explicit comic strips of situations familiar to the community (Figure 4). Furthermore, instructional videos can be watched about disinfection to prevent HCV transmission. The website offers personalized risk reduction advice based on sexual practices. Also, personalized test advice is given after answering questions on 6 risk factors, based on a previously validated risk score [30]. An anonymous hepatitis C testing service, which is described in detail in a later section, is incorporated in the website. It offers HCV-RNA tests at a reduced cost for €25 per test. A test subscription of 4 tests is offered for €80 to stimulate regular testing.

Figure 2. Screenshots of the desktop and mobile versions of the NoMoreC homepage (accessed June 10, 2020).

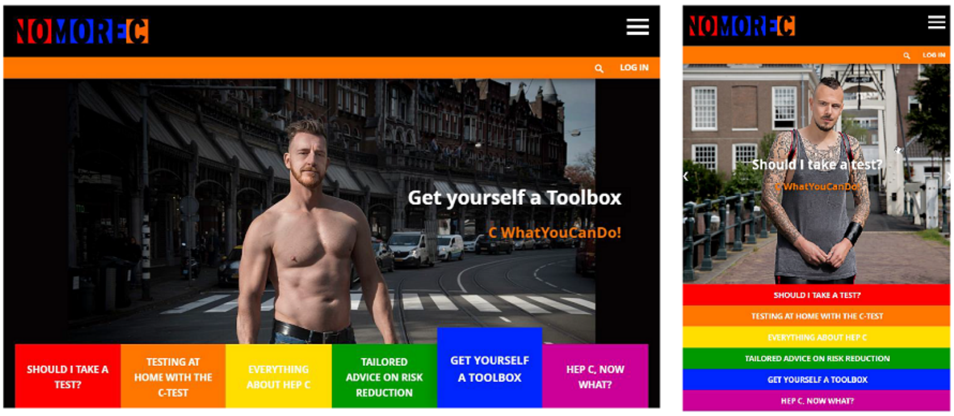
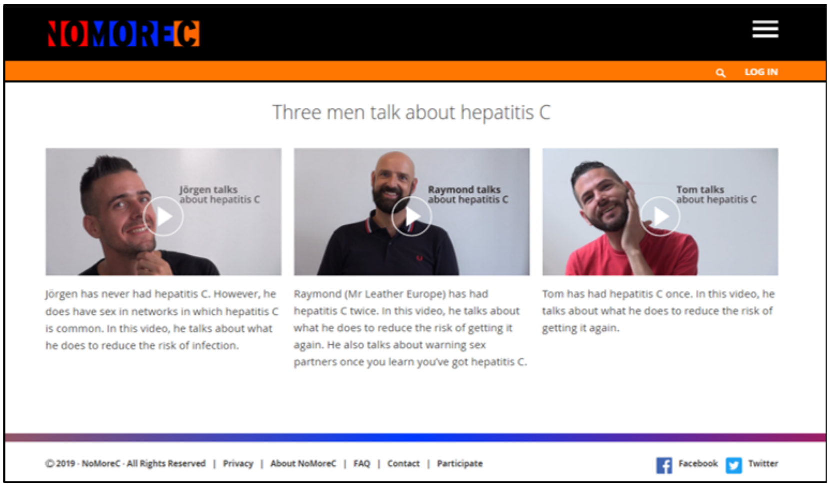


Figure 3. Video testimonials of men from the target population can be watched on the NoMoreC website (accessed June 10, 2020).



Three men talk about hepatitis C

Jörgen has never had hepatitis C. However, he does have sex in networks in which hepatitis C is common. In this video, he talks about what he does to reduce the risk of infection.

Raymond (Mr Leather Europe) has had hepatitis C twice. In this video, he talks about what he does to reduce the risk of getting it again. He also talks about warning sex partners once you learn you've got hepatitis C.

Tom has had hepatitis C once. In this video, he talks about what he does to reduce the risk of getting it again.

Figure 4. Illustration on the website of a risk reduction strategy: cleaning and disinfection of the play area, toys, and yourself before changing sex partners. More information about the products to use is given on the website.

Electronic Learning (e-Learning)

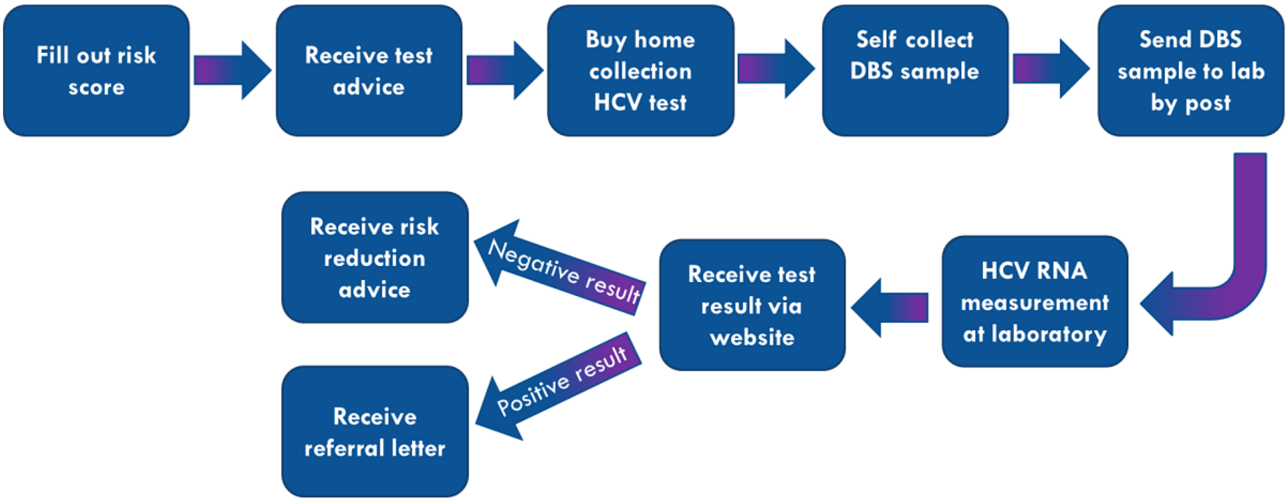
For professionals who see MSM at risk of HCV in their practice, NoMoreC offers an electronic learning (e-learning) package with 3 modules. Module 1 gives information about the NoMoreC project, its target population, and how professionals can use the NoMoreC products in routine clinical practice. Module 2 gives detailed information about HCV risk reduction. Professionals learn about risk factors, tailored risk reduction advice, and behavior change. In the last module, the obligation of health professionals to report hepatitis C to the public health service and partner management is discussed. The e-learning package is accredited by the appointed organizations for nurses and nursing specialists [31,32].

Anonymous Hepatitis C Testing Service

NoMoreC offers an anonymous hepatitis C testing service, using a validated home-based self-sampled dried blood spot (DBS) HCV-RNA test [33]. Users of this service are guided through different steps, as depicted in Figure 5, starting with filling out a validated 6-question risk assessment [30]. After receiving test advice, men can purchase the HCV-RNA home collection test kit online. Test packages are sent to the chosen address of the potential user (pseudonyms can be used). They are instructed to collect a DBS sample from a finger prick, a procedure that was validated prior to offering the test service [33].Paper instructions for DBS collection are included in the test package, and video instructions are accessible on the website. Users are instructed to send their DBS sample to the laboratory of clinical virology of the Amsterdam University Medical Centers for HCV-RNA testing. Test results are communicated within one week via a personal login at the project website. Users who test positive are given guidance on the next step to take, including confirmation of the positive test result at regular health services, access medical treatment and initiate partner notification. A referral letter is provided online to facilitate this follow-up, and a telephone number is given if the user would like to consult a nurse. Post-test information for users who test HCV-RNA negative addresses risk-reduction strategies and encourages frequent testing. The test service became available in February 2018.

During the development of this testing service, we encountered some challenges. Many community members expressed a strong preference towards receiving a positive test result by telephone call or face-to-face, instead of receiving their test result online. However, the possibility of being able to test anonymously was also seen as important. Therefore, the anonymous testing option was chosen with the possibility for men who test positive to be able to contact a nurse and facilitate linkage to care.

Figure 5. Flow chart of the hepatitis C testing service. DBS: dried blood spot; HCV: hepatitis C virus.



Face-to-Face Intervention Components

Risk Reduction Toolbox

The “NoMoreC Toolbox” contains products to assist in reducing the risk of contracting an HCV infection such as condoms, fisting gloves, safe drug use equipment, and disinfectants (Figure 6). We were advised on the right use and types of disinfectants by hygiene and infection prevention specialists of the National Center for Hygiene and Safety [34]. In addition, the toolbox includes a booklet with practical tips on how to reduce risk of transmission and instructions on the use of the products. Information is also given about testing, treatment, and notifying sex partners.

The toolbox is used by health care professionals of the STI clinic and HIV centers in Amsterdam to discuss risk behavior with MSM at risk of HCV and inform them about prevention strategies. The men are offered a box so they can go through it again at home, read the information booklet, and try out the products. The box is also used by the “NoMoreC Boy Scouts” during outreach activities to discuss HCV risk (reduction). Furthermore, the toolbox can be ordered online from the project website or picked up at a gay fetish shop free of charge. The toolbox became available in March 2018.

During the co-creation phase, choices were collectively made on what products the toolbox needed to contain. Consensus was easily reached on the inclusion of the majority of the products except for items for safe drug use. In particular, the suggestion to add needles and syringes to the toolbox led to an extensive discussion. There was disagreement between community members: Some believed that such items would be experienced as shocking while others brought forward that a small group of men inject (“slam”) drugs to enhance their sexual experience and that safe drug use items are essential for the prevention of HCV. A compromise was reached by adding a separate sealed off box to the toolbox, labeled with a sticker explaining that this small cardboard box contains items for safe drug use. After the contents of the toolbox was decided upon, items were ordered, and all boxes were packed by community members. The packing sessions proved to be an effective way to involve men in the project and create a “NoMoreC community.”

Figure 6. NoMoreC Toolbox (left) and contents of safe drug use box (right). The NoMoreC Toolbox contains a spray bottle, disinfectant for hands, hydrogen peroxide cleaning wipes, gloves, condoms, a hand washing instruction card, a cardboard safe drug use box and booklet with tips and tricks to reduce hepatitis C transmission risk. The safe drug use box is a small cardboard box that is included in the toolbox. It contains snorting straws, a sharps container, syringes, needles, mixing cups, and alcohol wipes. A sticker with the text “Never share drug use equipment. Pick your own color.” is stuck on the box.

Training for Health Professionals

The training developed for health professionals is a 4-hour interactive session about HCV risk behavior, risk-reduction measures, and partner management. Prior to the training, participants are asked to complete the e-Learning package. The focus of this training is on improving the participants’ communication skills by practicing motivational interview techniques. After the course, a participant is better equipped to ask a client about his risk behavior, give him tailored advice on risk reduction, and support behavioral change.

Tailored Advice to Sex on Premises Venues (SOPV)

In cooperation with infection prevention specialists of PHSA, we advise SOPVs in Amsterdam on HCV prevention and creating an enabling environment for risk reduction for their clients. SOPVs are commercial venues, such as gay clubs and saunas but not brothels, where men can engage in sex. The venues are visited to have a close look at the areas where clients have sex. For each location, tailored advice is given with recommendations for improvement. Points of improvement are given on the use of disinfectants, instructions for cleaning personnel, availability of gloves, single use anal douches, and safe needle disposal. The recommendations are discussed with the owner or manager of the venue 2 months after the visit, giving them the opportunity to ask for clarification. In addition, a workshop for owners of SOPVs is organized, and support is given to venues when requested.

NoMoreC Campaign

The NoMoreC intervention is promoted with a sex-positive campaign, accepting lifestyle choices of MSM at risk of HCV. The campaign was designed in close cooperation with the community. The goal of the campaign is to raise awareness about the different components of the project that target MSM. With the input of community members, the right words and promotion messages were carefully chosen so that they would resonate with the community. Special care was taken to ensure the messages would neither evoke fear nor stigmatize the target population. The campaign slogan “CWhatYouCanDo!” was chosen to encourage MSM, including men who do not use condoms, to think about which risk reduction strategies they can and are willing to apply to their (sex) lives.

A suite of promotional materials was developed with artwork appealing to the community. It includes posters (Figure 7), flyers, pocket-sized cards, and online banners. Posters hang on waiting room walls of HIV-treatment centers in Amsterdam, the STI clinic of PHSA, and fetish shops. Flyers are handed out to at-risk MSM by health professionals from HIV-treatment centers, the STI clinic, and general practice centers in Amsterdam. Furthermore, at a selection of pharmacies in Amsterdam, flyers are given to men who pick up their HIV medication or pre-exposure prophylaxis. Flyers and pocket-sized cards contain a discount code for the purchase of the NoMoreC HCV-RNA test and are also handed out by the “NoMoreC Boy Scouts” during their outreach activities. This campaign team attends gay venues and events to interact with men at risk of HCV. They have one-on-one discussions about hepatitis C, risk reduction strategies, and testing options; demonstrate the use of the Toolbox products; and host quizzes on HCV and risk reduction.

Banner advertisements are shown on gay (fetish) dating and chat apps, including Recon, Scruff, PlantRomeo, and Grindr, prompting men to visit the NoMoreC website, purchase an HCV-RNA test, or order a toolbox. The placement of the ads is scheduled around gay events (eg, Gay Pride Amsterdam, Folsom Berlin, The Cruise) to raise awareness about possible HCV transmission risks at these events and focus on the importance of testing. Promotional activities will continue until July 2020.

Figure 7. Promotional poster with the text: How do you reduce your hepatitis C Risk “I always use my own anal douche.” The model is a key figure from the target population.

Discussion

The NoMoreC multilevel intervention was created using a co-creation process involving members of the Amsterdam gay community, commercial stakeholders, stakeholders from within the gay community, and health professionals. This process has resulted in the implementation of web-based and face-to-face interventions, including an informative website, an anonymous HCV testing service, a risk reduction Toolbox, a sex positive campaign, a training package for health professionals, and tailored advice to SOPVs. We believe that co-creation has been one of the main strengths of the project, but it also had its challenges and limitations. Co-creation is a time-consuming and intensive process; it took 2 years from the first focus group discussion to the development of the final intervention. At times, exciting ideas could not be materialized, or a compromise had to be reached that was acceptable for the gay community members, health professionals, and researchers. This required good negotiation and cooperation skills.

To illustrate this, one idea proposed by some members of the gay community was the making of a short film to address hepatitis C risk reduction. In the film, different risk behavior settings and risk reduction strategies would be shown. This would have involved hiring actors and shooting explicit scenes of a group of men at a private sex party, using party drugs, and having sex with multiple partners. There was mixed enthusiasm for this idea. Instead of making a sexually explicit film, it was agreed to make explicit cartoons and instructional disinfection videos (how to disinfect your hands, play area, and sex toys) as an alternative. The cartoonist worked closely with a community member to draw realistic cartoons in a setting recognizable for the target population.

Another challenge was to balance the needs and preferences of the community and data collection needs of the researchers with regard to the HCV testing service. For example, the community members voiced their preference of ordering an HCV test without having to fill out the risk score. However, in order to evaluate the effectiveness of the test service (ie, test advice, orders placed, and test results in relation to the risk taken), this information is needed. Therefore, the wish of the community to order a test without filling out the risk score could not be granted.

The development of the NoMoreC Toolbox has been a positive experience for both the community and researchers. The co-creation sessions created an atmosphere of co-learning, where the researchers learned more about the context of risk behavior and community members became more knowledgeable about hepatitis C, HCV transmission routes, and risk reduction measures.

The NoMoreC project is ongoing and will run until the end of 2020. We continuously monitor the uptake and reflect on the successes and limitations of the intervention and make adjustments if indicated and possible. By trial and error, we find out how to best reach and involve the target group. The uptake of the intervention at the different levels and the acceptability of the NoMoreC project will be evaluated and reported at the end of the implementation phase.

In conclusion, using the process of co-creation, the multilevel NoMoreC intervention was developed and implemented. The intensive cooperation with the community and stakeholders has allowed us to gather their perspectives and incorporate their ideas in the different components of the intervention. The co-creational approach we have taken may serve as a rich and useful source for others who want to develop culturally and context appropriate HCV interventions.

Acknowledgments

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Authors' Contributions

All authors were involved in the conception of the study, the intervention design, and critical revision of the manuscript. TP drafted the manuscript. MvdV, JS, and MP obtained funding.

Conflicts of Interest

TP and MP report speaker fees and grants from Gilead Sciences, Merck Sharpe & Dohme, and AbbVie paid to their institute. MvdV's institute received unrestricted research grants and consultancy fees from Abbvie, Gilead, Johnson & Johnson, Merck Sharpe & Dohme, and ViiV Healthcare. JS reports nonfinancial support during the project from ROCHE Diagnostics and grants from Gilead Sciences, Merck Sharpe & Dohme, and Abbvie.

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Abbreviations

DAA: direct-acting antiviral
DBS: dried blood spot
e-Learning: electronic learning
HCV: hepatitis C virus
MC Free: Amsterdam MSM Hepatitis C Free
MSM: men who have sex with men
PHSA: Public Health Service of Amsterdam
SOPV: sex on premises venues
STI: sexually transmitted infection

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Original Paper

Protocol Development for HMU! (HIV Prevention for Methamphetamine Users), a Study of Peer Navigation and Text Messaging to Promote Pre-Exposure Prophylaxis Adherence and Persistence Among People Who Use Methamphetamine: Qualitative Focus Group and Interview Study

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Abstract

Background: Cisgender men who have sex with men (MSM) and transgender people (TGP) who use methamphetamine are disproportionately impacted by HIV acquisition. Pre-exposure prophylaxis (PrEP) is highly effective at preventing HIV, and interventions that support PrEP persistence and adherence should be evaluated among MSM and TGP who use methamphetamine.

Objective: We conducted formative work to inform the development of text messaging and peer navigation interventions to support PrEP persistence and adherence among MSM and TGP who use methamphetamine. In this paper, we describe how the findings from these focus groups and interviews were used to refine the study interventions and protocol for the Hit Me Up! study (HMU!; HIV Prevention in Methamphetamine Users).

Methods: Between October 2017 and March 2018, we conducted two focus groups and three in-depth interviews with MSM and TGP who use methamphetamine or who have worked with people who use methamphetamine. During these formative activities, we asked participants about their opinions on the proposed interventions, education and recruitment materials, and study design. We focused on how we could develop peer navigation and text messaging interventions that would be culturally appropriate and acceptable to MSM and TGP who use methamphetamine. Transcripts were reviewed by two authors who performed a retrospective content analysis to describe which specific opinions and recommendations influenced protocol development and the refinement of the interventions.

Results: Overall, participants thought that MSM and TGP would be interested in participating in the study, although they expected recruitment and retention to be challenging. Participants thought that the peer navigator should be someone who is nonjudgmental, has experience with people who use methamphetamine, and is patient and flexible. There was consensus that three text messages per day were appropriate, adherence reminders should be straightforward, all messages should be nonjudgmental, and participants should be able to tailor the timing and content of the text messages. These suggestions were incorporated into the study interventions via the hiring and training process and into the development of the text library, platform selection, and customizability of messages.

Conclusions: It is important to include the opinions and insights of populations most impacted by HIV to develop PrEP interventions with the greatest chance of success. Our formative work generated several recommendations that were incorporated into the interventions and protocol development for our ongoing study.

Trial Registration: ClinicalTrials.gov NCT03584282; https://clinicaltrials.gov/ct2/show/NCT03584282

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KEYWORDS

pre-exposure prophylaxis; methamphetamine; text messaging; peer navigation; men who have sex with men; transgender people

Introduction

HIV pre-exposure prophylaxis (PrEP) is a safe and effective method for reducing HIV acquisition that was approved for use in the United States in July 2012 [1-3]. Despite increasing knowledge about and use of PrEP nationally [4], HIV continues to disproportionately impact cisgender men who have sex with men (MSM) and transgender people (TGP) [5,6]. Furthermore, MSM and TGP who use methamphetamine are at particularly high risk for HIV [7-10]. In King County, Washington, USA, HIV incidence among MSM who use methamphetamine is nearly six times greater than that of MSM who do not use methamphetamine [11]. While there is a paucity of data regarding substance use and HIV risk among TGP, there is evidence that methamphetamine use and HIV acquisition disproportionately impact transgender women. Two studies of transgender women in different west coast cities in the United States both found that approximately 20% reported recent methamphetamine use [7,8], and HIV prevalence has been estimated to be 28% among transgender women [12]. While TGP are often excluded from research that focuses on MSM, it is important to include TGP in prevention research in order to address health disparities and target HIV prevention interventions to those at highest risk.

During our preliminary work in Seattle, Washington, we found that HIV-negative MSM and TGP who use methamphetamine had high levels of PrEP knowledge and insurance coverage, but few had enrolled in local PrEP programs [13]. Among people using PrEP, methamphetamine has been shown to be associated with poor adherence [14,15]. In our formative work, we identified both traditional barriers to PrEP uptake, adherence, and persistence (eg, lack of awareness and forgetting doses) and barriers specific to methamphetamine use. Participants suggested that peer navigation and text messaging could be helpful to support MSM and TGP who use methamphetamine to overcome barriers to effective PrEP use [16].

Peer navigation interventions have been used to improve healthy behavior in a wide variety of contexts. For people living with HIV, matching patients with a peer who shares key characteristics or experiences has been shown to improve HIV knowledge and antiretroviral treatment attitudes and decrease substance use [17-20]. Peer navigation may be an effective strategy to support PrEP persistence and adherence as well. Text message interventions also have promise to promote PrEP adherence. A systematic review of text messaging interventions for HIV and sexually transmitted infection (STI) prevention and treatment showed that some interventions were associated with increased HIV testing and self-reported adherence [21]. In one study, participants who received bidirectional text messages were more than twice as likely to be adherent to PrEP compared to those who did not receive text messages. Moreover, the majority of participants (88%) thought that receiving the texts was very or somewhat helpful [22].

In 2017, we received funding from the National Institute on Drug Abuse for the HMU! study (Hit Me Up!; HIV Prevention in Methamphetamine Users) (NCT03584282) to develop and conduct a preliminary evaluation of two interventions—peer navigation and text messaging—designed to promote PrEP adherence and persistence among MSM and TGP who use methamphetamine. This manuscript describes formative work that informed the development and refinement of these interventions and our study protocol.

Methods

Procedures

Between October 2017 and March 2018, we conducted two focus groups and three in-depth interviews with MSM and TGP who use methamphetamine or who have worked with people who use methamphetamine (eg, peer educators). Focus groups were facilitated by two authors (VMM and JDS) and interviews were conducted by VMM. Focus groups and in-depth interviews followed semistructured interview guides (see Multimedia Appendices 1 and 2) that included questions regarding what information about PrEP and the study should be provided to participants, what types of recruitment materials should be used, and whether participants thought people would be interested in participating in the study as well as specific questions to develop the peer navigation and text messaging interventions. The questions about the text messaging intervention included reviewing messages used in an earlier study by Reback et al [23], which were aimed at reducing methamphetamine use and sexual behaviors associated with risk for HIV acquisition. These text messages were developed using the Social Support Theory, the Health Belief Model, and the Social Cognitive Theory. The Social Support Theory posits that instrumental, informational, and emotional support from one's network can lead to positive changes in health behavior. The Health Belief Model describes how one's beliefs about health behaviors and risks to one's health are associated with engagement in protective behaviors. Finally, the Social Cognitive Theory describes how the interaction of the individual, their behavior, and the environment are related to health behavior. The study done by Reback et al demonstrated a reduction in methamphetamine use and unprotected anal intercourse with nonprimary partners among MSM who used methamphetamine [24]. Focus groups and interviews were anonymous and the audio recordings were transcribed.

The first focus group was done with 9 peer educators at Project Needle and Sex Education Outreach Network (Project NEON) of the Seattle Counseling Service. Project NEON is a harm reduction program that aims to reduce sexual and drug-related risks associated with the use of methamphetamine. In order to generate preliminary data for this project, the authors had collaborated with the Project NEON peer educators on earlier work to try to better understand PrEP use among MSM and TGP who use methamphetamine and to increase PrEP education in this community [13,16]. This work included developing PrEP education materials with the Project NEON peer educators and recommendations for evaluating text messages and peer navigation as potential supports for PrEP adherence among MSM and TGP who use methamphetamine.

The second focus group was recruited through Seattle Area Support Groups (SASG), now Peer Seattle, a nonprofit organization that provides peer emotional support and development services to lesbian, gay, bisexual, transgender, and queer or questioning individuals, plus other sexual and gender minorities (LGBTQ+). The second group consisted of 10 MSM who had used methamphetamine. For these two focus groups, the researchers gained access to participants through long-standing relationships with these two community organizations.

After conducting these two focus groups, we chose to conduct research activities with individuals who represented perspectives that had not already been shared, specifically LGBTQ+ youth and people who are not cisgender. We originally planned to conduct an additional two focus groups with up to 10 participants each representing these populations; however, we were advised that interviews would be more appealing to individuals who are not cisgender since there was less chance of being "outed" in a one-on-one activity. We recruited eligible interview participants through palm cards and word-of-mouth. Palm cards were brought to local agencies that provide services to LGBTQ+ youth and people who are not cisgender. The researchers also informally provided palm cards to, or discussed the study with, community members in these networks with whom they had up to two decades of collaboration. Despite these various approaches to recruitment, we only conducted three interviews out of the 20 planned.

At the end of each focus group or in-depth interview, participants were given a US $40 gift card to an online retailer. The University of Washington Institutional Review Board approved this study (#00004760). All participants were given an information sheet for participation; written consent was waived.

Protocol Development

The protocol was drafted in parallel with formative activities. Therefore, after each focus group and interview, the facilitators (VMM and JDS) met to discuss the major themes that arose during the discussion to inform ongoing study development in an iterative process. The first version of the study protocol was finalized in April 2018 and submitted for ethics review and approval.

Analysis

After completion of the formative work, two authors (VMM and NF) performed a retrospective content analysis [25] of the focus group and in-depth interview transcripts to describe which specific opinions and recommendations influenced protocol development and the study interventions. First, they reviewed transcripts individually and compared them to the final study protocol. Then they met and discussed which themes from the early formative work had most influenced the resulting interventions and protocol until they reached consensus.

Results

Overview

Across focus groups and interviews, participants reported that they thought MSM and TGP who use methamphetamine would be interested in the study. Participants offered a variety of suggestions about the peer navigation and text messaging interventions. Their recommendations focused on ways to make these interventions relevant and accessible to MSM and TGP who use methamphetamine.

Peer Navigation Intervention

Focus group and interview participants thought that the peer should be someone who is patient, nonjudgmental, not transphobic, and has experience with the target population.

> *I don't want a peer navigator that does not have any comfort with the addiction of methamphetamine. To just assign someone, a peer navigator, that doesn't have a clue about—or hasn't gone through any sort of addiction training—is a disservice to the addict that's actively using.* [Interviewee #2]
>
> *I'm not sure if everyone's comfort level or knowledge level would be the same with a trans man or trans woman. There's a lot of transphobia in the gay community...[So we should make] sure that we have [peers] that are willing...to work with that population.* [Interviewee #2]

Participants thought that it would be important for the peer to help with appointment reminders and medication support, including refills. One peer recommended the option of holding on to medications for participants, as the peer had prior experience providing a few days' supply of medications to someone he had sponsored and reported that it had helped with medication compliance. They also recommended that the peer be flexible in order to meet study participants outside of the "9-to-5" schedule and in a variety of settings.

> *A peer probably would have helped if [they could have] taken the [medication] bottles back for me...[I] probably would have kept going [to the doctor].* [Focus group #2, attendee #10]

They also discussed barriers the peer should anticipate, including difficulties reaching study participants.

> *Your peer is going to have trouble reaching people during three-day periods when they're at the bathhouse.* [Focus group #2, attendee #8]

Participants discussed how setting boundaries would be important for the peer, including appropriate times to expect them to answer the phone and what interactions would or would not be appropriate if the peer and participant were visible to each other on the internet (eg, on a hookup app).

> *[MSM and TGP who use methamphetamine] might listen to [a peer who]...can talk about losing teeth and having to go to the dentist or slamming dope or snorting crystal meth or going to orgies and stuff and going to random sex hookups in the bathhouse. [Who] can really kinda get down and talk about that stuff with a complete comfort level but be able to maintain those boundaries that are really important...* [Interviewee #2]

Text Messaging Intervention

The number of texts per day that participants thought would be appropriate ranged from two to six and there was general consensus that three per day was not excessive. Focus group and interview participants suggested that the study participants should be allowed to select the timing of the messages, since people who use methamphetamine may not be accessible during the daytime. There were variable responses to the example text messages that were shown to participants (see Table 1).

Some participants liked the content, as evidenced by the following quotes.

> *I liked [the text message examples]. I feel like they speak to the idea of remaining on your PrEP regimen and how important that is for overall health. I also like the idea that the research is not judging whether or not you're using meth. It's really about promoting the idea that we can use drugs if we choose to and still take PrEP.* [Interviewee #2]

> *I think [the example text messages] are real. It's like if your friend sent it to you.* [Interviewee #3]

The text messages from the Social Support Category were particularly liked.

> *I just don't know if I'd listen to any of these things because when I am on meth, I want what I want and I'm very selfish and I don't care about my family or what they think...But I do like the emotional support, like just having someone there caring. Even if I don't listen, I am going to remember when I am sober.* [Focus group #2, attendee #1]

> *When I'm laying down and going to sleep, I will say, "Thank god someone fucking told me to go to fucking sleep."* [Focus group #2, attendee #2]

In addition, text messages that provided "straightforward" information, like "Needle exchange 2nite @ __________," were preferred, although one participant said receiving these may make them feel guilty.

> *[The messages that just contain information about services] might cause guilt...My first reaction is "I've got to go get an HIV test now that I'm high."* [Focus group #2, attendee #8]

Some other examples of potential text messages were regarded less highly.

> *The ones that are involved with helping me stay adherent and abide by my health stuff, that's great. But then some of the random—like public health announcement ones—like...“gums bleeding—gargle with peroxide.” That's just some random health tip. That would get on my nerves. I would be annoyed.* [Focus group #2, attendee #4]

Table 1. Example text messages shared for feedback during formative work.

Theory or model	Example text messages
Social Support Theory	There's no such thing as a good sore. Mix Viagra and Poppers? U may come and then go. Gums bleeding? Gargle with peroxide. Rehydrate and rest!
Health Belief Model	Stop B4 U rub it raw. RU drippin' while UR trippin? Don't let NE1 tell U what UR limits R! Don't let Tina take you down.
Social Cognitive Theory	Sharon Needles? She's bad news. Peace of mind is priceless. Know UR health info, B informed! Needle exchange 2nite @ ______________.

The variety of opinions on our example text messages resulted in us developing many text message options: 540 text messages across 11 content categories.

Focus group and interview participants consistently recommended that study participants should be able to choose their own text message content.

> *At the point someone [is] signed up to be a part of this [study], maybe [let them select] different categories. "Hey, do you want information or to receive text messages about this subject, this subject, this subject, or this subject?" Because if I don't want to know about, say, club use or whatever, then I wouldn't click on that.* [Focus group #1, attendee #4]

Across focus groups and interviews, there was consensus that straightforward PrEP reminders would be best (eg, "take your pill") and that we should "change up" the messages so they were not the same each day. Daily PrEP reminders were discussed in the context of the effects of methamphetamine, including "losing days." One participant recommended including the passage of days within the texts themselves to help participants be aware of what day it is and how much time is passing.

> *Why not say, "It's Monday, take your pill. It's Tuesday, take your pill. It's Wednesday, take your pill..." It's letting them know that time has passed.* [Focus group #2, attendee #1]

Multiple participants recommended using email in conjunction with text messages, because it is common to lose one's phone.

> *Email [would be the best way for the peer to help me make appointments], because I have lost my phone so many times. So, yeah, email and text.* [Interviewee #1]

Participants also emphasized that using emojis was very important and could help "with discretion."

> *If you can have [emojis in the text messages], then do it...People are gonna read it, it's just more appealing, catchy, cute.* [Interviewee #3]
>
> *I think it's okay to send [a pill emoji] and a green heart or a thumbs up or a hug, like a PrEP hug...Because I think it's simple. And if someone's looking over your shoulder, "Well, what do they mean, 'Take your PrEP?'"...And they can be like, "It's someone saying, 'Do I have pills, do I have OxyContin'" or whatever. They can play it off however they want. I think it's really important.* [Interviewee #2]

Finally, in our second focus group, one participant reported a technology phobia when high on methamphetamine and advised that receiving texts could cause paranoia for some.

> *If I saw [an email and text message reminder to take my PrEP] it would send me into a psychotic little scare. That technology and stuff isn't awesome at that point. So if I saw something like that pop up, I'd freak out...I might not be thinking of what that was or I might start getting paranoid about it if I'm at that point...* [Focus group #2, attendee #10]

Endorsement of potential paranoia in this population by focus group attendees led to a protocol exclusion criterion regarding discomfort with technology.

PrEP Education, Recruitment, and Study Operations

In the focus groups and interviews, we shared educational materials that had been previously developed during formative work done with Project NEON to increase PrEP education and uptake among MSM and TGP who use methamphetamine [19]; we then asked participants for feedback about the card images and content. Participants liked the nonjudgmental phrasing "we aren't here to judge your drug use" but recommended replacing "your drug use" with "you." Some, but not all, participants thought that the inclusion of the word "tweaker" was stigmatizing; however, there was consensus that the word "partying" would be a preferable word choice and widely understood among the LGBTQ+ community to refer to methamphetamine use. Using terms familiar to individuals who engage in party and play (ie, having sex while using methamphetamine) was liked and recommended (eg, "parTy" or "PnP" [party and play]). Participants recommended images that did not blatantly show drug use or sex but conveyed these activities discretely (eg, smoke in the background and an image suggestive of a sex act). Images that were gay friendly and transgender inclusive were also endorsed.

> *[I think a good image could be] a man that's holding a pipe, but it's the picture of the man doing something, and the pipe's just in his hand...* [Interviewee #3]
>
> *What about...getting an image where it doesn't show anything; it's soft core, but it's suggesting a sex act?* [Focus group #1, attendee #3]

Participants were concerned that our recruitment approach and materials would not reach a subset of MSM and TGP who use methamphetamine and who may be at particularly high risk for HIV, including those who are homeless and engage in survival sex work.

> *[The party or die crowd are] isolated. They're not in bathhouses. They're not in this scene. They're not in the gay bars. They're not seen on Capitol Hill. They're the unseen ones that are homeless and basically being passed around a crowd of men and drug dealing assholes.* [Focus group #2, attendee #5]

Participants recommended that we have later hours for study visits (ie, after 5 PM) to make the study more accessible to potential participants.

> *You're dealing with an after-5, up-all-night crowd...When are you gonna have those hours that are not in the realm of 9 to 5? Because addicts don't live a normal kind of day. Their days are kind of upside down, much like the homeless community. We can't always get them into services at 5 because they don't have any idea of time...I think that's gonna be your biggest hurdle—getting people to actually show up during the day when it's light out.* [Interviewee #2]

Participants thought that retention may be challenging among MSM and TGP who use methamphetamine and, to retain participants, it would be important to be nonjudgmental.

> *Ten [per intervention group] is not a lot of people...if three of them start using meth regularly and don't show up, what happens to your data?...I think [retention is] more of a concern [among MSM and TGP who use methamphetamine than others]...the only thing I think that might help people stay engaged is any lack of judgement. Yeah, any lack of judgement. Like there's no disapproval of whatever is going on. They have to be able to be truthful. No shame.* [Focus group #2, attendee #4]

There was general consensus that our planned reimbursement of a US $20 gift card to an online retailer for study surveys three times during the study period was sufficient. However, one participant thought it would be better to provide a gift card to a brick-and-mortar store due to the lack of internet access among the target population.

> *...people don't have phones, they don't have access to computers, so they can't spend [gift cards] anyway. They just end up selling it on the street for, like, half price or something, you know what I mean? So there's, like, even [names of local grocery and drug stores]...[where] they can use [a gift card]. They'll get food or whatnot. You know what I'm saying? You can't really do anything with [name of an online retailer], that's online.* [Interviewee #3]

Using Formative Data to Develop the Protocol and Interventions

The initial version of our study protocol was implemented in June 2018 (see Multimedia Appendix 3). In addition to meeting the criteria for PrEP use at the clinic of enrollment, eligible participants have to be 18 years of age or older; must be MSM or TGP; must be able to understand, read, and speak English; must report methamphetamine use in the past 3 months; must have a cell phone that can send and receive text messages; and must intend to remain in the King County area for at least 6 months. Exclusion criteria include PrEP use in the prior month; circumstances that preclude provision of informed consent, make participation unsafe, or make it unlikely that they would be able to participate for 6 months; or discomfort or anxiety with regard to text messaging. The criterion of discomfort or anxiety with text messaging was a direct result from our formative work.

Study procedures are summarized in Table 2 and the specific intervention components and procedures that resulted from our formative work are listed in Table 3. Briefly, eligible participants who choose to enroll are provided a link to a baseline survey and, if they complete it within 3 days of their initial PrEP appointment, they are randomized to one of the four study interventions: standard of care, text messaging, peer navigation, or combined text messaging and peer navigation. Participants are followed at 1 month, in accordance with the clinic's procedures; 3 months; and 6 months. Follow-up surveys are sent to participants at 3 and 6 months; for each completed survey, participants are sent a US $20 gift card to an online retailer by email. All participants are invited to participate in an in-depth interview when they complete or discontinue the study. Participants are provided an additional US $40 gift card to an online retailer for completing an in-depth interview. We chose not to include a gift card option to a brick-and-mortar store because we needed the ability to send the gift cards to individuals electronically, since online study surveys are administered remotely and end-of-study interviews can also be done via teleconference or phone.

Table 2. Timing of procedures for the Hit Me Up! study.

Procedures and length of clinic visits	Enrollment[a]	Month 1	Month 3	Month 6	Early discontinuation
Clinical procedures					
HIV testing	X	X	X	X	X
Hepatitis B surface antigen testing	X				
Creatinine testing	X	X	X	X	X
Sexually transmitted infection screening	X		X	X	X
Adherence counseling	X	X	X	X	X
Research procedures					
Research consent	X				
Online computer-assisted self-interview	X		X	X	X
Blood collection for dried blood spots		X	X	X	X
Clinic visit length (min)	90	30	30	30	30

[a] The research procedures for the enrollment visit may be performed on the same day of the initial pre-exposure prophylaxis (PrEP) clinical visit or on the following day.

Table 3. Study procedures implemented based on formative research findings.

Study procedure category	Study procedures
Peer navigation	Require peers to have experience working or networking with substance users, particularly people who use methamphetamine Peer works flexible hours Peer role includes working remotely Peer training includes boundary setting
Text messaging	Study sends three messages per day Various adherence reminders are sent Reminder messages are straightforward Participants select two ranges of 2-hour time periods for messages in baseline survey Participants select content area of some messages in baseline survey Participants select the word they want in their adherence reminders in the baseline survey Text message platform has the ability to send emojis
Educational and recruitment materials	Some cards use “PnP” (party and play) Images used do not overtly show methamphetamine or sex Some materials use symbols indicating inclusion of transgender participants
Other study procedures	Participants with a phobia of technology are excluded Some study clinics have evening and weekend hours

We incorporated suggestions from our formative work into the peer position and training. We included *prior experience working or networking with substance users, particularly methamphetamine users* as a required criterion for the peer position and created a role with flexible work hours and locations. Upon hiring, study onboarding includes standard research training sessions as well as training sessions with specific modules related to peer support, substance use, and boundary setting. Peers also receive ongoing peer support. The peer attempts to meet with all participants randomized to the peer navigation intervention within one week. During this initial contact, the peer completes a harm reduction–based needs assessment (see Multimedia Appendix 4). We anticipated that a peer would be able to provide assistance to 7-10 participants based on a recommendation from leaders of a local peer counselor program for persons who use methamphetamine. However, because the peer navigation is individually tailored and participants have varying levels of need, the study team meets regularly to ensure that the number of participants the peer is assisting is appropriate, and additional peers can be hired as needed.

The peer checks in with participants receiving the peer support intervention at least once per week to help support PrEP persistence, adherence, and study retention. The peer provides tailored support and referrals (eg, to shelters, needle exchanges, etc) in response to participants’ needs, which may include appointment reminders, direct coordination with the pharmacy and PrEP clinic, and providing transportation.

Based on our focus groups and interviews, participants are asked to select the timing of text messages and content areas in the baseline survey. The survey asks participants to select two ranges of 2-hour time periods within 24 hours (eg, 12 AM-2 AM and 2 AM-4 AM) during which to receive the messages. Each participant receives one daily PrEP adherence reminder, one text containing general PrEP information, and a third text from the content areas of their choice. Participants can select as many content areas as they choose, including local social and health services; general health information; harm reduction information for safer methamphetamine use or injection drug use; bondage and discipline, dominance and submission, and sadism and masochism (BDSM) and toys; PnP; STIs; condoms; anal care; and communication. Participants are also asked in the baseline survey which word they prefer for the daily adherence reminder (ie, “PrEP,” “pill,” “medication,” or other); their preference is programmed into their daily text messages.

Since the messages that were reviewed during our formative work aimed to reduce methamphetamine use and sexual behaviors for HIV and were not specific to PrEP, we created additional categories of messages related to PrEP knowledge and adherence. In response to suggestions from the focus groups and interviews, our text messages include emojis and the PrEP reminder texts are straightforward. In addition, we created a variety of PrEP reminder messages so they can vary throughout study participation as recommended by participants in our formative work. Based on the baseline survey selections, text messages are randomly selected from our text library and programmed to be sent at the chosen times. We chose Telerivet [26] as our text messaging platform because it is affordable and has the functionality for two-way messaging, including emojis in text messages, and for uploading personalized text message schedules for participants.

Finally, our education and recruitment materials were modified based on the suggestions from focus group and interview participants, as shown in Figure 1.

Figure 1. Revised educational cards that include the recommendations of focus group and interview participants. HMU: Hit Me Up; PrEP: pre-exposure prophylaxis; STD: sexually transmitted disease.

TAKEN DAILY, PREP CAN PREVENT HIV.

TIPS FOR TAKING PREP

* Take every day. *
* Match to a daily routine. *
* See your doctor *
* EVERY 3 months *
to check in and renew your PREP.
*PREP does NOT prevent other STDs. *

* FIND OUT MORE *

prep@gaycity.org OR 206.860.6969
prep@kelley-ross.com OR 206.324.6990

Discussion

In this paper, we describe protocol development and implementation for a study that aims to evaluate the acceptability and feasibility of peer navigation and text messaging to support PrEP adherence and persistence among MSM and TGP who use methamphetamine. It is important to involve individuals from the target communities in trial and intervention design in order to optimize participant experience and study outcomes. Prior to fully developing our interventions and study protocol, we conducted focus groups and interviews with the study target populations and then integrated the findings of our formative work into the study interventions and protocol.

Overall, participants thought MSM and TGP would be interested in participating, although they expected recruitment and retention to be challenging due to concerns for stigma, competing priorities, and nontraditional schedules. They shared that the peer navigator should be someone who is nonjudgmental, flexible, and has experience with methamphetamine. There was consensus that three texts a day were appropriate, messages should be straightforward and nonjudgmental, and participants should be able to tailor the timing and content of the messages. We incorporated these recommendations into the peer training process and selection of our text message platform, library, and procedures.

There are limited data regarding peer navigation or intervention development among MSM and TGP who use methamphetamine. Reback et al conducted a formative study to develop text messages specifically for MSM who use methamphetamine to reduce use and high-risk sexual behaviors that were based on behavioral change theories (ie, the Health Belief Model, the Social Support Theory, and the Social Cognitive Theory) [23]. In our study, we assessed the relevance of a subset of those messages with our target study population and found that messages providing informational and emotional support resonated the most with participants. Another study, with young Black men that also used focus groups to refine procedures and content of their HIV-prevention text messaging intervention, found a similar preference for straightforward, factual texts. However, participants in those focus groups recommended including humor throughout the texts, which we did not hear from our participants [27]. A range of text frequencies across different populations have been reported as appropriate; in the study above with young Black men, three messages per week were recommended, whereas another formative study among adolescent MSM found that 8-15 texts per day were acceptable [27,28]. While there was a range in our formative work, three texts per day were within the acceptable range across participants, and more than six would have been unacceptable.

This study has a number of limitations. First, our findings represent the opinions of participants in two focus groups and three interviews, which may not be generalizable to the larger community of MSM and TGP who use methamphetamine in King County, Washington. Moreover, these findings may not be relevant to communities who use methamphetamine outside of Seattle, where PrEP use is prevalent and generally easy to access. Second, our study focused on PrEP adherence and persistence and did not identify barriers to PrEP access. PrEP studies should support MSM and TGP who use methamphetamine across the PrEP cascade. Third, PrEP knowledge and technological advances are changing rapidly over time, and our findings regarding information and technological features that participants desired may be less relevant for interventions being designed today.

Finally, while we tried to include TGP so that we could develop interventions that were culturally appropriate for participants who are not cisgender, we had a difficult time recruiting people for these activities and only had two interviews with individuals who were not cisgender. We also had limited representation of people of color, who are disproportionately impacted by HIV. Future work developing HIV-prevention interventions, including peer navigation and text messaging, should aim to incorporate transgender participants, specifically transgender women and transgender MSM, and persons of color to ensure cultural relevancy to communities at the highest risk for HIV. During the period of this study, we have supported local events for transgender awareness and brought our educational and recruitment materials to in-person spaces and online platforms that may reach more people who are transgender and persons of color, including social media and hookup apps. Our study has a data safety and monitoring board (DSMB), which monitors the study to ensure participant safety. In order to represent needs of study participants who may be especially vulnerable, the DSMB includes TGP of color.

Our study is currently enrolling participants, and results regarding the peer navigation and text messaging interventions to support PrEP use among MSM and TGP who use methamphetamine will be published elsewhere. Through the focus groups and interviews described herein, we aimed to incorporate the opinions and feedback of MSM and TGP who use methamphetamine in the refinement of our interventions and protocol. Incorporating populations most impacted by HIV in the design of PrEP interventions increases their chance for success and thus maximizes PrEP's potential as a tool for ending the HIV epidemic.

Acknowledgments

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Conflicts of Interest

VMM reports involvement in the iPrEx, iPrEx open label extension (OLE), and ECLAIR studies, which received study products from Gilead and ViiV, and participation in a Gilead-funded Patient Community Support grant for hepatitis C prevention and treatment. JDS reports involvement in the HPTN 069/ACTG A5305 study, in which Gilead and ViiV contributed study medications, and attended a Gilead Latinx Advisory Board Meeting in 2018. JMB reports participation in advisory committees for Gilead Sciences, Jansen, and Merck. For the remaining authors, no conflicts of interest were declared.

Multimedia Appendix 1
Focus group discussion guide.
[DOCX File , 23 KB - formative_v4i9e18118_app1.docx]

Multimedia Appendix 2
In-depth interview discussion guide.
[DOCX File , 22 KB - formative_v4i9e18118_app2.docx]

Multimedia Appendix 3
Initial version of study protocol.
[DOCX File , 56 KB - formative_v4i9e18118_app3.docx]

Multimedia Appendix 4
Needs assessment.
[DOCX File , 26 KB - formative_v4i9e18118_app4.docx]

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Abbreviations

BDSM: bondage and discipline, dominance and submission, and sadism and masochism
DSMB: data safety and monitoring board
HMU!: HIV Prevention in Methamphetamine Users; Hit Me Up!
LGBTQ+: lesbian, gay, bisexual, transgender, and queer or questioning individuals, plus other sexual and gender minorities
MSM: men who have sex with men
NIH: National Institutes of Health
OLE: open label extension
PnP: party and play
PrEP: pre-exposure prophylaxis
Project NEON: Project Needle and Sex Education Outreach Network
SASG: Seattle Area Support Groups
STI: sexually transmitted infection
TGP: transgender people

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Original Paper

MyPath to Home Web-Based Application for the Geriatric Rehabilitation Program at Bruyère Continuing Care: User-Centered Design and Feasibility Testing Study

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Abstract

Background: When older adults return home from geriatric rehabilitation in a hospital, remembering the plethora of medical advice and medical instructions provided can be overwhelming for them and for their caregivers.

Objective: The overall objective was to develop and test the feasibility of a novel web-based application called *MyPath to Home* that can be used to manage the personalized needs of geriatric rehabilitation patients during their transition from the hospital to home.

Methods: This study involved (1) co-designing a patient- and clinician-tailored web-based application and (2) testing the feasibility of the application to manage the needs of geriatric rehabilitation patients when leaving the hospital. In phase 1, we followed a user-centered design process integrated with the modern agile software development methodology to iteratively co-design the application. The approach consisted of three cycles in which we engaged patients, caregivers, and clinicians to design a series of prototypes (cycles 1-3). In phase 2, we conducted a single-arm feasibility pilot test of *MyPath to Home*. Baseline and follow-up surveys, as well as select semistructured interviews were conducted.

Results: In phase 1, semistructured interviews and talk-aloud sessions were conducted with patients/caregivers (n=5) and clinicians (n=17) to design the application. In phase 2, patients (n=30), caregivers (n=18), and clinicians (n=20) received access to use the application. Patients and their caregivers were asked to complete baseline and follow-up surveys. A total of 91% (21/23) of patients would recommend this application to other patients. In addition, clinicians (n=6) and patients/caregivers (n=6) were interviewed to obtain further details on the value of the web-based application with respect to engaging patients and facilitating communication and sharing of information with the health care team.

Conclusions: We were successful at designing the *MyPath to Home* prototype for patients and their caregivers to engage with their clinicians during the transition from geriatric rehabilitation to home. Further work is needed to increase the uptake and usage by clinicians, and determine if this translates to meaningful changes in clinical and functional outcomes.

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KEYWORDS

geriatric rehabilitation; care transition; technology; hip fracture

Introduction

Approximately 30,000 Canadians a year are admitted to the hospital with hip fractures [1]. With the increasingly aging population, our hospitals face constant pressure to discharge patients earlier, resulting in the need for more complex care to be delivered at home [2]. Best practice guidelines exist to ensure the quality of care of patients with hip fractures [3]. These guidelines recommend all patients with hip fractures receive active rehabilitation following their acute care stay, with rehabilitation beginning no later than 6 days following surgery [4]. This recommendation is consistent with findings that early access to an inpatient geriatric rehabilitation program after hip fracture increases the likelihood of patients returning home [5]. However, our challenge is that the health system does not always have the means to operationalize these guidelines.

When older adults return home from geriatric rehabilitation in a hospital, remembering all the medical advice and all the medical instructions can be overwhelming for them and for their caregivers. Care transition from the hospital to home is a vulnerable time, during which approximately one out of five adults experience an adverse event [6]. Communicating discharge instructions in an easy to understand way is very important [7]. Older adults and their caregivers require information that is accessible and can be easily shared with their primary care team. Currently, the paper discharge documents that patients receive are standardized, and we need to better accommodate the unique circumstances of each patient. The use of health information technologies can help patients and their caregivers access their personalized discharge information in order to better manage their health care needs while navigating our complex health care system [8]. The increased presence of mobile and wireless technologies, and advances in their application offer a potential solution to engage geriatric rehabilitation patients, engage them in shared decision making, and ultimately help them to better manage their personalized needs during care transition from the hospital to home. However, it is important that the intervention is well accepted, that it is used by the target population, and that it is adaptive to patients' specific and evolving needs.

In order to improve the care transition from the hospital to home, hospitals need to improve how they engage patients and caregivers in terms of care, particularly during the discharge planning period [6]. Co-design is a participatory approach in which targeted end users, relevant clinicians, and researchers work together on all aspects of intervention development from needs assessment to content development, pilot testing, and dissemination [9,10]. This approach means that interventions are developed with an understanding of the local context and that the final product meets all stakeholder needs. Solutions designed in this way are more likely to be acceptable to both clinicians and patients/caregivers and therefore more likely to be adopted and sustained [11]. The purpose of this project was to co-design and test the feasibility of the novel *MyPath to Home* web-based application to manage the personalized needs of geriatric rehabilitation patients during their transition from the hospital to home.

Methods

Study Design and Setting

We conducted a user-centered design and feasibility testing study. The study took place in the Geriatric Rehabilitation Service at Bruyère Continuing Care, Ottawa, Ontario, Canada between July 2018 and March 2019. The study consisted of the following two phases: (1) co-designing the patient- and clinician-tailored *MyPath to Home* web-based application and (2) feasibility pilot testing of the application to manage the needs of geriatric rehabilitation patients when leaving the hospital. The detailed study protocol has been published elsewhere [12].

Phase 1: Co-Design of the MyPath to Home Web-Based Application

Study Design

We followed a user-centered design process, integrated with a modern agile software development methodology [13-16]. The approach was iterative and consisted of three cycles in which we engaged patients, caregivers, and clinicians to design a series of prototypes of a patient- and clinician-tailored application (cycles 1-3), adjusting them according to end user feedback.

We collaborated with NexJ Health Inc, a provider of cloud-based population health management solutions, to design and configure the personalized care transition *MyPath to Home* web-based application (a minimum viable product for a mobile phone, tablet, or computer). The Connected Wellness platform of NexJ Health is a well-developed technology solution that is designed to support multichannel communications among patients, caregivers, and clinicians.

Participants

Posthip fracture surgery patients were eligible to participate based on the following inclusion criteria: (1) age 65 years or older; (2) English speaking; and (3) discharged to home or a community facility within the last 90 days. Caregivers aged 18 years or older who spoke English and any clinicians who were part of the Geriatric Rehabilitation Service were also eligible to participate. If a participant did not have their own personal mobile device or computer in the hospital, they were provided with a loaner iPad (Apple Inc). Additional training and support with the application were provided as needed.

Data Collection

Cycle 1: Modeling the Care Transition Process

In the modeling phase, we conducted a process mapping exercise and a needs assessment using semistructured interviews with patients, caregivers, and clinicians (physicians, nurses, physiotherapists, occupational therapists, and social workers) from the Geriatric Rehabilitation Service to identify the specific user requirements, workflow, goals, metrics, and data sources that would inform the design of the application. The different requirements were reconciled between the participant groups using a model to develop common ground regarding the system requirements [17].

Cycle 2: Implementation of the MyPath to Home Application

In the implementation cycle, the software development team and researchers (CB, LP, and CK) configured the *MyPath to Home* prototype and mapped the implementation of the clinical concepts and the inputs obtained from the intended users in the modeling phase.

Cycle 3: Evaluation of MyPath to Home Application Support for the Care Transition Process

In the evaluation cycle, we conducted audio-recorded talk-aloud sessions with the intended users (ie, patients, caregivers, and clinicians) to evaluate the usability of the personalized care transition *MyPath to Home* application while it was being used in real time. Participants were encouraged to talk aloud and provide feedback on the proposed step-by-step workflow and to comment on their experience with the prototype. Talk-aloud testing was chosen because “users verbalize their thoughts while performing prespecified tasks” [18]; this can be helpful in identifying potential barriers to adoption. Modifications to the software were based on user feedback in order to integrate patients’ and clinicians’ needs and preferences prior to the implementation of the single-arm feasibility pilot test.

Data Analysis

Interviews and talk-aloud sessions were recorded and transcribed verbatim. For the interview and talk-aloud transcripts, we conducted a qualitative content analysis [19] to provide a comprehensive and accurate descriptive summary of the participants’ perspectives. Two researchers (IG and CB) conducted the analysis independently. Data management software [20] was used to support the qualitative data analysis.

Phase 2: Single-Arm Feasibility Pilot Test

Study Design

In phase 2, we conducted a single-arm feasibility pilot test of the *MyPath to Home* application. The specific objectives were to (1) determine whether it was feasible to provide the application to geriatric patients with hip fractures and their caregivers; (2) determine whether this application was acceptable to this population; and (3) refine the methods for a larger study.

Participants

We invited patients (n=30) who were being discharged from the Geriatric Rehabilitation Service to participate using a convenience sample. The sample size was not determined using sample size calculation, because the primary outcome of this study was not dependent on effect sizes. For feasibility studies, a sample size of approximately 24 to 50 has been previously recommended by other researchers [21-23]. The inclusion criteria were patients aged 65 years or older who had hip fracture surgery and informal caregivers aged 18 years or older who had access to a mobile or computer device.

Data Collection

Baseline (t=0)

After obtaining consent, patients, caregivers, and clinicians received training on how to use the *MyPath to Home* web-based application prior to obtaining access to it. Patients and their caregivers were asked to complete a survey of sociodemographic information (ie, age, gender, ethnicity, highest level of education, relationship status, and living situation) and the 16-item technology readiness index (TRI) 2.0, a scale that classifies participants by their level of technology adoption from 1.0 (low) to 5.0 (high) [24,25]. The TRI 2.0 has been verified for validity, reliability, and usefulness in a specified population subgroup like the one proposed in this study [26]. Patients and their caregivers were also asked to provide information about their specific needs and preferences (eg, goals of care), and review discharge and transition information (ie, workbooks). For the purpose of this study, a research assistant uploaded the discharge information from clinicians to the application.

Follow-up (t=1)

At 30 days after discharge, all patients (and their caregivers) were invited to complete a follow-up survey consisting of eight Likert scale questions. We also conducted select follow-up phone call interviews with patients (n=5), caregivers (n=1), and clinicians (n=6) to ask for their perspectives on the discharge processes and for their perspectives on the value of the *MyPath to Home* application with respect to its ability to engage patients and to facilitate communication and sharing of information with the health care team.

Data Analysis

We used descriptive statistics (ie, means) to summarize the survey results. The TRI 2.0 [24,25] was analyzed using mean scores for items that comprise the domains of *optimism*, *innovativeness*, *discomfort*, and *insecurity*. Scores were reverse coded for the inhibitor domains. A mean total score for technology readiness was computed.

Interviews were transcribed verbatim. The transcripts were analyzed independently by two researchers (IG and CB) using content analysis [19] to identify important contextual influences and practices related to the implementation and evaluation of the *MyPath to Home* web-based application.

Results

Demographics

Overall, 34 patients, 19 caregivers, and 20 clinicians participated in the study. The overall participant demographics for each study phase can be found in Table 1.

Table 1. Demographics of the study participants (N=73).

Occupation/role	Phase 1 Needs assessment, n	Phase 1 Talk-aloud sessions, n	Phase 2 Feasibility pilot, n
Patients (n=34)	1	3	30
Male	0	1	11
Female	1	2	19
Caregivers (n=19)	1	0	18
Clinicians[a] (n=37)	6	11	20
Physiotherapists	1	2	7
Social workers	1	2	3
Occupational therapists	1	2	4
Physicians	1	0	6
Nurses	1	4	0
Managers	1	1	0

[a] A total of 20 unique clinicians participated in the study.

Phase 1: Application Design

We developed the *MyPath to Home* web-based application to serve as a digital care transition record for geriatric patients with hip fractures. The *MyPath to Home* web-based application was designed to provide patients and their caregivers with access to all their personalized discharge information in one place. With the application, patients and their caregivers were able to securely access the discharge records and to access them seamlessly across a number of mobile devices, including smartphones, tablet computers, and laptop computers. The records were synchronized between these devices, helping the patients and their caregiver stay up to date.

According to the survey results, the *MyPath to Home* application had the key features requested by both patients/caregivers and clinicians. The five key features included (1) access to a discharge plan upon admission to geriatric rehabilitation; (2) sharing of preferences and needs with the “circle of care” team members; (3) access to multiple resources through the health library (ie, workbooks) on their dashboard; (4) access to their personal rehabilitation goals of care; and (5) access to personalized discharge information including discharge date, follow-up appointments, who to contact, equipment needs, home accommodation, community resources, and list of medications. Clinicians can review each of their patient’s specific preferences and needs during their rounds, assign specific resources to the health library (ie, workbooks), and upload all individualized discharge information and resources.

In addition, according to the information requirements identified in the study and with the help of clinicians, 11 workbooks were developed for patients and caregivers. These included general information about (1) geriatric rehabilitation; (2) equipment and devices (occupational therapy); (3) mobility (ie, list of physiotherapy community clinics, where to purchase gait aids, and medical supplies); (4) community resources; (5) safety in the home (preventing falls); (6) changes in behavior or mood; (7) safe medication use; (8) pain management; (9) when to call the doctor; (10) things to remember; and (11) additional web and telephone resources.

The talk-aloud transcripts were coded based on a usability testing framework [18]. Table 2 provides examples of participant suggestions for each of the domains of the framework (usability, visibility, content, understandability, usefulness navigation, and workflow).

Table 2. Examples of quotes.

Code	Examples
Usability	*I think you'll have to try it to, to figure out what to modify. I do think a lot of them will struggle with the technology, but I think we should try it and see how it works and then make adaptations.* [Clinician #5]
Visibility	*So what's missing is a phone number or a… an internet number of some kind.* [Patient #1] *So, this is their website.* [Interviewer]
Content	*Is there a self-care one? You have mobility, is there a self-care one there?* [Clinician #3]
Understandability	*I don't understand the first question, which is when to call the doctor.* [Patient #1]
Usefulness	*Yes, this application is useful.* [Patient #1]
Navigation	*Go? Push this?* [Patient #2] *Yeah, you can press on the line.* [Interviewer]
Workflow	*Yeah. So if that's something sort of at the start of their admission, then that, that would kind of take the burden off of them at the end.* [Clinician #3]

Phase 2: Single-Arm Feasibility Pilot Test

Baseline (t=0)

In the baseline survey, we collected sociodemographic information on the participants (n=30). The mean age was 81 years. We had representation from both female participants (19/30, 63%) and male participants (11/30, 37%). Most patients lived alone (12/30, 40%) and were widowed (16/30, 53%). Further information on the participants can be found in Table 3.

Table 3. Sociodemographic information.

Patients	Value (N=30), n (%) or mean (range)
Age (years)	81 (67-96)
Gender	
Female	19 (63%)
Male	11 (37%)
Ethnicity	
Caucasian	28 (93%)
Other	2 (7%)
Highest level of education completed	
Elementary school	4 (13%)
High school	12 (40%)
College level	5 (17%)
University level	7 (23%)
Graduate level	2 (7%)
Relationship status	
Single/never married	2 (7%)
Married or domestic partnership	11 (37%)
Widowed	16 (53%)
Separated	1 (3%)
Living situation	
Alone	12 (40%)
With partner	8 (27%)
With children	3 (10%)
With relatives	6 (20%)
Retirement home	1 (3%)

The mean TRI 2.0 score was 3.26 out of a maximum score of 5, indicating a moderate level of technological adoption among the study cohort participants. The mean scores for innovativeness and optimism were 2.87 and 4.28, respectively. The mean scores for insecurity and discomfort were 2.57 and 3.32, respectively.

Usability of the Application (t=1)

During the pilot study period (phase 2), there were a total of 147 logins by patients, caregivers, and clinicians. Caregivers (n=16) accessed the application the most and also logged into the application the most frequently (38 logins). Usability data are provided in Table 4.

Table 4. Usability data.

Role	Value, n	logins 1-2, n	logins 3+, n	Total logins, n
Caregivers	16	11	5	38
Patients	7	3	4	26
Physicians	5	3	2	14
Physiotherapists	7	4	3	27
Occupational therapists	4	1	3	26
Social workers	3	1	2	16
Total	42	23	19	147

Follow-Up Surveys of Patients and Caregivers After Discharge (t=1)

In the 30-day postdischarge follow-up survey, patients and caregivers were questioned (n=23). Patients/caregivers felt that the information in the application was easy to understand (21/23, 91%), was helpful (21/23, 91%), helped to understand what they needed to do to prepare for discharge (22/23, 96%), and helped to identify the skills they needed to have for a successful discharge (20/23, 87%). Approximately 78% (18/23) of patients and caregivers found that the organization of the application made sense and that it was easy to navigate. Finally, 91% (21/23) of patients and caregivers would recommend this application to other patients.

Follow-Up Interviews With Patients, Caregivers, and Clinicians (t=1)

Patients (n=5), caregivers (n=1), and clinicians (n=6) participated in follow-up interviews. The clinicians who participated were physiotherapists (n=2), occupational therapists (n=2), a social worker (n=1), and a physician (n=1).

Participants described that an application, like *MyPath to Home*, was essential to help manage the personalized needs of geriatric rehabilitation patients during their transition from the hospital to home.

Specifically, patients and caregivers made the following statements:

> *This is the way to go!* [Patient #2]
>
> *Access to the application was quite helpful, the font was big enough!* [Patient #4]
>
> *Could be advertised more, some staff did not know about it.* [Caregiver #1]
>
> *Layout of the application and coaching on how to use it was good.* [Patient #3]
>
> *Good for someone who likes technology.* [Caregiver #1]
>
> *Having most of my care done at The Ottawa Hospital, this could be integrated with myChart.* [Patient #2]

Clinicians who used the application and participated in the follow-up interviews also described the challenges and benefits to this type of technology. Specifically, clinicians described the challenges with using this type of technology as follows:

> *This application added to my workload, it was more time consuming to log in.* [Clinician #1]
>
> *Easier use and having more mobile devices would be helpful.* [Clinician #2]
>
> *More education to the clinicians about the application would be useful.* [Clinician #5]

Despite these challenges, clinicians saw benefits of the technology. For example, "*It gave patients an opportunity to be involved in their care.*" [Clinician #4].

Discussion

Summary of the Findings

Our findings validate the use of *MyPath to Home* for geriatric rehabilitation patients after hip fracture, who are discharged from the hospital to home. This study directly integrated input and feedback from all relevant stakeholders (patients, caregivers, and clinicians) in the design and development of the personalized care transition application *MyPath to Home* for managing the needs of geriatric rehabilitation patients and for facilitating shared decision making. The application also included essential information as per the recommendations from Health Quality Ontario on patient care for patients with hip fractures and their caregivers [7].

Despite the co-design approach used in this study, there were still usability issues that emerged related to the clinician portion of this application. Further research on how this application can be better integrated into day-to-day practice is key to address the needs of all stakeholders involved [11]. These usability issues may have arisen owing to the nature of the research study, which was performed in addition to all regular day-to-day activities conducted by clinicians. Full integration of the application would require senior leadership support and a change in practice in order to be truly embedded into practice.

Comparison With Previous Research

The use of web-based or mobile applications to assist patients during the transition between acute and subacute care is limited [27]. Our results were similar to those in another study [28], where barriers to the use of an application were identified. This included patient-related barriers and barriers related to the view of the application as being a second opinion and the application being seen as an external burden. As reported by Scott et al [28], an application needs to be highly engaging to improve uptake. In our study, we engaged clinicians, patients, and caregivers in the design of the web-based application in order to ensure adoption. The application was designed to provide tailored discharge and care transition information. Engaging patients and their caregivers in the discharge and care transition process is important to ensure that they are well prepared before going home, are active in their care, and are equal partners [29].

Our study was not designed to evaluate the impact of the application on health outcomes or care processes. However, we observed that some clinicians felt that the use of the application resulted in them having more control over care processes. We also observed that some patients felt they had more control during the care transition. However, there was no mention of substantial changes in their roles or in the relationship with clinicians. This may be because it was still too early to observe the effects on the patient-clinician relationship. However, it may also have to do with the limited integration with care processes or the limited information that can be accessed through the application. Furthermore, some patients and clinicians pointed out that the application played only a small role in their interactions.

The next step is to refine *MyPath to Home* and expand the application for the entire episode of care in the geriatric hip fracture population from admission to acute care, acute hospitalization, discharge from acute care, admission to geriatric rehabilitation, inpatient rehabilitation stay, and finally discharge to home or to the community.

This new and improved application will need to be further tested for effectiveness with a larger audience. Specifically, we will use the findings to inform a larger-scale study to develop an understanding of the specific mechanisms by which the *MyPath to Home* application is effective for patients, caregivers, and clinicians. We will test implementation and evaluate the technology-based intervention for effectiveness in a larger randomized study. Future research will more rigorously evaluate the health and economic benefits to inform wide-scale adoption of the technology.

Strengths and Limitations

It is possible that the use of the technology led to unintended consequences (ie, increase in resource use rather than a decrease). For the purpose of this study, all data were entered directly into the application with no ability to receive data from other systems or send data to other systems; thus, some of the data might be duplicated in other systems (ie, hospital electronic health records). Future developments of this technology can include integration with electronic health records or other standard electronic health applications (ie, myChart).

Conclusion

We were successful at designing the *MyPath to Home* prototype for patients and their caregivers to engage with their clinicians during the transition from geriatric rehabilitation to home. Further work is needed to increase the uptake and usage by clinicians, and determine if this translates to meaningful changes in clinical and functional outcomes.

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Authors' Contributions

CB was a major contributor in writing the manuscript. All coauthors were involved in the design of the project, and critically appraised and edited the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

TRI: technology readiness index

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Original Paper

Role of a Digital Return-To-Work Solution for Individuals With Common Mental Disorders: Qualitative Study of the Perspectives of Three Stakeholder Groups

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Abstract

Background: Although effective return-to-work (RTW) interventions are not widely available for individuals with common mental disorders on sick leave, there is potential for transforming such interventions into a digital solution in an effort to make them more widely available. However, little is currently known about the viewpoints of different stakeholder groups, which are critical for successful development and implementation of a digital RTW intervention in health care services.

Objective: The aim of this study was to examine stakeholder groups' perspectives on the role and legitimacy of a digital RTW solution called mWorks for individuals with common mental disorders who are on sick leave.

Methods: A purposeful snowball sampling method was utilized to recruit respondents. Semistructured individual and focus group interviews were conducted for stakeholder groups of service users, RTW professionals, and influential managers regarding their experiences, needs, and preferences for mWorks. Content analysis generated themes and categories that constituted the main findings.

Results: The legitimacy of a digital RTW solution was high among all stakeholder groups since such a tool was perceived to enable service users to take control over their RTW process. This was mainly a product of accessible support and promotion of service user decision making, which had the potential to empower service users. All respondents stressed the importance of fostering a positive user experience with usability and emphasis on service user resources and strengths, as opposed to various limitations and shortcomings. Stakeholder groups highlighted critical content to facilitate RTW, such as the need to clarify a back-to-work plan, accompanied by an accessible RTW network and strategies for handling mental health problems. Implementation challenges primarily involved influential managers' concern of legislation incompatibility with innovative technology, and RTW professionals' concern of the possibility that digital solutions may replace them to a certain extent.

Conclusions: This formative research emphasizes the importance of shifting power from RTW professionals to service users. mWorks can play a role in mediating service user control over the RTW process, and thereby increase their empowerment. A digital RTW solution may facilitate the circumvention of implementation barriers associated with introducing evidence-based RTW interventions in a traditional RTW context.

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KEYWORDS

qualitative method; mental health; mHealth; quality improvement; vocational rehabilitation

Introduction

Employment is important for one’s identity, financial security, and sense of involvement in society [1,2]. Common mental disorders (CMD) such as depression and general anxiety disorders are acknowledged as the current leading cause of sick leave and unemployment [3,4]. CMD are associated with an increased risk of extended sick leave (absenteeism), not working at full work capacity (presenteeism), and early retirement [5-9]. Unfortunately, effective return-to-work (RTW) interventions are not widely available for individuals with CMD [10].

RTW can be defined as both a process and an outcome connected to when an individual returns to work after sick leave [11]. In Sweden, RTW is endorsed by different welfare actors (ie, health services, social insurance agency, public employment service, social services, and employers) [12]. However, research has highlighted insufficient collaboration among these actors and employers, contributing to a service and knowledge gap in the RTW process [10,12,13]. Single interventions are performed in a stepwise “train-then-place” manner that are neither coordinated nor integrated into one overall solution to facilitate a person-centered RTW process for individuals with CMD [10,14]. The traditional stepwise approach results in prolonged periods of sick leave and unemployment [15], which in turn negatively impact mental health and well-being [2], empowerment, and the hope and belief that such individuals can work (ie, self-efficacy) [16,17]. During sick leave, individuals often get stuck between mental health services and the next RTW actor [18-20]. In addition to this service gap, there is also a knowledge gap among RTW professionals and employers about how to prevent, recognize, and manage mental health issues [13].

Supported Employment is recognized as the most effective RTW intervention to increase employment among those with severe mental disorders [21] and CMD [22,23], and is distinct from the traditional stepwise approach. Supported Employment is a person-centered, strength-based, and recovery-oriented RTW model characterized by the early introduction of job seeking and rapid placement in employment by a “place-then-train” approach. Thus, instead of performing single interventions in the stepwise and “train-then-place” tradition, Supported Employment is integrated into an overall RTW service corresponding to individual needs [24]. For individuals with CMD, cognitive strategies are included in the Supported Employment approach [22,23]. One Supported Employment intervention is the Individual Enabling and Support model. This model has proven to be more effective in achieving RTW, increasing quality of life, decreasing depression [22], and increasing empowerment [17]. However, effective RTW interventions are not widely available for individuals with CMD due to implementation difficulties, which are largely caused by conflicts between different rehabilitation paradigms when introducing a “place-then-train” RTW approach into a traditional “train-then-place” context [25,26]. In such circumstances, the use of digital interventions that fit the needs of users with CMD have the potential to make RTW interventions more accessible [27,28].

Digital mental health interventions enable service users to gain access to welfare services and interventions regardless of geographical circumstances, time, and place [29], resulting in encouraging user participation and empowerment [30,31]. Some efforts have been made to transform evidence-based, face-to-face interventions such as cognitive behavioral therapy into more accessible mental health interventions such as internet-based cognitive behavior therapy [32]. The effects of these transformations have shown good results in reducing mental health symptoms [33]. These findings motivated the development of a digital RTW intervention called mWorks. The overall mWorks project attempts to transform the Individual Enabling and Support model into a digital solution using mobile phones. To assure its usefulness and implementation, mWorks should be developed in close connection to the implementation context of primary and general mental health services. In particular, understanding of the legitimacy of a complex intervention among stakeholder groups (ie, whether it is recognized as right or acceptable) helps to identify implementation barriers and facilitators before embarking on a lengthy and expensive process of development and evaluations [34]. Therefore, it is critical to address the preferences, needs, and interests of different stakeholder groups at an early stage of development.

The majority of mobile health apps or interventions have not been developed and evaluated in connection to service users’ needs, preferences, and interests [35]. Likewise, it is critical to address implementation challenges at the organization and delivery level of complex interventions [36]. Thus, consideration of the views of different stakeholder groups is important before development of the mWorks intervention to assure that it will become a user- and implementation-friendly digital solution [37]. As a first step, rigorous formative research on service users and other stakeholder groups is required to inform the mWorks design process based on service users’ needs and preferences [35,38]. Second, elucidating potential barriers and success factors that are likely to impact usability, successful development, design, and implementation of mWorks is critical. Accordingly, the aim of this formative study was to gain insight into the role and legitimacy of mWorks, a proposed digital RTW solution for individuals with CMD on sick leave, from the viewpoint of different stakeholder groups, including service users, RTW professionals, and influential people in managerial positions, within the context of primary and general mental health services. A further aim was to inform the development of mWorks.

Methods

Design

Formative research helps to identify the needs, preferences, and interests of stakeholder groups that influence usage and delivery. A qualitative descriptive research design with an inductive approach [39] was used to acquire knowledge about the role and legitimacy of mWorks. Ethical approval for the overall mWorks project, of which this study is a part, was obtained from the regional ethics committee in Lund, Sweden (Dnr 2017/324).

Recruitment and Respondents

Three stakeholder groups were identified (see Table 1). The first group was service users, which include individuals with experience of being on sick leave and of having a CMD such as depression (including depression episodes in bipolar disorder) or an anxiety disorder. The second group was professionals who regularly provide care and support in the RTW process of individuals with CMD, including psychologists, rehabilitation coordinators, physiotherapists, supported employment specialists, occupational therapists, and medical doctors in primary care and mental health services. The last group was stakeholders who held influential, strategic, or managerial positions within the future implementation context. The inclusion criteria for all stakeholder groups were individuals of working age (18-65 years) and able to speak Swedish.

A purposeful snowball sampling method was utilized to find respondents [40]. This sampling method was chosen to find respondents with significant knowledge about the RTW process, the implementation context of primary care and general mental health service organizations, and their digital strategic planning. This allowed for ongoing accrual of new, information-rich respondents who were not known by the study researchers. Initially, the researchers identified stakeholders from each group who had broad connections within the RTW context. A health care strategist in the Skåne County Council was initially contacted by the last author (UB) to identify influential stakeholders. The health strategist was familiar with the RTW research field and knowledgeable about other influential respondents within the organization. Similarly, known RTW professionals within health services were initially contacted, and the first two service users were contacted by the RTW professionals. Each stakeholder was asked about other suitable people who might contribute to the study with valuable information. The snowball sampling method generated participants for both individual and focus group interviews. The choice of interview method was dependent on available resources (time) and existing group affiliation or constellation (eg, psychologists, employment specialists, or service user panel members with experience of CMD and being on sick leave).

Table 1. Respondent characteristics (N=46).

Stakeholder group	Age (years), mean (range)	Men/women (n)
Service users (n=18)		
Individual interviews (n=12)	30 (24-48)	7/5
Service users; one focus group interview (n=6)	55 (44-74)	4/2
RTW [a] professionals (n=20)		
Individual interviews (n=12)	44 (30-60)	3/9
Employment specialists; one focus group interview (n=4)	40 (26-61)	0/4
Psychologists; one focus group interview (n=4)	40 (38-47)	1/3
Influential managers in County Council (n=8)		
Individual interviews (n=8)	53 (39-59)	1/7

[a] RTW: return-to-work.

Data Collection

Data were gathered using semistructured individual interviews [41] and focus group interviews (see Table 1) [42]. The interviews aimed to identify stakeholder experiences, needs, and preferences for digital RTW solutions for people on sick leave due to CMD. Interviews were conducted at stakeholder workplaces or at the university of the researchers. The first (PE), third (AL), or last author (UB) conducted the interviews. The semistructured interview guide was based on the questions, structure, and content of a stakeholder study that was similar to the present study, which aimed to develop a digital service in a health service context [43]. The guide contained four topics: (1) earlier experience and interests of digital interventions in an RTW context, (2) perspectives on critical features and content of mWorks to meet the needs of service users, (3) possible obstacles for the implementation of mWorks, and (4) possible success factors. Additionally, probing questions connected to the RTW process were added [41]. The same guide was used for all interviews and stakeholder groups. Prior to the interviews, researchers informed the respondents about the study, and informed consent was obtained from each respondent. Individual interviews were performed by one interviewer (PE, AL, or UB), whereas the focus group interviews were performed by two interviewers with the last author (UB) as the moderator. Each interview was audio-recorded. After each interview, field notes were written by the interviewers, with the additional aim of storing information about the context and setting during the interview.

The intention of the individual interview was to generate a broad range of topics, whereas the intention of the focus group was to reveal additional insight about the respondents' more sensitive and personal disclosures that are likely to emerge and to allow for discussions about the respondents' experiences, needs, and preferences for a digital RTW solution. These revelations are more likely to occur in a focus group setting where respondents from a rather homogenous group have the opportunity to explore their group identity and challenge aspects inherent to their subculture, thereby exposing aspects that normally are out of reach in an individual interview setting [44]. Individual interviews lasted 30 to 45 minutes, and the focus group interviews lasted between 45 and 60 minutes. Each transcript was assigned an anonymous code to safeguard respondent confidentiality. The data were stored on a USB drive secured in a fireproof locker at the research facility, with access restricted to the involved researchers.

Data Analyses

All interviews were transcribed verbatim in Microsoft Word by an independent professional transcriber. The transcribed interviews were initially analyzed inductively by the first author (PE), utilizing Graneheim and Lundman’s [39] framework for conducting qualitative content analysis. The procedure initially involved reading the material several times to gain a sense of the whole content. In the next step, meaning units that corresponded with the overall aim of the study were identified. The meaning units were subsequently condensed into smaller meaning units that still represented the original statement. The condensed meaning units were then coded and organized into categories that illustrated the same phenomenon and represented the manifest content derived from the transcribed interviews. The coding procedure was performed until consensus was reached by three of the authors (PE, UB, AL). Finally, the categories were sorted into themes and a main theme based on knowledge from the literature and the researchers’ professional experience, and these themes constituted the study results. All authors participated in the category sorting. In accordance with manifest content analysis, the level of interpretation and abstraction were kept to a minimum. Throughout the analysis, the focus was to describe the visible and obvious components from the transcripts to best represent what the respondents said in their own words, with exception of the process of establishing themes. The themes presented in Textbox 1 are at a higher level of abstraction than their accompanied categories. To further increase the credibility of the findings, the first author (PE) revisited the raw data in terms of audio files and field notes as well as the transcripts. It was also critical to include citations. Additionally, two different inquiry methods were used to support agreements in findings: individual and focus group interviews [39].

Textbox 1. Subthemes and categories of the main theme that a digital solution enables service users to take control over their return-to-work (RTW) process for individuals with common mental disorders.

Supporting service user empowerment

- Owning one’s RTW process
- Promote decisions with user consent
- Accessible RTW chain

Addressing implementation challenges

- Professional attitudes and beliefs
- Legitimacy of digitalization
- Surrounding legislation and policy
- Unforeseen costs

Create a positive user experience

- Simplicity
- The importance of design
- Emphasis on resources and strengths
- Alternative communication approaches

Critical content for return to work

- Accessible rehabilitation network
- A clear plan
- Strategies for handling stress and anxiety

Results

Themes

A main theme and four connected subthemes with categories (Textbox 1) were identified. Overall, stakeholders viewed a digital RTW solution with optimism. The main theme was *a digital solution enables service users to take control over their RTW process*. This theme was derived from the themes indicating that *supporting service user empowerment* may have a positive impact on a digital RTW solution for the service users. Furthermore, respondent statements also elucidated the importance of *addressing implementation challenges* of a digital RTW solution. They perceived implementation barriers to involve personal attitudes among staff, surrounding legislation on a policy level within the organization, and unforeseen costs. Service users thought that it is important to *create a positive user experience* by designing a simple, low-threshold, usable digital RTW solution with an emphasis on service user resources and strengths, and that service users should be able to choose alternative communication approaches. Furthermore, respondents voiced desire for *critical content for RTW*, highlighting the need for an accessible RTW network, clear RTW plan, and strategies for handling stress and anxiety. The findings are represented below by each theme and the accompanied categories (in italics).

Subthemes and Categories

Supporting Service User Empowerment

One of the main positive products of a digital RTW solution that emerged was *owning one's RTW process*. Respondents (ie, participants from all stakeholder groups) stated that a digital solution would benefit service users in gaining increased control and participation in their RTW process. Service users described the lack of support from mental health services for individuals who want to take control of their RTW process themselves, and believed that mWorks could fill that need. One service user stated:

> *Well, the mental health service is aimed at those people who are not self-sufficient, those who actually are [self-sufficient] don't get access to adequate support….But you are still forced to go there while getting worse and worse.*

Respondents described the positive aspects of having service users formulate their own authentic plans and goals to achieve RTW. This was thought to create ownership of the RTW process. Influential managers emphasized the potential and importance of a digital solution to empower the service user. By doing so, their own agencies were perceived as becoming more effective, flexible, and accessible. An RTW professional expressed that the service users themselves are the ones who are best informed about their preferences, needs, and interests in relation to RTW. However, some RTW professionals had reservations about a digital tool and cautioned that it could contribute to shifting the responsibility of becoming well or returning to work from the welfare professionals to the service users. They feared that the individual would be left to handle their situation on their own, without the aid of professionals to support them.

Furthermore, respondents thought that a digital solution should *promote decisions with user consent*. A digital RTW solution was perceived as empowering the service user with knowledge and information to prevent decisions made by authorities without service user consent. The ability of service users to lead and control their own RTW process was viewed as positive. The RTW process was described as becoming more transparent with a digital solution, and was otherwise perceived as difficult to grasp and coordinate in traditional services. A digital RTW solution could provide users with knowledge and a voice, while minimizing the potential for authorities to make decisions instead of or without the user, which was considered to be a common process at present. One influential manager of primary care stated: "You would own the process yourself, in the app, and have access to what is needed, and (you) do not have to think about whether something is going on behind your back."

Influential planners and managers also thought that digital RTW solutions would result in a more *accessible RTW chain*. The threshold for managing the RTW process was anticipated to be lower. Service users described that conventional modes of practice were perceived as rigid and too great of a threshold to overcome. Face-to-face meetings and phone calls were described as stressful to coordinate in a timely manner, but were described as the only viable option for the RTW process. The threshold for contacting the RTW network was described as being lower if there was an opportunity to choose the approach according to individual needs and preferences. Service users validated this perspective by stating that these barriers prevented them from doing anything about their situation. One service user said: "Calling the authorities is something I always try to avoid, because it's so complicated and difficult."

Addressing Implementation Challenges

The stakeholder groups of influential managers and RTW professionals voiced the need to address implementation challenges. They stated that clinicians or *professional personal attitudes and beliefs* toward digital solutions in general seem to play an important role in the adoption of a digital RTW solution. RTW professionals stated that some of their coworkers perceived challenges and were reluctant to implement new technology. They highlighted that using digital solutions might threaten their ability to keep their jobs, as new and effective work methods could make them redundant. One RTW professional said:

> *Say that you have a new method, because that means a lot of doubts, if you would create an app that is so good that my job is no longer needed. Then you would not like to support it, would you.*

Furthermore, respondents explained how some welfare actors lack the necessary technical skills to utilize new and innovative methods of practice. One service user explained:

> *The authorities can stand in your way. You have to get them to work together, especially when it comes to technology. I worked with the county council for a while, with their IT department… And that's terribly bad...So getting them to adapt to ... I believe is one of the biggest obstacles.*

The integration of digital solutions could be perceived as an extra workload for which RTW professionals did not have the resources or time. They reasoned that some of their coworkers lacked interest in learning about innovative technology. Individual factors such as attitudes, beliefs, interests, and age were described as important to consider when developing and adopting new technology and the role it might play in their organization. Early voluntary engagement with technology was a predictor for the future willingness to adopt digital solutions. The older coworkers were considered to be less familiar and experienced with technology and how to use it. In contrast, the younger generation was seen as being able to approach digital solutions with greater ease and willingness. The *legitimacy of digitalization* was high among the majority of the influential managers. They felt that a digital RTW solution holds great promise and highlighted the emergence of electronic health and digital solutions as positive, and something they would want to continue to develop in their organization. Influential managers mentioned that the digitalization of welfare services are "the future," "knocking on the door," and waiting to be more widely utilized.

Influential managers and RTW professionals expressed that the *surrounding legislation and policy* regulation of privacy and confidentiality made it difficult to use innovative technology in the RTW process. Constant and rapid technological developments made it difficult for legislation and regulations to keep up with technology advances. This was seen as a barrier and one of the reasons potential digital solutions were not fully utilized in their organizations.

Unforeseen costs were perceived as a barrier for adopting a digital RTW solution. Service users were afraid that the software would cost money, and thus that they would not be able to afford the app. One service user stated: "That it might be…I don't know if it should be free of charge, but it would have been good, or at least that it doesn't cost that much."

Both service users and RTW professionals explained that most of the current mobile apps available were free of charge, and therefore it would be discouraging to pay for an app. RTW professionals noted that not every service user has access to a smartphone since they are expensive. One would need to pay for an internet connection to fully utilize a digital RTW solution, and this was considered to be an additional unforeseen cost for the service user. RTW professionals and influential respondents explained that service users are an economically disadvantaged group and were therefore afraid that expensive software would be a hindrance for adoption.

Create a Positive User Experience

The importance of *simplicity* in fostering a positive user experience emerged as an important factor. Respondents emphasized that a smooth, responsive, and fluid user experience, without software bugs, hiccups, and minimal buttons clicks, was important. One RTW professional proposed a "where am I now" function to guide and help the service user orientate and navigate in the app; one should never have to stop and wonder "where am I?" The importance of usability reemerged throughout the data as an important factor for adoption. Excessive information or overly complex configurations were described as cognitively demanding and able to contribute to service user loss of motivation. RTW professionals were concerned that service users would find an overly complex digital solution as overwhelming and an extra workload. They explained that lack of simplicity could generate a loss of interest and adherence, which eventually would result in "dropouts." Respondents thought that the spoken or written language must be easily understood or should even utilize emojis, symbols, and icons instead of text. This was particularly emphasized by RTW professionals and service users.

Respondents explained *the importance of design* within a digital RTW solution to facilitate continuity and avoid service users' immediate discontinuation of use. In a focus group discussion about design, an occupational specialist emphasized the value of creating a good first impression: "You have to make a good first impression, I see that as the key to making a successful application—how to make a good first impression."

Service users wished for universal commands and idioms, utilizing similar design patterns from well-known social media such as Facebook and Twitter. Furthermore, respondents highlighted the importance of being able to adjust the digital solution, in terms of esthetic design, mood, and cognitive ability, to foster individualization. One service user expanded upon the idea of the possibility to alter the degree of simplicity in relation to the capacity or affective state, which may alter from person to person and from day to day. For example, if the user was experiencing cognitive pressure and emotional overload due to stress or anxiety in a particular situation, the need to alter the app for cognitive effort would make it accessible at all times. Service users further explained that the degree of simplicity should vary depending on the stage of their RTW process. Those that were recently on sick leave were perceived as less likely to prefer a complicated app as compared to someone who was about to return to work. One service user explained:

> *What I feel, when I have been down, when everything is difficult, to go through a mobile with lots of,…lots of settings that I perhaps normally would like….So, when I am down I have no strength for that, …then I would almost like to have it baby-simple.*

Furthermore, respondents expressed the importance of *emphasis on resources and strengths* of service users, instead of their various shortcomings and limitations. The need to create a positive user experience with focus on the normality of service users' conditions, free from judgment and negative reinforcement that might impact the users' view of themselves, was expressed. One service user articulated the need for a digital RTW solution to be objective and normalizing:

> *Absolutely. It needs to be very normalizing, I really believe it, because,…because otherwise it is so,…"oh, how ill you are," so it needs be very like "yes, but this is nothing strange!"*

The need for providing *alternative communication approaches* emerged as important for promotion of a positive user experience. Service users observed that conventional means of communication (eg, phone calls and face-to-face meetings) were stressful and anxiety-provoking. The suggestion was that communication be accessible and supported through group chats, text messages, and digital meetings, and the respondents felt positively about these alternative communication approaches. In contrast, some RTW professionals had reservations about fewer face-to-face meetings. They warned that the loss of personal, face-to-face meetings would increase isolation and reduce the amount of social contact among service users. An operating manager from the public employment service stated that RTW professionals viewed face-to-face meetings as superior to alternative communication approaches: "We must be aware and reconciled about our overconfidence in face-to-face meetings, which we often believe to be superior in comparison to digital meetings."

Respondents highlighted the benefits of introducing more viable communication options within their RTW network and noted progress toward RTW in a manner that felt suitable and comfortable to service users. They articulated the desire to be able to digitally record and retain documentation from RTW meetings. They often perceived meetings as stressful and indicated that it was difficult to register all of the information. Service users experienced being misinterpreted as lazy when they had difficulty understanding and remembering what was said during the meetings because of stress. As a consequence, one respondent explained being discharged by the psychiatrist:

> *People always assumed I didn't care, but I was just misunderstood. I've always cared, but they thought: "She doesn't care, why should we help her?"*

Critical Content for RTW

A wide variety of content was suggested as facilitating RTW for service users. An *accessible rehabilitation network* was considered to be paramount. Respondents explained that this network usually involved welfare actors who were assigned to support the service user until employment, such as occupational therapists and physiotherapists, supported employment specialists, social workers, medical doctors, handling officers at the national social insurance agency and public employment service, as well as family members, spouses, or friends. Service users proposed that contact information could be available to provide shortcuts in their RTW network. Having quick access to the rehabilitation network and to certain RTW professionals was perceived as an advantage that could prevent stress and anxiety-provoking scenarios. One service user said:

> *The reason why I think it must be as quick as possible, is...because of stress….The cause of stress is, of course, that it does not go (away) fast enough. Another reason is that you do not have anything to do, but…if you are on sick leave for one or another reason, just waiting is the most dreadful thing that exists. That's another negative thing that can happen, and so you have to solve it immediately. It can occupy your thoughts a whole week until you have solved it.*

Respondents perceived that access to the RTW support network was limited and inefficient due to travel distances. An accessible RTW support network was described as fast, with efficient means of communication regardless of geographical circumstances. Service users conveyed that an accessible RTW support network contributes to a sense of safety, because they know that they have access to support if needed. However, a psychologist raised concerns about being available around the clock. They suggested that the RTW professional network should only be available during working hours.

To create *a clear plan* for the service users was commonly recommended regardless of the stakeholder group. The importance of a calendar, schedule, and reminder features was emphasized. The building blocks or strategies for back to work need to be clear. The service user position or stage in the RTW process needs to be located, and the important goals or steps that need to be taken, along with the appropriate strategies to carry out at each step must be well-defined. In conjunction, a "to do list" that illustrates needed actions was suggested. RTW professionals, especially psychologists, proposed these kinds of functions to enhance motivation by establishing feasible and meaningful milestones and goals. Thus, users could measure and monetarize their own progression through a clear RTW plan.

Strategies for handling stress and anxiety were proposed as important. Functions to support coping with anxiety and stress when such emotions arise at the workplace or everyday life were stressed, mainly by service users and RTW professionals. Features like mindfulness, cognitive behavior therapy strategies, and relaxation or recovery exercises were recommended. One influential manager for a primary health care facility proposed that the RTW solution could contain a "first-aid kit" with personalized strategies to cope with stressful and anxiety-imposed scenarios. Respondents thought that there should be interactive functions for access to fast and reliable information about service user symptoms and problems. Service users explicitly wished to understand their thoughts and emotions when stress and anxiety arose. They proposed links to external webpages with reliable sources of information.

Discussion

Principal Findings

These findings show that a digital RTW solution has a role to play in the RTW process, and has legitimacy among stakeholder groups. A wide variety of factors need to be considered as an important precursor of the development of mWorks. The primary finding is the importance and capacity for mWorks to foster service users' control of their RTW process. According to the themes, a digital RTW solution that can satisfy stakeholders and will enhance service user empowerment needs to be developed in relation to existing implementation challenges, while fostering a positive user experience and focusing on the different stages and parts of the RTW process.

All stakeholder groups favored empowering service users and agreed that the forthcoming mWorks should promote conditions for service user participation and ownership of their RTW process. This same theme emerged in recent qualitative research on digital solutions [45,46]. According to the respondents, regardless of group affiliation, one way of promoting such conditions would be to lower the threshold for service users to manage and control their RTW process, irrespective of their mental health. Our findings also suggest that mWorks needs to focus on making the user RTW support network accessible, regardless of time, place, or pace [29]. Previous research has identified having an overview of critical RTW actors and professionals as a critical RTW factor [47] that makes the service user more informed and in charge of the RTW process. Thus, mWorks has the potential of increasing service user empowerment along with their sense of control over the different RTW steps and the RTW support network, which has previously been inaccessible or difficult to comprehend. Our research elucidated several implementation barriers that might be encountered with a digital RTW intervention.

Although legitimacy was high among all stakeholder groups, managers raised concerns about the legislation and policy regulations of privacy and confidentiality. These circumstances are likely to impede implementation of novel digital interventions if not accounted for during the design and implementation process. There are implementation challenges at several levels that influence the RTW process, not only aspects at the individual level but also those related to legal or organizational structures. In a systematic review, Powell and colleagues [48] stressed the importance of addressing barriers associated with implementing mental health service interventions at multiple levels within the implementation context. On an individual level, our findings suggest that stakeholder attitudes and beliefs toward digital RTW solutions may constitute a barrier. For instance, RTW professionals indicated negative biases toward digital RTW interventions because of a lack of time, resources, interest, and the potential threat of job loss. The latter has been found in earlier qualitative research, in which mental health service staff reported reluctant attitudes toward digital interventions due to the potential for them to replace clinical care [49]. Addressing professionals' views on digital solutions is important to foster successful adoption and implementation of such interventions [29,46]. These conservative stances suggest the need to highlight the added benefits (ie, increased effectiveness, and flexible and accessible support [30]) for both service users and RTW professionals when incentivizing digital RTW solutions. Rather than replacing face-to-face interventions in health care services, Berry et al [46] reported that a digital solution can enhance existing support. Therefore, a digital RTW solution should be understood as complementary to traditional support rather than replacing it.

Another implementation barrier pertains to reliance on access to a mobile device and internet connection. While it is true that service users are an economically disadvantaged group [50,51], research shows that individuals with severe mental disorders have almost as much access to mobile devices as the general adult population. Although it seems reasonable to assume that individuals with CMD may have a better financial situation than those with severe mental disorders, one of the most common barriers for mobile device ownership is the monthly subscription plan expenses [52]. Previous research had suggested discount programs to address the affordability of digital solutions for service users [53].

With regard to usability, our findings highlight the need to design a simple digital solution that fosters a positive user experience for individuals with CMD who may have a lack of motivation or difficulties in comprehending information. Some of the service users thought that complex digital interventions are likely to generate a lack of engagement. Our research emphasizes the importance of a focus on user strengths and resources rather than on problems and shortcomings. Comparable results were found in qualitative research when respondents stated that digital solutions need to foster positive feelings, without focusing on the negative aspects of CMD and symptoms that could lead to ruminating and catastrophizing [46]. To assure that mWorks promotes a positive user experience, service users must be included in the inquiry and design process. Users will not enjoy or adopt products that focus on their limitations, but they are capable of suggesting ways to reduce focus on the negative aspects of CMD [54]. User-centered research with a participatory, iterative design should be employed to ensure that mWorks is grounded in service user preferences that enhance their strengths and resources. Participatory design is compatible with the Individual Enabling and Support model, which focuses on individual preferences and needs [24], and further validates the need to make the Individual Enabling and Support model more accessible through a digital solution. To create a positive user experience, the introduction of mWorks should be paired with informational or educational efforts to help service users get started and thus minimize the risk of their immediate termination of use [55]. The app's digital pedagogical presentation, and how that is understood by the user, should also be considered. These findings highlight the importance of introducing digital solutions that are attuned to individual RTW needs and preferences, as well as the need for pedagogic structure and information on usage.

According to the stakeholders, the role and legitimacy of a digital RTW solution are associated with having access to adequate RTW support, regardless of time or place. In addition, the content should help service users gain a clear overview of the RTW environment. The development of mWorks might make the RTW steps more visible and tangible for service users. The opportunity to make a clear, individualized plan of how to get back to work, mediated through a schedule or "to do" list, can provide a setting with feasible goals. This kind of goal setting has been shown to generate increased levels of self-efficacy [56]. In turn, self-efficacy is one of the most important determinants for RTW [57,58]. Using goal-setting strategies to establish meaningful goals could help service users manage and prioritize their next appropriate step toward RTW.

Another way to help service users establish and reach their goals would be to borrow from motivational theories [59]. Similar suggestions have been mentioned in earlier research about how to help users set and reach goals through increased motivation and engagement [35,60-62]. Motivational interviewing can be successful in helping people identify their goals [63] and RTW [24]. Bakker et al [35] suggested the value of self-determination theory in the development of a digital solution that would increase service users' intrinsic motivation. Another proposal to enhance goal achievement would be to utilize game elements. The use of gamification has shown promising results in research that used goal setting theory to increase engagement [63-67].

Our findings highlight the importance of including cognitive strategies in mWorks to cope with stress and anxiety at work and in everyday life. Doing so would generate a sense of safety since users would have access to cognitive strategies and their RTW support network regardless of geographical circumstances. However, the service user group warrants a swift but reliable contact with professionals in their RTW network, as opposed to one psychologist who expressed concern about the need for psychologists to be available to service users around the clock. This concern emphasizes the importance of making cognitive strategies accessible outside of office hours. Internet-based cognitive behavioral therapy is an effective strategy to address stress and anxiety [32,33], and can be fully delivered as automated conversational apps that foster self-management [68]. These cognitive components can serve an important role in promoting an mWorks service user who manages and controls their RTW process.

Methodological Considerations

We used the Consolidated Criteria for Reporting Qualitative Research guide [69], which is a 32-item checklist to ensure the quality of the study. Carrying out formative qualitative research with stakeholder groups throughout the design and development process has been identified as an important cornerstone to tailor digital interventions to service users' needs and preferences [70]. To enhance the transferability (ie, external validity) of the findings, we took field notes, which allowed for a more in-depth description of the research setting and data collection procedure [71]. Purposeful snowball sampling was considered to be a desirable method of recruiting interview respondents because the researchers had no previous insight into potential respondents. Nevertheless, the snowball sampling method can be criticized for skewing the sample in a specific direction [41]. To increase transferability, the researchers asked the respondents to suggest only one or two potential respondents per person per stakeholder group. The utilization of individual and focus group interviews was selected to allow for a wider variety of data to emerge so as to not rely on only one source of inquiry. This helped the researchers reach adequate saturation and enhance the credibility of the findings [71]. Individual interviews are highly effective at generating a broad range of topics, while focus group interviews are more likely to produce sensitive and personal disclosures [44]. The respondents did not get the opportunity to check the transcripts or the interpretations, which negatively affects the credibility and is a limitation of the current study [71].

The authors constitute an interdisciplinary research team with expertise in their respective research fields, including public health (PE); digital development and participatory research (PS); occupational therapy, CMD, and RTW in relation to service users, employers, and RTW professionals (AL, UB); and mental health services and implementation research (UB). UB created the project idea about translating the Individual Enabling and Support model into a digital format called mWorks. Additionally, the first author (PE) has knowledge of the RTW process through his own experience of sick leave and CMD. This contributed to a healthy mixture of perspectives during the analysis process, and minimized the chances of having personal biases influence the findings. This in turn enhanced the credibility (ie, internal validity) of the findings, and therefore increases the level of trustworthiness of the current study [39].

Conclusions

mWorks may facilitate the avoidance of conflict between different RTW paradigms. This conflict has been a major implementation barrier of introducing a "place-then-train" model in a "train-then-place" RTW context [25,26]. Shifting the power from health care professionals to the service users is a clear priority [72,73]. Service user empowerment is emerging as a focal point in mental health research and reforms, but the understanding of how to implement such a paradigm shift is still underdeveloped [74]. mWorks may have a role to play in such a paradigm shift. Further research should focus on conducting user-centered research with a participatory iterative design to best understand service user needs and preferences when developing digital RTW solutions.

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Conflicts of Interest

None declared.

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Abbreviations

CMD: common mental disorders
RTW: return-to-work

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Original Paper

Telerehabilitation to Address the Rehabilitation Gap in Anterior Cruciate Ligament Care: Survey of Patients

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Abstract

Background: Evidence shows that after anterior cruciate ligament (ACL) reconstruction, patients may have varied access to physical therapy. In particular, physical therapy input may end many months before patients reach full recovery. Telerehabilitation may provide an opportunity to address this *rehabilitation gap* and improve access to evidence-based rehabilitation alongside physical therapy at all stages of care.

Objective: This study aims to understand the opinions of patients who have undergone ACL surgery and rehabilitation on the use of telerehabilitation as part of ACL care and define the population and explore their experiences and views on the acceptability of telerehabilitation after ACL reconstruction.

Methods: This study was a cross-sectional, voluntary, web-based survey combining both closed and open questions. Ethical approval was obtained from the Yale School of Medicine Institutional Review Board. Participants were aged 16 years or older at the time of recruitment and had undergone ACL reconstruction within the past 5 years. A 26-item survey was developed using the Qualtrics survey platform. No items were mandatory. Responses were multiple choice, binary, and qualitative. The CHERRIES (Checklist for Reporting Results of Internet E-Surveys) was used to ensure the quality of reporting of surveys in the medical literature. Data were analyzed using Stata version 15. Qualitative data were analyzed using NVivo 11. The theoretical framework for this analysis is based on the Capability, Opportunity, and Motivation-Behavior model of behavior change.

Results: A total of 100 participants opened the survey. All completers were unique. The participation and completion rates were each 96% (96/100). Patients reported their physical therapy care ended at an average of 6.4 months and that they felt fully recovered at an average of 13.2 months. Only 26% (25/96) of patients felt fully recovered at the end of physical therapy. Of these 96 patients, 54 (60%) were younger than 30 years, 71 (74%) were recreational athletes, 24 (24%) were competitive athletes, 72 (75%) had private insurance, 74 (77%) were not familiar at all with telerehabilitation, and 89% (85/96) felt capable. They preferred to use telerehabilitation at different stages of care. Reported benefits included resource saving, improved access to care, improved learning, and greater engagement. Concerns included incorrect performance of exercises or unmanaged pain being missed and less access to manual therapy, motivation, and opportunities to ask questions. Participants' priorities for a future telerehabilitation intervention included its use as an adjunct to physical therapy rather than a replacement, with content available for each stage of care, especially return to sports. Participants stressed that the intervention should be personalized to them and include measures of progress.

Conclusions: These findings helped understand and define the ACL reconstruction population. Participants found telerehabilitation acceptable in principle and highlighted the key user requirements and scope of future interventions.

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KEYWORDS

anterior cruciate ligament; telerehabilitation; rehabilitation; eHealth; knee; survey; telehealth; patient experience

Introduction

An estimated 150,000 to 250,000 anterior cruciate ligament (ACL) injuries occur each year in the United States [1-3]. The cost is estimated at more than 3 billion dollars annually, not including the psychosocial costs incurred by patients, their families, and clinical teams involved [4]. The postoperative rehabilitation process can be lengthy [5] and includes predominantly evidence-based exercise interventions led by physical therapists through clearly defined stages of care [6-11]. It takes most patients 9 to 12 months after surgery to pass the return-to-sports criteria [5].

The return-to-sport stage of rehabilitation is crucial for those who intend to participate in sports after anterior cruciate ligament reconstruction (ACLR), particularly as returning to sports too soon risks re-injury [12,13]. It includes complex decision making around when and how to progress through physical and psychological challenges to facilitate optimum function and minimize the risk of re-injury [12,14]. It requires appropriate return-to-sport tests that recreate the physical challenges of sports in a controlled way and measure the individual’s ability to perform the necessary physical tasks of their sport [9,12,13]. Delaying return to sports until an individual passes these return-to-sport milestone tests helps prevent re-injury [3,15,16]. Negotiating this without a supervising physical therapist presents challenges, particularly as evidence suggests there is a difference between athletes’ perceived and actual readiness to return to sports [17].

A recent web-based survey of more than 1000 American physical therapists found that rehabilitation practice varied significantly in terms of the content and duration of supervised care [14]. Specifically, with regard to the length of treatment, supervised physical therapy ranged from 1 to 3 months (15% of respondents) to 12 months (11% of respondents). Overall, 56% of respondents reported 3 to 5 months or less of supervised physical therapy. These data suggest that many patients leave supervised care before the return to sports rehabilitation or achieving a return to sports [5]. This suggests the existence of a *rehabilitation gap* between the end of care and return to sports. Greenberg et al [14] concluded that this gap may contribute to patient confusion and suboptimal outcomes.

Telerehabilitation interventions may provide an option to address this rehabilitation gap. Telerehabilitation can provide evidence-based information, education, and exercise guidance and is acceptable to patients [18,19]. This technology has the potential to improve adherence to rehabilitation by engaging with mechanisms of behavior, including personalized features such as prompts, goal setting, and exercise logs [18,20]. Some of these interventions are wearable [21], some are app or website based [18,22], and some are delivered to home [19,20]. The latter study used a three-dimensional camera to facilitate communication between the physical therapists and the patients [20]. In this context, *telerehabilitation* has been employed as a catch-all term for digital rehabilitation methods and is variously called digital health, eHealth, or mobile health; the term is increasingly used to describe digital tools, including video consultation. However, in this paper, we use this catch-all term to describe digital rehabilitation strategies that may or may not include video consultations.

The rehabilitation gap appears to be caused by patients only being allowed (or able to afford) a certain number of appointments. Using telerehabilitation through the rehabilitation process as an adjunct to face-to-face care may create an opportunity to prolong physical therapy by stretching the allocated appointments over a longer period. Patients have previously used telerehabilitation for knee injuries with high fidelity and noted improved confidence and motivation with their rehabilitation [18-20]. The attitude of patients toward this technology after ACLR is unknown.

Objectives

This study aims to understand the acceptability of patients who have completed ACL surgery and rehabilitation regarding the use of telerehabilitation as part of ACL care. Our objectives are as follows:

1. obtain patients’ experiences and opinions on their access to physical therapy throughout ACL rehabilitation,
2. explore the patients’ understanding of telerehabilitation, and
3. explore patients’ opinions about the acceptability of telerehabilitation as part of ACL care.

Methods

Design

We used a cross-sectional, voluntary, web-based survey combining both closed (fixed-response options) and open questions.

Ethics

Ethical approval was obtained from the Yale School of Medicine Institutional Review Board (IRB), and proper consent procedures were employed for all participants.

Participants and Recruitment

Potential participants were drawn from the Yale New Haven Hospital Healthcare database. Patients aged 16 years or older at the time of recruitment who had undergone ACL reconstruction within the past 5 years were invited to give their “thoughts and opinions regarding a potentially new approach to post-surgical rehab” and introduced to the possibility of telerehabilitation in addition to usual care (Multimedia Appendix 1). Potential participants were provided with an IRB-approved patient information sheet and informed that completing the survey was entirely voluntary. Consent was implied by participation. Participants were offered the opportunity to enter a draw for a US $50 Visa gift card as an expression of gratitude for their participation [23]. This was an exploratory study; therefore, no formal sample size calculation was used [23].

Survey Development

This survey was developed using the Qualtrics survey platform. The study authors designed the questionnaire based on expertise and previous research in the field. Input on the content was sought from research and clinical peers. A total of 4 orthopedic surgeons and 5 physical therapists reviewed the questionnaire over email. This led to the removal of marginally relevant questions and the addition of questions to identify patient self-described activity levels. The questionnaire layout was organized under the guidance of a Qualtrics survey expert at Yale University. The survey was then piloted with 8 colleagues (4 physiotherapists and 4 orthopedic surgeons) and patients who had undergone ACL but were not in the study for comprehension, interpretation, and availability of appropriate responses. Questions were further edited or removed for repetition or clarification, and new response options were added. A short video example of telerehabilitation was provided.

The survey included 26 question items on the survey distributed over 4 screen pages. A total of 4 questions focused on demographic details such as age, gender, race, and socioeconomic status. The remaining questions explored participants' experience of ACL postoperative care and their attitudes toward telerehabilitation and obtaining data on knee health. The final 3 questions of the survey invited respondents to put forward opinions about what they saw as the potential benefits and concerns of telerehabilitation and how they felt it would be best utilized in the management of patients after ACLR.

We used Likert scale answers in 2 questions. The scale chosen was a 5-point scale; however, only points 1, 3, and 5 were labeled. Points 2 and 4 were unlabeled but offered a second scale point between 1 and 3 or 3 and 5 to indicate either a slightly negative or slightly positive score that was not wholly positive or wholly negative and not neutral at 3. The challenge of measuring Likert scales is much discussed; as an ordinal scale, responses can be rated or ranked, but the space between *often* and *sometimes* cannot be empirically measured [24]. Although arguments have been made regarding parametric testing of Likert scales with normal distributions, in this instance, the Likert results are described in their ordinal categories [25].

Participants were prompted to complete questions before clicking through; no items were mandatory, which allowed participants to choose not to answer certain questions. Responses were multiple choice, binary, and qualitative. Neither randomization nor adaptive questions were used. Participants could use a *back* function to change a response if they chose to do so. A copy of the survey is available in Multimedia Appendix 2.

Survey Distribution

The survey was distributed to patients through the Yale Qualtrics software. It was distributed on October 7, 2019, and 2 follow-up emails were sent to the nonresponders 1 week apart. Participants were advised as to the purpose of the survey.

Data Analysis

Responses were collected through a web database. The survey responses were entered manually into a database, with the exception of time taken on the survey and percentage completed, which were captured automatically. The Checklist for Reporting Results of Internet E-Surveys, known as the CHERRIES statement, was used to ensure the quality of reporting of surveys in the medical literature [26]. The checklist is included in Multimedia Appendix 3. Eysenbach et al [26] suggested that as there is no standard methodology, authors should avoid the term *response rate*. They defined the participation and completion rates as recommended measures and calculated the participation rate as a ratio of those who click on the survey link and then chose to partake: "Count the unique number of people who filled in the first survey page (or agreed to participate, for example by checking a checkbox) divided by visitors who visit the first page of the survey."

Data were analyzed using Stata version 15 (StataCorp). Descriptive statistics were used in the primary analysis of data to summarize the frequency and distribution of responses. Secondary analysis to determine relationships between patient demographic characteristics and multiple-choice opinion responses were performed using a chi-square test. Likert responses were analyzed in relation to patient demographic characteristics using a one-way analysis of variance (ANOVA; parametric distribution) or Kruskal-Wallis ANOVA (nonparametric distribution). Missing data were accounted for by multiple imputation techniques using means.

Qualitative questionnaire data were analyzed using NVivo 11 (QSR International). A pragmatic thematic analysis was conducted to analyze responses with respect to the research question. The process was deduced from the data driving the analysis. The themes that arose from each question were grouped so that data relating to a patient's opinion were clear. Quotes from the survey support themes. Data are weighted and reported secondary to the frequency of occurrence or explanatory value [27]. The data were coded and analyzed independently by 2 members of the research team. Textual answers were coded into a word frequency cloud diagram that illustrates a hierarchy of terms at the heart of the participant's responses.

The theoretical framework for this analysis is based on a model of behavior change that relates the capability, opportunity, and motivation to behavior (COM-B). [28]. In rehabilitation, the target behavior is most often exercised. Michie et al [29] designed a system in which capability, opportunity, and motivation are understood in relation to the target behavior. This model identifies that to perform the target behavior (ie, exercise), patients must be physically and psychologically capable, must have social and physical opportunities, and must be motivated to engage in behavior in the form of deeper desires and reflective planning [30]. Applying the COM-B theory to the survey results can aid further understanding of patient acceptability of telerehabilitation as a tool for ACL rehabilitation.

Data Protection

Data were anonymized, and no personal medical data were stored or analyzed. Qualtrics survey software and the local Yale University servers were used to protect the data. Anonymized data were stored on encrypted laptops.

Results

First, the survey response and characteristics of respondents are described, followed by the results for each objective of the study;

then, the respondents' experiences of physical therapy after ACLR, their previous experience of telerehabilitation, and views on the acceptability of telerehabilitation are reported.

Survey Response

A total of 213 patients were contacted; 29 emails bounced and 184 were delivered. Of these, 100 respondents clicked on the survey. On the basis of internet protocol addresses, all completers were unique throughout the study. Cookies were not used to assign identifiers to each computer.

On examination of the data, 4 responses were found to be empty and were therefore excluded. Therefore, the analysis included 96 responses. The participation and completion rates were calculated according to the CHERRIES guidance [26]. For this study, the participation rate was 96% (96/100). The completion rate is calculated as the ratio of users who finished the survey relative to those who clicked on the survey link and agreed to participate. The completion rate was 96% (96/100). The view rate was not applicable. Participant characteristics are detailed in Table 1. Missing data were minimal (26/2112, 1.2%) and therefore accounted for by a multiple imputation technique using means.

Table 1. Demographics and patient characteristics (N=96).

Characteristics	Values
Frequency of age at surgery (years), n (%)	
15-19	4 (4)
20-24	18 (19)
25-29	32 (33)
30-34	8 (8)
35-39	4 (4)
40-44	9 (10)
45-49	13 (14)
>50	8 (8)
Year of surgery; frequency, n (%)	
2014	5 (5)
2015	14 (15)
2016	27 (28)
2017	16 (17)
2018	23 (24)
2019	11 (11)
Surgical procedure; frequency, n (%)	
ACLR[a] alone	57 (60)
ACLR with meniscus repair	36 (37)
ACLR with another procedure	3 (3)
Gender; frequency, n (%)	
Female	55 (57)
Male	40 (42)
Trans or nonbinary	1 (1)
Race/ethnicity; frequency, n (%)	
Asian	14 (15)
Black or African American	5 (5)
Hispanic or Latino	12 (13)
Native Hawaiian or other Pacific Islanders	1 (1)
White	64 (66)
Insurance; frequency, n (%)	
Commercial (eg, Blue Cross/Blue Shield and Cigna)	72 (75)
State (eg, Medicaid and Medicare)	21 (22)
Uninsured	3 (3)
Level of sport; frequency, n (%)	
Competitive sport/activity	24 (25)
I am not active	1 (1)
Recreational sport/activity	71 (74)
Returned to the same level; frequency, n (%)	
No	39 (41)
Yes	57 (59)
Did you have sufficient physical therapy; frequency, n (%)	

Characteristics	Values
No	22 (23)
Yes	74 (77)
Determining factors to end physical therapy[b], n (%)	
Determined by the expense	14 (15)
Determined by the insurance	36 (38)
Determined by the physical therapist	66 (69)
Determined by you	49 (51)
I was fully recovered	25 (26)
Other	12 (13)
Too far away	7 (7)
Too time consuming	18 (19)
Percentage of knee function compared with previous, mean (SD); range	82.6 (13.8); 25-100
Months you had physical therapy, mean (SD); range	6.4 (4.8); 2-30
Patient’s stated ideal length of physical therapy (months), mean (SD); range	7.25 (4.3); 2-36
When did you feel fully recovered (months)?, mean (SD); range	13.17 (8.3); 0-60

[a] ACLR: anterior cruciate ligament reconstruction.

[b] Multiple responses were permitted; % will not add up to 100.

Characteristics of the Respondents

More than half of patients (54/96, 56%) were younger than 30 years at the time of their surgery. There were more female respondents (55/96, 57%) than male respondents and more White respondents (64/96, 66%) than other ethnic groups. The participants identified themselves mostly as recreational athletes (71/96, 74%); 25% (24/96) identified themselves as competitive athletes, and 1% (1/96) reported that they were not active. Most participants had ACL reconstruction alone (57/96, 59%), although concomitant meniscal repair was also common (26/96, 38%). Overall, 59% (57/96) of participants reported that they returned to their pre-injury performance level. When asked to compare their knee before injury on a scale of 0 to 100, the mean knee score was 82.6 (SD 13.82). Response rates were lowest in patients who underwent surgery in 2014 but were otherwise unremarkable. Most respondents had private insurance (72/96, 75%). The results are shown in Table 1.

Experiences of Physical Therapy

Only 26% (25/96) of patients felt that they had fully recovered at the end of their physical therapy; 77% (74/96) of patients felt that they had sufficient physical therapy, whereas 23% (22/96) did not. Moreover, 69% (66/96) of patients stated that their physical therapy was ended by their physical therapist, whereas 51% (49/96) ended physical therapy themselves, and 39% (37/96) said that travel, time commitments, and other factors were causal for ending their physical therapy Patients recalled that they had a mean of 6.4 (4.8, 2-30) months of physical therapy after ACLR. The mean preferred length of physical therapy was 7.25 (4.3, 2-36) months. The mean time to fully recover was 13.17 months. These results are shown in Table 1.

Experience and Views on the Acceptability of Telerehabilitation: Quantitative Data

As indicated in Table 2, 92% (88/96) of patients had never used a telerehabilitation tool. Approximately 77% (74/96) reported that they were not familiar at all with telerehabilitation; 25% (24/96) of people felt there would be challenges to using telerehabilitation, although most were not overly concerned about data protection (48/96, 50% *not at all*; and 29/96, 30% were less than *somewhat concerned*). When asked in which phase they preferred to use their allocated physical therapy appointments, 60% (58/96) said they preferred face to face in the early stages of care, 33% (32/96) said they preferred to use face to face with the return-to-sport care, and 6% (6/96) chose other. Most patients (85/96, 89%) felt capable of using physical therapy, further, a secondary analysis using a chi-square test showed no significant association between capability and gender, age, level of sport, or race and ethnicity. However, we interpret this with caution, given that there was no formal sample size for this exploratory study, and there is some risk of a type 2 error.

Table 2. Experiences and opinions on telerehabilitation quantitative data (N=96).

Characteristics	Values
Previous use of telerehabilitation; frequency, n (%)	
No	88 (92)
Yes	8 (8)
How familiar are you with telerehabilitation; frequency, n (%)	
1 (not familiar at all)	74 (77)
2	11 (12)
3 (somewhat familiar)	9 (9)
4	1 (1)
5 (very familiar)	1 (1)
Concern about data protection; frequency, n (%)	
1 (not at all concerned)	48 (50)
2	29 (30)
3 (somewhat concerned)	13 (14)
4	3 (3)
5 (very concerned)	3 (3)
How would you prioritize use of physical therapy appointments; frequency n (%)	
Other	6 (6)
Early phase	58 (61)
Return-to-sport phase	32 (33)
Do you feel capable of using telerehabilitation; frequency, n (%)	
No	11 (12)
Yes	85 (88)
Association of feeling capable by chi-square, *P* value	
Age	.94
Insurance	.75
Gender	.91
Race and ethnicity	.30
Level of sport	.79

Experiences and Views on the Acceptability of Telerehabilitation: Mixed Qualitative and Quantitative Data

About 25% of patients perceived challenges in using telerehabilitation at home. When participants described these challenges, 2 themes emerged and are shown in Table 3 "Resources" and "Value placed on face-to-face care." Participant quotes are identified with the letter P and an anonymous identification number. First, access to technology such as appropriate computers with high-quality cameras for two-way communication and access to the internet were cited as potential limitations. Space and proper equipment with which to exercise were also mentioned as limitations to exercising at home. Second, patients emphasized the value they place on in-person therapy. In particular, meeting with their physical therapist afforded them the opportunity to make sure that exercise techniques were correct and that pain levels were normal. In addition, patients reported being motivated by their physical therapy and having improved confidence based on face-to-face physical therapy. They also mentioned the individualized nature of face-to-face care and the potential need for manual therapy.

Table 3. Experiences and opinions on telerehabilitation: mixed data.

Questions	Responses
Are there challenges to telerehabilitation use? Frequency, n (%)	
No	72 (75)
Yes	24 (25)
If yes, what are they?	
Concerns about resources	• “No computer.” (P10) • “Lack space.” (P86) • “Lack of equipment or space for exercise time management.” (P24) • “not having access to equipment” (P39) • “unreliable wifi” (P43)
Value placed on face-to-face physical therapy	• “Direct one on one instruction is irreplaceable.” (P11) • “being able to talk through new movements” (P42) • “Knowing what level of pain is ok.” (P16) • “How do you know you are doing the movements correctly?” (P20) • “Some of my rehab had to have been done by a physical therapist. I could not do the manipulation.” (P7)

Experiences and Views on the Acceptability of Telerehabilitation: Qualitative Data

Within each qualitative question, patients were invited to give their opinions on telerehabilitation. Table 4 shows the 3 questions asked and the themes that arose.

Responses regarding the potential benefits of telerehabilitation were collated into 4 themes: telerehabilitation as a resource-saving companion to physical therapy care, improving access to care, a learning tool during and after physical therapy, and to engage patients more with the education and exercises of their care (Textbox 1). Patients emphasized the potential value of telerehabilitation as an adjunct to usual physical therapy care. They emphasized its potential to facilitate *saving* appointments or to fill the gap at the end of rehabilitation. Patients placed significant emphasis on how telerehabilitation could improve their access to care. They commonly cited a lack of transport options, cost of transport, or bad weather as limiting their access, and they saw telerehabilitation as a way to improve this. Patients who had concluded physical therapy believed that it has a potential benefit of having access to telerehabilitation, such as an app, in an ongoing way to provide maintenance advice and reminders. Respondents identified their understanding of the role of telerehabilitation in motivating and engaging them in personal care plans. Goal setting, progress measures, and modes of encouragement were all mentioned as benefits of using telerehabilitation.

Table 4. Experience and opinions of telerehabilitation: qualitative data.

Question	Theme 1	Theme 2	Theme 3	Theme 4
What, if any, do you see as potential benefits to the use of telerehabilitation following ACL[a] reconstruction surgery?	Companion to physical therapy	Improving access to care	Telerehabilitation as a learning tool over the long term	Telerehabilitation as a tool to motivate and engage
What, if any, are your primary concerns regarding the use of telerehabilitation following your ACL reconstruction surgery?	Clinical concerns: biopsychosocial needs of patient	Sociopolitical	—[b]	—
What would you need from a telerehabilitation program to make it right for you to use?	Utilized alongside physical therapy	Preferred timing of telerehabilitation use	Personalized	—

[a] ACL: anterior cruciate ligament.

[b] Themes were not present for all questions.

Textbox 1. What are the potential benefits of telerehabilitation? (PT: physical therapy).

Question asked: What, if any, do you see as potential benefits to the use of telerehabilitation following anterior cruciate ligament reconstruction surgery?

- Telerehabilitation as a resource-saving companion to physical therapy care:

  "It might be useful for the home exercises, but would have to be paired simultaneously with in-person treatment to be useful." (P24)

  "Also you could save your Dr visits when it counts the most." (P10)

  "Physical therapy was mostly for the initial recovery (for the first three months at most). I wish I had more sessions for 'return-to-sport' type exercises. Of course being supervised would be ideal but perhaps 'return-to-sport' type rehab can be done remotely." (P19)

  "For patients who have a time constraint and who have run out of in person rehab, this may be a more affordable option." (P20)

  "Saving rehabilitation appointments until later." (P60)

- Telerehabilitation as a resource to improve access to care:

  "Tele-rehab would save the commute from home or class to a PT center, which is difficult directly post-surgery, and especially so if the patient (such as a student) lives on their own." (P83)

  "In case you are not able to make it to your appointments." (P2)

  "Reduction in commuting costs." (P68)

- Telerehabilitation as a learning tool during and after physical therapy:

  "Don't know what the correct exercises are now to keep strengthening it. I would love to have specific exercises so I would go on your tele rehab app now." (P23)

  "Improvement in return to activity and return to full prior level of activity—and maintenance after." (P21)

  "I felt like I was released from PT before my recovery was 'complete,' but I had passed the tests. This would hopefully help prevent that from happening." (P13)

- Telerehabilitation to motivate and engage patients:

  "I would use tele-rehab daily, because having a program that measures your progress and fulfilment of daily goals is more encouraging than a doctor's note that tells you to do 'x' repetitions of some exercise, which I would be less likely to do regularly." (P83)

Patient concerns with telerehabilitation predominantly focused on the clinical issues of patients and their biopsychosocial needs (Textbox 2). They were concerned about a negative impact on their care if they were performing exercises incorrectly or if they were not managing their pain well. Access to manual therapy, motivation, and opportunities to ask questions were again cited as reasons why they would require one-on-one sessions in addition to telerehabilitation. One patient expressed a strong opinion that telerehabilitation was providing a solution to the problem of not enough health care insurance. One participant described wanting to be able to progress at her own rate. Others commented simply that it should be personalized or specific.

Textbox 2. What are your potential concerns about the use of telerehabilitation in care?

Question asked: What, if any, are your primary concerns regarding the use of telerehabilitation following your anterior cruciate ligament reconstruction surgery?

- Clinical concerns: biopsychosocial needs of patient

  "In the initial recovery phase, I wouldn't be confident enough to judge what's OK and what's not." (P19)

  "It would slow rehab process due to lack of personal contact." (P11)

  "No instructor there to tell you if you are doing the movements incorrectly. I know there is a camera but does it pick up on minor nuances?" (P20)

  "Not pushing myself especially if there is pain." (P84)

  "I need someone to push me." (P88)

- Sociopolitical concerns

  "The state of healthcare in this country is deplorable. If the reason for a tele-rehab program is that insurance won't cover enough in person visits, the insurance system needs to be fixed, not the treatment system." (P24)

The final question was, “What would you need from a telerehabilitation program to make it right for you to use?” The predominant theme was that telerehabilitation needed to be used as an adjunct to physical therapy rather than instead of it. Further themes focused on the *preferred timing* of a telerehabilitation tool and a necessity to be personalized so that a patient’s individual plan is reflected in their care needs (Textbox 3).

Patients discussed the necessity of progress testing and supervision of physical therapy as important to their recovery and outcomes. They re-emphasized the value they place on face-to-face care and had differing views on whether they would prefer to use telerehabilitation in different stages of care. Many patients expressed that they would prefer to have access to face-to-face rehabilitation in the early stages of care. Some patients emphasized the appeal of having return-to-sports content on a telerehabilitation tool and discussed telerehabilitation as being adaptive to their individual needs.

Textbox 3. What would you need from a telerehabilitation program to make it right for you to use? (PT: physical therapy).

Question asked: What would you need from a telerehabilitation program to make it right for you to use?

- Utilized alongside physical therapy

  “I would need to intersperse the program with visits to an actual PT centre, where therapists would check in on my progress and either tell me to go harder or back off on the intensity of the exercises.” (P83)

  “I wouldn’t have it replace all face to face appointments, but I would think it might be a good idea to use on every other appointment.” (P68)

- Preferred timing of telerehabilitation use

  “Mid-late phase is ok.” (P11)

  “If it can help me with the ‘return-to-sport’ type exercises (at various levels), I would be interested.” (P19)

  “I would like to use it after the first month or two of in person rehab.” (P20)

  “I would prefer to have (a) professional at least in early stages of recovery process rather than tele-rehabilitation.” (P63)

- Personalized

  “I would want to have the option to make exercises more difficult: younger bodies recover faster than older ones, and I was often frustrated during my therapy by how basic some exercises were, especially early during the recovery.” (P83)

  “Specific.” (P9)

Discussion

Principal Findings

These results provide a detailed impression of participants’ knee health, their recollections of access to physical therapy, and their opinions on the role of telerehabilitation in ACL rehabilitation. Missing data were minimal, and the results demonstrated that for many patients, a rehabilitation gap exists between the time they are discharged from care and the time they recovered. It is unlikely that an average patient would have passed the return-to-sport criteria when care was completed at 6 months, given that 9 and 12 months have been given as typical [5,12,31]; return to sports before 9 months increases the risk of re-injury by 51% [13], and returning to sports without meeting the specific physical criteria also increases the risk of re-injury [16]. It is, therefore, highly likely that patients, including those in this cohort, are discharged from care before they can undertake advanced rehabilitation or be subjected to the return-to-sport criteria testing, and this may expose them to an increased risk of re-injury.

Recovery after ACLR was also measured by a return to the previous level of activity. Feucht et al [32] reported that 91% of athletic patients expect to return to the same level of sport. In this study, 99% of patients identified as being either competitively or recreationally athletic, indicating that the goal of return to sports was likely commonplace. Typically, 55% of patients returned to compete in sports at the same level as before their injury [31]. In line with these findings, 59% of our study respondents reported return at the same level. Although the overall reported knee health was 83% of the pre-injury level, this figure is difficult to interpret because of its subjectivity and demonstrates the importance of objective outcome measures such as the Knee Injury and Osteoarthritis Outcome Score (KOOS), which can indicate in which area of function or daily life the knee deficit persists [33]. The data in this study contributed to the knowledge that patients undergoing ACLR see themselves as competitive or recreationally athletic, and a lack of guidance during the advanced rehabilitation and return-to-sports phase could contribute to overall suboptimal outcomes for return to previous levels of activity [14].

When considering participants’ access to physical therapy, there are some contradictory responses for which we can suggest possible explanations. The finding that 77% of patients felt that they had sufficient physical therapy appears to contradict the finding that only 11% of patients felt that they had fully recovered at the end of physical therapy. The possible explanations for this are that patients were satisfied with the level that they had achieved despite not reaching full recovery or that they continued to progress through rehabilitation independently or with support from outside physical therapy such as athletic trainers, coaches, or personal trainers.

It is also important to note that some patients may choose not to return to sports, and older patients (30% of respondents were older than 40 years) were more likely than younger patients to choose to modify their activities rather than returning at the same level [34]. The fear of re-injury is frequently cited as a cause of people not returning to sports [35]. Some participants with less physically challenging goals may have completed their rehabilitation at 6 months; however, this does not include people who are returning to high-demand sports such as football, lacrosse, and soccer.

The aim of this study is to investigate the acceptability of telerehabilitation tools in ACL rehabilitation. It is thought that telerehabilitation may have positive benefits for delivering exercise interventions and create opportunities for improved self-management and progress measurement [36]. There is growing availability and popularity of health apps and other telerehabilitation tools [37,38]; however, they have not been widely integrated into rehabilitation practice or tested under research conditions. As such, patient experience and knowledge may be minimal. Indeed, our data suggested that 92% had never used telerehabilitation. Patients in this study primarily expressed concern over how telerehabilitation is integrated into current care, with an emphasis on not wanting telerehabilitation to replace face-to-face care but to be offered alongside it. Concern about the security of their data was less of an issue for this cohort (20%).

The COM-B model of behavior change suggests that having the capability, motivation, and opportunity to perform a given task is associated with behavior outcomes [29]. In rehabilitation, the target behavior is often the exercise. This analysis considered participants' survey responses in relation to their understanding of exercise and rehabilitation behavior. Participants were not concerned about being able to use telerehabilitation; 89% of the patients felt that they were capable, indicating that they would have the knowledge and skill to engage with this process. There was no indication of a digital divide among respondents, with no significant interaction being found between capability and participant demographic group (Table 3); however, digital literacy may have excluded some people from a web survey at the first instance. One-fourth (25%) of patients who expressed concern were predominantly focused on having the physical capability or skill to perform exercises correctly without the supervision of a physical therapist. Any implemented telerehabilitation tool would need to address this concern through careful development.

Opportunities to change behavior can be both physical and social. Physical opportunities for rehabilitation include the availability of resources and the environment to facilitate behavior. A social opportunity might pertain to cultural norms and standards that are familiar. About 25% of patients identified potential physical opportunity challenges to using telerehabilitation, such as access to computers, physical space, and Wi-Fi. They further referenced social norms and beliefs about the values of traditional physical therapy. They expressed anxiety about how telerehabilitation might be integrated into care and potential loss of face-to-face therapy. About 60% of patients expressed that they would prefer to use fewer appointments in the early stage of their care and *save* them for later, whereas the remaining identified that they would prefer to use telerehabilitation in the return-to-sports phase.

Patients also endorsed opportunities to adapt to norms. They highlighted the potential benefits of telerehabilitation alongside physical therapy to improve care and create physical opportunities such as saving time and money by avoiding commutes. A number of patients also identified the potential of telerehabilitation as a maintenance tool after discharge from physical therapy, whereas some reported that they felt their care ended prematurely.

Motivation to exercise is a significant factor in rehabilitation behavior, and, similar to other psychological factors, it is positively correlated with successful outcomes in ACL rehabilitation [39,40]. Digital health tools are thought to influence motivation and adherence to exercise programs [18,41,42]. Motivation can be reflective, including goals and plans, and automatic, where it interacts with wants, needs, and impulses [29]. One participant stated that being able to set and fulfill their own goals through telerehabilitation would be "more encouraging." They discussed the benefit of measures of progress, which is a common function of telerehabilitation tools, where they can collect outcomes such as KOOS and pain scores to measure and record progress over time and motivate the patient to continue to set and pursue goals in a validated way [18,20].

Limitations

Limitations of this survey include the potential for recollection bias with regard to how much physical therapy patients had, and participants who had undergone surgery more recently may have been less able to offer a long-term view. The study had a relatively small sample size, and, as an exploratory study, psychometric properties were not calculated, which may inform the reliability of results.

All surveys are limited to the data gathered, and it is known that participation can be affected by socioeconomic condition and education or digital literacy levels, where some populations are known to be less likely to access internet surveys [43]. This may include a population for whom telerehabilitation is not appropriate, and therefore, face-to-face rehabilitation would need to be provided. Future work should include a measure of insurance type in the data set where possible so that socioeconomic biases can be identified. For example, this study had few Medicaid patient responses, but it is not known whether this is related to fewer invites issued to Medicaid patients or if it could be considered to be related to socioeconomic disadvantage where Medicaid patients are known to be at a greater risk [44-46].

Conclusions

Physical therapy care most commonly ends before patients reach the return-to-sport phase of care. This indicates that there is a rehabilitation gap where patients may not have access to the best guidance for return-to-sports rehabilitation. This may have implications for their injury risk and successful return to sports. Telerehabilitation may provide an alternative way for patients to access evidence-based ACL rehabilitation in this phase. The results suggest that telerehabilitation is acceptable to patients as part of their rehabilitation following ACLR but would need to be an adjunct to care rather than a replacement.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Introductory email.
[DOCX File , 12 KB - formative_v4i9e19296_app1.docx]

Multimedia Appendix 2
Survey.
[DOCX File , 22 KB - formative_v4i9e19296_app2.docx]

Multimedia Appendix 3
CHERRIES (Checklist for Reporting Results of Internet E-Surveys).
[PDF File (Adobe PDF File), 835 KB - formative_v4i9e19296_app3.pdf]

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Abbreviations

ACL: anterior cruciate ligament
ACLR: anterior cruciate ligament reconstruction
ANOVA: analysis of variance
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
COM-B: Capability, Opportunity, and Motivation-Behavior
IRB: institutional review board
KOOS: Knee Injury and Osteoarthritis Outcome Score
NIHR: National Institute for Health Research

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Original Paper

Optimizing Health Information Technologies for Symptom Management in Cancer Patients and Survivors: Usability Evaluation

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Abstract

Background: Unmanaged cancer symptoms and treatment-related side effects can compromise long-term clinical outcomes and health-related quality of life. Health information technologies such as web-based platforms offer the possibility to supplement existing care and optimize symptom management.

Objective: This paper describes the development and usability of a web-based symptom management platform for cancer patients and survivors that will be implemented within a large health system.

Methods: A web-based symptom management platform was designed and evaluated via one-on-one usability testing sessions. The System Usability Scale (SUS), After Scenario Questionnaire (ASQ), and qualitative analysis of semistructured interviews were used to assess program usability.

Results: Ten cancer survivors and five cancer center staff members participated in usability testing sessions. The mean score on the SUS was 86.6 (SD 14.0), indicating above average usability. The mean score on the ASQ was 2.5 (SD 2.1), indicating relatively high satisfaction with the usability of the program. Qualitative analyses identified valued features of the program and recommendations for further improvements.

Conclusions: Cancer survivors and oncology care providers reported high levels of acceptability and usability in the initial development of a web-based symptom management platform for cancer survivors. Future work will test the effectiveness of this web-based platform.

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KEYWORDS

cancer survivorship; eHealth; patient-reported outcomes; digital health; symptom management; supportive care

Introduction

Improvements in early cancer detection and treatment effectiveness have led to an increasing number of individuals living with and surviving cancer in the United States. By 2029, it is estimated that the number of individuals affected by cancer in the United States will exceed 21 million [1]. Despite the advances in early detection and treatment success, the survival benefit can be offset by chronic and debilitating cancer-related side effects and symptoms. Unmanaged side effects and symptoms can compromise long-term treatment success, and can lead to worsening health-related quality of life and clinical outcomes among patients diagnosed with cancer [2,3].

Assessing patient-reported outcomes (PROs), or the patient-reported experience of symptoms and concerns, is key for comprehensive cancer care. PRO assessment to guide care can improve patient satisfaction and has been associated with enhanced clinical outcomes [2]. Integrating the systematic monitoring of PROs into care provided in clinical settings can improve symptom monitoring and enhance opportunities for patient engagement in symptom self-management. When symptoms detected by measuring PROs are managed quickly by the care team, adverse events and toxicities may be more effectively prevented, reversed, or managed [2,4].

Although the use of PROs to inform clinical care is not novel, newer technologies can facilitate the collection of PRO data, which can then be used more efficiently to improve patient care [5]. Recently, Basch and colleagues [6] implemented a web-based program that allowed patients to routinely and remotely report ePRO symptoms to their clinicians. Patients in the trial showed improved symptoms and longer survival within a randomized single cancer center trial, demonstrating the potential for web-based ePROs to have a favorable impact on survival. ePROs have also been embedded into clinical care through electronic health records (EHRs). For example, within the Northwestern Medicine health care system, patients in ambulatory oncology complete ePROs of physical symptoms and psychosocial concerns through a patient-facing web portal (Epic MyChart) that is linked to the EHR. PROs are incorporated into the EHR, and EHR-based alerts automatically trigger to inform clinicians of their patients' clinically elevated ePRO symptoms [7-9]. Patients who triggered alerts based on their elevated ePRO scores had more health care service encounters in the ensuing month, demonstrating that ePROs may be an effective method of connecting patients with necessary care [7].

Collectively, the literature supports the feasibility and preliminary efficacy of systematic ePRO symptom monitoring and the integration of ePROs into EHRs. As part of the National Cancer Institute (NCI) Cancer Moonshot [10], our team is implementing and evaluating a fully EHR-integrated oncology ePRO symptom assessment and management program across Northwestern Medicine's 7-hospital health care delivery system. The research team worked with patients diagnosed with cancer, and identified an opportunity to improve these patients' access to relevant, concise, focused symptom management resources by creating an innovative electronic resource of patient treatment–related education and supportive care resources. Although there are numerous cancer online resources available, cancer patients have expressed a preference for obtaining health information from reputable websites such as those associated with universities and health systems [11]. Our web-based platform, called "My NM Care Corner," moves beyond providing only symptom management information and further provides patients with tailored feedback on their recently completed PRO assessments that is linked to evidence-based symptom management information, including resources to enhance health-related quality of life. The My NM Care Corner platform will be available in both English and Spanish, and is integrated with the Epic EHR system; thus, there is high potential for dissemination across health systems using Epic.

The purpose of this research was to evaluate the usability of this new health information technology tool in preparation for its implementation. In this paper, we briefly describe the development of My NM Care Corner and present findings from the usability trial of the My NM Care Corner website.

Methods

Prototype Development

The prototype of My NM Care Corner was designed and developed by a multidisciplinary team with expertise in design, clinical science, and information technology. Because the ultimate goal of this research is for the web-based platform to become a part of standard care, we followed the style guide requirements mandated by the Northwestern Medicine health care system. The style guide requirement included guidelines on font size, colors, and website layout. The requirements for the clinical content provided by My NM Care Corner were primarily drawn from the NCI-funded "Improving the Management of symPtoms during And following Cancer Treatment" (IMPACT) consortium, which focused on providing patient-centered information on common cancer-related symptoms (eg, pain, fatigue, nausea, physical functioning, insomnia, anxiety, depression, constipation), evidence-based approaches to symptom management, and resources available to cancer patients and survivors at Northwestern Medicine.

The primary features of My NM Care Corner are described in Table 1. The dashboard, symptom library, and patient resources (Enhancing Well-Being, Diet & Nutrition, Support Services & Resources, Financial & Practical Matters, Treatment & Symptom Management) were included to provide health-related quality of life–enhancing materials and to provide educational materials that focus either on symptom management or health-related quality of life, which are our primary study outcomes for the larger trial. The welcome video was included based on user feedback gathered early in the course of this usability testing. The majority of the content in My NM Care Corner was derived from previous technology-assisted pilot studies that focused on improving patient symptom management and health-related quality of life among diverse patients with cancer diagnoses [12-16]. In My NM Care Corner, symptoms flagged as elevated based on ePRO responses are visible to users when they access their dashboard. Because patients may be interested in reading about symptoms that were not elevated on their most recent ePRO responses, information about all symptoms was placed under the “Symptoms” tab, and information about how to deal with symptoms and enhance well-being were placed under the “Patient Resources” tab. Users can also mark information as “favorite,” which will be saved under the “My Favorites” tab. The health care system–specified style guide and the requirements from the grant provided a framework for the prototype, and the user interface was examined for usability and perceived usefulness within this framework.

Table 1. Features of My NM Care Corner.

Section	Description[a]
Welcome Video	Brief user engagement video that orients patients to My NM Care Corner
Dashboard	Displays information about symptoms that are flagged based on ePRO[b] completion
Symptom Library	Includes information about the following symptoms: pain, fatigue, depression, anxiety, insomnia, physical function, nausea and vomiting, shortness of breath, constipation, diarrhea
Patient Resources	
Enhancing Well-Being	Includes information about talking with your health care team, social support, stress management, physical activity, problem solving, smoking cessation and substance abuse, sun protection, supportive oncology, managing hair loss, and body image concerns
Diet & Nutrition	Includes information about the importance of healthy eating, healthy foods, maintaining a balanced diet, managing weight loss, managing weight gain, dealing with loss of appetite, nutrition tips
Support Services & Resources	Includes information about supportive oncology at Northwestern Medicine, local support groups and communities, one-to-one support from cancer survivors, support online and by phone
Financial & Practical Matters	Includes information about managing the cost of treatment, managing legal and workplace issues, managing transportation during treatment
Treatment & Symptom Management	Includes information about palliative care, integrative care, cancer rehabilitation services, cancer survivorship services
My Favorites	Allows the user to save pages from the Patient Resources section to view later
Contact Us	Provides information on contacting the study staff by email or telephone

[a] All content is available in English and Spanish and is audio-accessible.

[b] ePRO: electronic patient-reported outcomes.

Recruitment

We recruited a convenience sample of participants in the fall of 2019. Inclusion criteria for cancer survivors required that individuals have a past or present cancer diagnosis, a history of receiving care at Northwestern Medicine’s cancer center, and the ability to speak and read English. Inclusion criteria for staff and clinicians were current employment at Northwestern Medicine, with at least a portion of their work being focused in the cancer center.

Although staff are not among the intended end users of My NM Care Corner, recruitment to behavioral clinical trials is often enhanced by clinician investment in interventions [17]. We also included staff in this early qualitative work to ensure that My NM Care Corner content would enhance and not contradict the care they provide patients. Staff and clinician participants were recruited via direct email invitations. We recruited 10 patient participants and 5 staff participants based on research demonstrating that 15 participants typically find 90%-97% of existing usability problems [18].

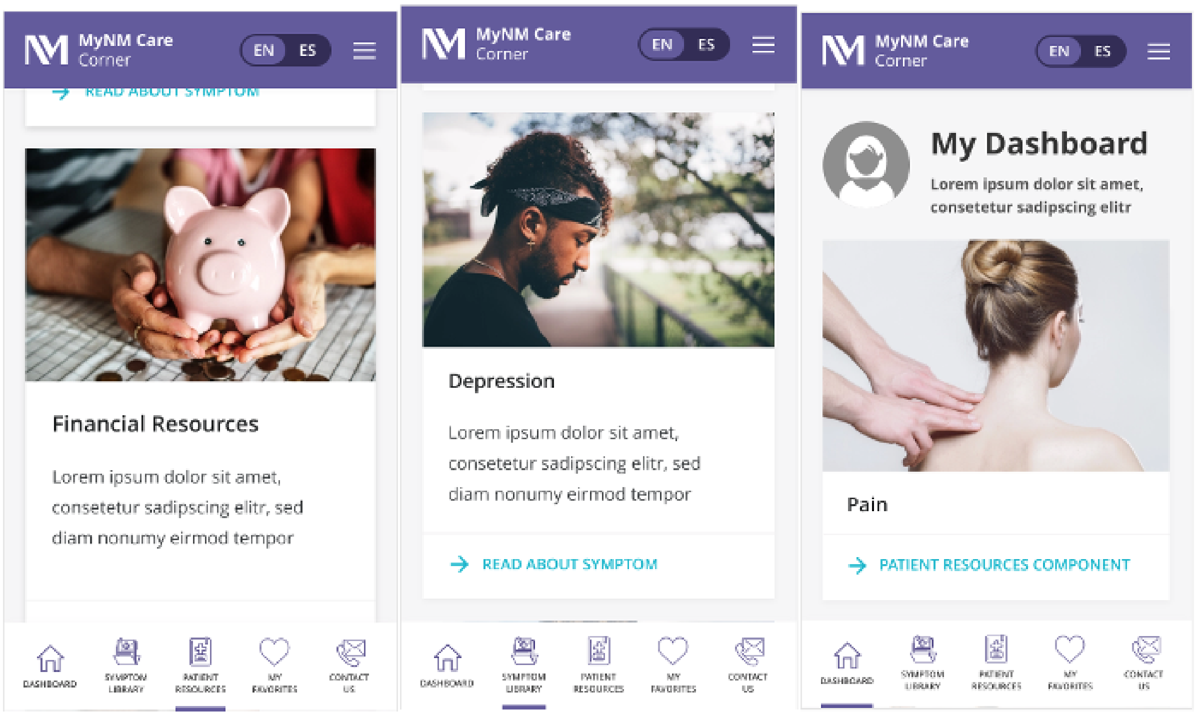
Ethics Approval

The research procedures were initially reviewed by the university Institutional Review Board, and it was determined that the study was exempt from full review. The research procedures did not meet the definition of human subjects research because the study focused on participant reactions to the website rather than on the participants themselves. To ensure ethical conduct, participants were provided with an overview of the study and provided verbal consent prior to participation.

Procedures

Patient participants were asked if they typically look up health information on a smartphone or on a computer. They were then introduced to a prototype of My NM Care Corner that matched their preferred device (smartphone or computer), and were instructed to think aloud while completing specific tasks (see Figure 1 for representative screenshots of the smartphone prototype, and Multimedia Appendix 1 for screenshots of the computer prototype). Specific tasks included: (1) finding information about fatigue, (2) finding information on diet and nutrition, and (3) sending a message to the study staff. After completing these tasks, participants were shown the alternate version of the web-based platform (smartphone or computer) and were prompted to find the same information. Staff participants were first shown the computer-based prototype and were instructed to complete the same tasks as the patient participants. Staff participants were shown the smartphone prototype of the website, but because the intent of staff testing was more about content acceptability and organization rather than usability, they were not asked to find information on the smartphone prototype.

Figure 1. Screenshots of the mobile-friendly My NM Care Corner prototype.



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Following prototype testing, all participants participated in a brief (approximately 15 minutes) interview that addressed participant impressions of My NM Care Corner, including ease of use and perceived usefulness, and prompted participants to generate ideas about ways to improve the design of the web-based platform. Following the brief interview of the user's impression of My NM Care Corner, participants completed usability questionnaires.

Measures

The System Usability Scale (SUS) [19] and the After Scenario Questionnaire (ASQ) [20] were administered to provide quantitative measurements of usability.

The SUS is a 10-item questionnaire that prompts participants to rate their level of agreement with statements related to system usability. Example items include "I thought the system was easy to use" and "I found the system unnecessarily complex." Participants respond to items on a 5-point scale ranging from "strongly agree" to "strongly disagree," and after scoring procedures, the total scores on the scale range from 0 to 100. Past research has demonstrated that a SUS score above 68 is indicative of above average usability [21].

The ASQ is a 3-item questionnaire that prompts participants to rate their satisfaction with the usability of a program. Example items include "Overall, I am satisfied with the amount of time it took to complete the tasks in this scenario" and "Overall, I am satisfied with the ease of completing the tasks in this scenario." Participants respond to items on a 7-point scale ranging from 1, which indicates "strongly disagree," to 7, which indicates "strongly agree." After scoring, the total scores range from 1 to 7, with higher scores indicating higher levels of satisfaction with usability.

Analytic Plan

This study included both qualitative and quantitative data that we analyzed using a mixed methods approach. We adopted this approach to usability testing because, while quantitative data can identify usability issues and dissatisfaction with program design, qualitative data provide information about the root of the usability issues and potential methods for program optimization. The usability testing session interviews served as the primary source of qualitative data. Interviews were transcribed, and the transcripts were analyzed using a conceptual content analytic approach. Coding of these transcripts was completed using NVivo [22]. Quantitative data collected included a demographic questionnaire, rates of task errors, rates of repeat task errors, and scores on SUS and ASQ. These data were analyzed using descriptive statistics.

Results

Participants

Ten patients and five clinical staff participated in the study. In regard to sex, 5 patients identified as cisgender males and 5 identified as cisgender females. The mean age was 55.3 years (SD 12.7) ranging from 39 to 74 years. The majority of patients identified as non-Hispanic White (n=8), with one patient identifying as Hispanic White and one identifying as Hispanic but declining to identify their race. Four of the patient participants were breast cancer survivors, two were renal cell carcinoma survivors, and the other four patient participants reported diagnoses of melanoma, ovarian cancer, tonsil cancer, and base of the tongue cancer, respectively. Three of the 10 patient participants were in active treatment (which included adjuvant chemotherapy), and the mean time since diagnosis was 36.8 months, ranging from 8 to 83 months.

Staff participants included two clinical psychologists, one social worker, one patient educator, and one medical oncologist. One of the five staff participants was a cancer survivor and one of the five staff participants identified as cisgender male (the remaining four identified as cisgender female). Four of the five staff participants identified as non-Hispanic White and the remaining staff participant identified as Asian. The mean staff participant age was 44.4 years (SD 11.7), ranging from 30 to 61 years.

Usability Testing Performance

Nearly all participants (9 out of 10 patient participants and 4 out of 5 staff participants) were able to complete all tasks on My NM Care Corner as assessed on the usability protocol. In the first task of the protocol, participants were prompted to find information about fatigue and all participants were able to find this symptom information without difficulty. However, 7 of the 10 patient participants and all 5 of the staff participants experienced some difficulty completing the second task of the protocol, in which they were asked to find information on diet and nutrition; most of these participants first looked under the Symptom section of the website before exploring the Patient Resources section. Despite the high level of initial confusion, only 2 of these participants (1 patient participant and 1 staff participant) did not persist through searching for the information and requested guidance from the interviewer to resolve. The participants who experienced these errors reported that they would have likely been able to find the requested information if they had been provided with an orientation or introduction to My NM Care Corner. All participants were quickly able to complete the third task, in which they were asked to find where they could send a message to the study team.

Completion times for the usability tasks were highly variable. The variability in completion time appeared to be primarily related to individual styles in reviewing the presented information (eg, some participants skimmed through text, while others read all of the content presented) and did not appear to be a reliable metric for program usability. Although the participants had been instructed to complete the tasks and comment primarily on the navigation and general design of My NM Care Corner, some participants read all of the content closely and provided detailed feedback on the content.

There were very low rates of repeat errors. Although the majority of participants had some level of difficulty finding information about diet and nutrition on their first pass through My NM Care Corner, none of the participants had difficulty finding this information in their second pass through the web-based platform, indicating a high level of learnability.

Usability Feedback

Quantitative usability feedback was generally positive, with a mean score on the SUS of 86.6 (SD 14.0, range 52.5-100), indicating above average usability. The mean score on the ASQ was 2.5 (SD 2.1, range 1-5.6), indicating a relatively high level of satisfaction with the usability of the My NM Care Corner prototype.

Qualitative analyses revealed several strengths noted in the initial design of My NM Care Corner, and there was an overwhelming positive response to the functions of the web-based platform. Primarily, participants appreciated the desktop and mobile-friendly format, information on self-management strategies, and noted that the Northwestern branding enhanced trust in the information. Participants voiced appreciation for having quick access to personally relevant symptom information that is available 24 hours a day.

Most participants liked the concept of the dashboard, which served as the landing page. All of the patient participants were familiar with completing PRO measures through the EHR, and many wondered where that information was transmitted. Several participants reported that being able to access personally relevant symptom information would be beneficial to them. One patient (Pt 104) noted, “I like the idea of the dashboard a lot. I mean it’s nice to know that when I provide information it’s not just going onto some file somewhere and no one’s really reading it.”

Anticipated uses of My NM Care Corner by patients included being able to mark as favorite and review information about issues of interest. Respondents also highlighted the benefit of knowing a trusted source of information. They voiced interest in being able to get information about both symptoms and self-management strategies to try between appointments. As Pt 108 commented:

> *I think “Strategies to try at home” should be really big because I’m looking on a computer about fatigue because I’m not in front of my doctor and I can’t say, “Hey, what can I do about fatigue?” And strategies at home are what I think exactly what I think I’d be looking for.*

Patient participants also envisioned themselves using My NM Care Corner to ease anxiety by reviewing information about common symptoms, especially during “off hours” of the clinic. They anticipated that some patients would use the site to orient themselves when coping with a new diagnosis.

Staff participants were also generally enthusiastic about the features of the web-based platform and viewed it as a valuable supplement to care. Staff participants envisioned using My NM

Care Corner as a referral resource for patients and to reinforce concepts discussed during appointments. Additionally, there was recognition that physicians do not always discuss self-management strategies at length with patients before prescribing medications to help manage side effects of treatment, and that this program could help to reinforce self-management. One staff participant (Pt 204) noted:

> *I think if we had something that was NM [Northwestern Medicine] branded, looks like everything else that gets sent to them. It would be much easier to say "Stay off the internet, get off breast cancer chat groups. Go here for a start."*

Similarly, another staff participant (Pt 205) commented:

> *I think it rounds out the care. I think it allows patients to look at a list of potential options that could be utilized for constipation and decide what they think resonates with them. Instead of like, "My doctor told me that I should do this, so can I do this also? Or is that not something I should do?" I think it allows a little bit more of a portfolio.*

Participants voiced appreciation for the web-based platform being available in both a desktop and mobile-friendly format. Pt 104 noted, "But it's nice to know that it doesn't really vary because sometimes you have a desktop version and it's nothing like the mobile version and you can't get through anything on the mobile version." There were no notable differences in feedback from patient participants who viewed the mobile version of My NM Care Corner first relative to those who viewed the desktop version of My NM Care Corner first. Feedback on both modes of delivery was generally positive. This appeared to be more related to how participants typically accessed health information rather than differences in formatting between the computer and mobile-friendly versions.

There was also positive reception of the general design, and many found that they had the intuitive ability to navigate through My NM Care Corner. As one participant (Pt 107) commented, "Well it's not, it's not hard to navigate at this point, per se. At this point I mean, it's pretty logical." Similarly, another participant (Pt 104) stated, "It was pretty self-explanatory. Everything is listed at the bottom so it's easy to find."

The format was perceived as easy to follow for potential users who may be feeling fatigued or unwell. As a staff participant (Pt 201) noted:

> *I like the way that, the boxes kind of give you a little bit of information of what the next page will include. I think that's really helpful because if you're especially not feeling well, it's easy to get overwhelmed or distracted so I like the simplicity of it, it's not going into a lot of dialogue where you have to kind of search for what it is that you need.*

Avoiding information overload is key when designing health information programs, and most participants found this program usable in that regard.

A majority of participants described the design of My NM Care Corner as "neat" and "clean looking." A few participants indicated that the design of the web-based platform felt unfamiliar to them. Although comments such as the following from Pt 106, "It was very confusing to look to see, you know, if you don't find it here you could find it you know, because usually what I have experienced with websites is that you have one area where … you have everything," were relatively infrequent, this sentiment points to the need for clear guidance or training on how to use My NM Care Corner and for what it can be used. Indeed, the most commonly identified areas for improvement were increasing the font size, adding a search tool, and adding instructions or an orientation on what types of resources and information one can expect to find in this web-based platform.

As noted in the Methods section, health system style guides and health system branding were used on My NM Care Corner. This branding appeared to enhance participants' trust of the information presented. As Pt 108 commented:

> *Nutrition, fatigue, those are things cancer patients are going to be looking for. People are going to be looking for when they get on. It's branded with Northwestern Memorial so I'm like "Oh okay, I know I'm in the right spot."*

However, some participants felt that the standard format of the web-based platform was too clinical and not emotionally engaging. As Pt 101 noted, "I don't know, something that makes me want to not be so, I guess, clinical. Um, make it a little more happy."

Discussion

Principal Findings

Results of this study demonstrate that the My NM Care Corner prototype was usable and engaging for both cancer patients and cancer center staff. Both patients and staff reported a high level of perceived utility of My NM Care Corner, and expressed ways that the platform could be useful to a variety of patients receiving care within the cancer center.

This study presented an opportunity to examine how incorporating hospital-required branding into formative design work informed the development of the prototype. While My NM Care Corner is being developed for a clinical trial, our team explicitly aimed to develop the platform in a manner that could result in it becoming standard of care following completion of the trial. Thus, we designed the platform to meet the needs of patient stakeholders, provider stakeholders, and health system stakeholders. Designing to the requirements of these different stakeholder groups meant that competing needs had to be prioritized and weighed against one another to make design decisions [23]. For example, although some participants found the color schemes less pleasing than desired, the branding of the web-based platform as part of the health system took priority. Consistent with past research on perceptions of health care brand images [24,25], many participants reported trust in the prototype due to its Northwestern Medicine branding.

Because My NM Care Corner is being designed for all adult patients at our cancer center, there were initial discussions about the level of detail to be presented (eg, related to specific cancer types, treatments, or phases of the care continuum). There are challenges inherent in designing programs that feature universally accessible informational resources [26]. It is well established that patients' needs change throughout their journey with a cancer diagnosis [27]. Attempts to provide patients with information to meet all possible needs can quickly leave patients feeling overwhelmed, resulting in informational resources being underutilized [28,29]. The resulting model of presenting core symptoms and side effects (eg, pain, fatigue, nausea, physical functioning, insomnia, anxiety, depression, constipation) was deemed useful by participants, who primarily found the specificity of information to be appropriate.

Feedback gathered during sessions prompted changes to interface design such as adding images to the landing page, changing the font sizes, and designing a more recognizable hierarchy of headings and subheadings based on font. These changes were integrated into the current version of My NM Care Corner. Based on participant feedback, we also will include an introductory video to the website to enhance user engagement. Additional participant feedback such as a request to add a search function to the website will be added to future versions.

The cancer patient participants in the study were particularly interested in receiving tailored information based on their ePRO scores, and some participants commented that they had wondered why they had not previously received this information. This interest highlighted the commonly held desire of patients to receive personalized feedback and instruction on self-management practices through web-based and eHealth platforms [30-32]. My NM Care Corner was generally perceived as filling a gap in the support they received through the provision of tailored information.

Limitations

Participants were recruited based on convenience sampling and all participants spoke English as their primary language. We plan to release My NM Care Corner in both English and Spanish, and although the navigation through the site is unlikely to be significantly impacted by language, there could be cultural preferences that were not identified in this round of testing on an English-language prototype [13,33]. The participants were not homogenous in regard to gender, cancer type, or age; however, the majority of participants identified as non-Hispanic White. In this study, perceived utility of the platform did not appear to vary by cancer type, but because this was a small sample, we cannot definitively conclude this point. We will examine perceived utility and use of the platform by cancer type in future research. Additionally, although the purpose of this phase of usability testing was on navigation through the web-based platform, some participants expressed interest in reading all available written content to rate the usefulness and applicability of the content. Because content was not fully developed at the time of the usability testing sessions, we were unable to subject the entire content to usability testing. Thus, although we determined that the prototype of My NM Care Corner was rated as highly usable in concept and was viewed as generally easy to navigate, this phase of the usability testing did not extend to an examination of the usability of clinical content. However, the majority of content in My NM Care Corner was derived from previous technology-assisted pilot studies that focused on improving patient symptom management and health-related quality of life among diverse patients with cancer diagnoses, and thus have support for acceptability [12-16].

Future Directions

The next step of this initiative is to launch the My NM Care Corner web-based platform to patients being served at our cancer center. We will evaluate the platform using a pragmatic type I effectiveness-implementation hybrid trial [34]. In this trial, we will compare patients who are randomized to receive access to My NM Care Corner to patients who are randomized to standard of care on symptom burden and health-related quality of life. We will also examine differences in health care use (eg, number of emergency department visits, hospitalizations, supportive care visits) and cancer care delivery (eg, unscheduled treatment breaks, provider response time to EHR-generated alerts), adjusting for disease-specific and demographic factors (eg, cancer type, level of education, age, and race). In the upcoming trial, patients randomized to receive standard of care will still complete their ePROs and will have clinical alerts sent to oncology but will not have access to the My NM Care Corner platform.

Conclusion

This study demonstrates the development and positive evaluation of a prototype version of a web-based platform called My NM Care Corner that links web-based, EHR-integrated PROs with tailored, evidence-based symptom management information for patients diagnosed with cancer. The study also confirms interest in and perceived usefulness of this platform from both cancer patients and cancer center staff. Ongoing research is examining the uptake and effectiveness of the My NM Care Corner platform through a randomized trial.

Acknowledgments

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Conflicts of Interest

FJP is a paid consultant for Blue Note Therapeutics—a digital therapeutics company that is digitizing his cognitive behavioral stress management intervention for cancer survivors.

Multimedia Appendix 1
Computer screenshots of My NM Care Corner.
[DOCX File , 549 KB - formative_v4i9e18412_app1.docx]

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Abbreviations

ASQ: After Scenario Questionnaire
EHR: electronic health record
NCI: National Cancer Institute
PRO: patient-reported outcome
SUS: System Usability Score

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Original Paper

Feasibility of Self-Monitoring Rheumatoid Arthritis With a Smartphone App: Results of Two Mixed-Methods Pilot Studies

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Abstract

Background: Several mobile apps that monitor symptoms of rheumatoid arthritis (RA) exist, but a recent systematic review indicated that high-quality apps are lacking. When patients self-monitor their own disease with patient-reported outcomes (PROs) and self-initiate care at the right moment, it may be possible to reduce the frequency of their clinic visits, which would reduce health care burden and costs. We developed an app, that is, the MijnReuma Reade app, for this purpose and performed 2 pilot tests with weekly self-monitoring.

Objective: The primary objective of this study was to design, develop, and evaluate the usability, satisfaction, and usage of the MijnReuma Reade app—an app that allows patients with RA to monitor their own disease. The secondary objective was to review the patients' perspectives on app usage and its intended purpose.

Methods: This app was designed in collaboration with patients with RA, rheumatologists, and information technology experts. Two 1-month pilot studies were performed, after which satisfaction (0-10 scale), usability (system usability scale, 0-100), and usage (proportion of completed questionnaires) of this app were assessed. After the second pilot study, semistructured interviews were performed to determine patients' perspectives and the promoters and barriers of app usage.

Results: In the first and second pilot study, 42 and 27 patients were included, respectively. Overall, the patients were satisfied (medians, 8 and 7) and found the app usable (mean system usability scores, 76 and 71) in pilot studies 1 and 2, respectively. App usage declined over time in both the pilot studies; 61% (17/28) and 37% (10/27) of the patients who disclosed their usage statistics completed the final weekly questionnaire in pilot study 1 and pilot study 2, respectively. Approximately 81% (25/31) of the patients indicated they would like to skip hospital visits if the self-monitored disease activity is low. In the semistructured interviews, technical problems, internal resistance (respondent fatigue, the app reminded them of their disease), and a lack of symptoms were identified as barriers for usage. Patients reported that "experiencing more grip on their disease" and "improved communication with their physician" were promoters for usage. Patients reported that pain positively mediated usage, that is, more pain promoted and less pain discouraged app usage.

Conclusions: This study illustrates the feasibility of the MijnReuma Reade app that enables self-monitoring of the disease activity in patients with RA with the overarching aim to allocate clinical consultations according to need. Satisfaction with the app and usability of the app were found to be high; however, app usage declined over time. Patients acknowledged the potential of the app to self-monitor their own disease and would like to be able to skip clinic visits if the monitored disease activity is low. To evaluate this strategy, a randomized controlled trial is underway.

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KEYWORDS

mHealth; eHealth; patient-reported outcome, smartphone app; rheumatoid arthritis; self-monitoring; telemonitoring; mobile phone

Introduction

eHealth—the health care practice supported by electronic processes and communication—is an upcoming theme in medicine [1]. One of the quickly developing fields within eHealth is mobile health (mHealth) care. mHealth promises to provide medical support for patients through mobile devices such as smartphones or tablets [2]. In rheumatology, we can use mHealth to enable patients to self-monitor their own conditions with patient-reported outcomes (PROs) [3-5], which in turn could support self-initiated care [6]. Most patients visit their rheumatologist every 3-6 months to evaluate disease activity [7]. The value of many of these consultations might be low, as many patients, at least in the affluent societies, have minimal disease activity [8]. Furthermore, due to the capricious nature of rheumatoid arthritis (RA), clinically relevant flares that occur between visits may be missed when patients visit the outpatient clinic according to predetermined schedules [9]. With mHealth, it is possible to monitor disease activity frequently [4,10], and thus, it may improve the clinical management of patients by better allocating clinical consultations according to need [11,12]. Several mobile apps that self-monitor disease activity already exist [13]. However, multiple studies have indicated that there is still a lack of high-quality apps for self-monitoring RA disease activity [13-15]. The quality of the apps can only be confirmed after a thorough and repeated clinical evaluation. This paper reports the development of an app to self-monitor RA disease activity and the results of 2 mixed-methods pilot studies. The research questions in the pilot studies were as follows:

1. Primary research question: Is it feasible to let patients with RA self-monitor their disease with the use of the MijnReuma Reade app, in terms of satisfaction, usability, and app usage?
2. Secondary research question: What are the perspectives of the patients regarding the app and self-monitoring with the purpose of reducing unnecessary consultations?

Methods

Setting and Subjects

The pilot studies were performed at Reade, a center for rheumatology and rehabilitation in Amsterdam. The city of Amsterdam along with its surroundings is an ideal setting for mHealth studies, as network coverage is excellent, download speeds rank 6th worldwide, and 87% of the adult population in Amsterdam own a smartphone [16-18]. In 2015, Reade started improving its information technology infrastructure [19]. The first goal was to digitize PROs. This facilitates electronic questionnaire assessment and integration of clinical data such as laboratory results, radiology reports, and severity scores with the PROs. Reade has now set the aim to extend the electronic PRO infrastructure to outside the walls of the hospital. In order to do this, we built an app that allows patients to access and complete PROs. Patients were informed about the app and invited to participate in the pilot studies during regular outpatient clinic consultations by their treating rheumatologists. When patients indicated an interest to participate in these pilot studies to their rheumatologist, they were called by a researcher (SR). Interested patients were included if they met the following criteria: diagnosed with RA, 18 years or older, able to read Dutch, and own a smartphone or tablet with an Android or iPhone operating system. No exclusion criteria were set. All patients signed informed consent.

Study Design

Patients were asked to download the app from the app store and complete a questionnaire in the app every week for 4 weeks. In pilot study 1, the weekly questionnaire comprised the full multidimensional Health Assessment Questionnaire (HAQ, including an RA disease activity index and symptom list). In pilot study 2, we downsized the weekly questionnaire to Routine Assessment of Patient Index Data 3 (RAPID3) with additional questions regarding fatigue, sleep, morning stiffness, anxiety, stress, and social participation as found in the HAQ-II. After 4 weeks, a questionnaire was sent to the patients through email to evaluate the usability, satisfaction, and qualitative outcomes. Patients who stopped the study or never installed the app were not sent the final questionnaire. Technical problems reported by patients were recorded in an Excel logbook. The local Reade/Slotervaart hospital medical ethical committee issued a waiver for this study.

Outcome Measures and Data Collection

The primary outcomes of the pilot studies were satisfaction, usability, and app usage. Overall satisfaction was measured on a 10-point Likert scale (eg, How would you rate the app?). Alternatively, patient satisfaction was measured with the Net Promoter Score (NPS); this tool allows patients to rate the extent to which they would recommend the use of the app to a friend or colleague [20]. This tool, often used in customer loyalty research, predicts how likely a customer would recommend a product on an 11-point Likert scale. Patients who scored the app 9 or 10 were considered as promoters of the app, 7 or 8 were considered as neutrals or passive enthusiasts, and 0-6 were considered as detractors. Grouping patients into these 3 categories, that is, promoters, passive enthusiasts, and detractors, provides a simple intuitive scheme that accurately predicts the users' behavior (ie, in business: the repurchase rate). The NPS is calculated by subtracting the proportion of critics from the proportion of promoters. Usability was evaluated with the system usability scale. The system usability scale has proved to be a valuable evaluation tool since it is highly robust and reliable [21,22]. The average system usability scale score is 68; a mean score of 52 indicates OK usability and 72 indicates good usability [23]. The final questionnaire included 2 additional questions regarding usability rated on a 10-point Likert scale ranging from “definitely agree, 10” to “definitely disagree, 1” (eg, “I use every function in the app” and “I think the explanation on how the app works is clear”). As proxy for app usage, we used the weekly response rate for RAPID3. All outcomes were presented in descriptive statistics.

Patients' Perspectives in Pilot Study 1

To assess the patients' perspectives, the final survey included statements regarding the app, its purpose and possible features, and a free text field. The statements were adapted from Vorrink et al [24] for use in rheumatology and are presented in Multimedia Appendix 1. Patients were presented 17 "overall feedback" statements and 9 "privacy statements," which they could score on a 10-point Likert scale (ranging from 1=definitely do not agree to 10=definitely agree). In the next section of the questionnaire, patients could (optionally) provide their opinion on what aspects of the app were unnecessary, unclear, or could be improved and what sections were useful and clear in a free text field.

Semistructured Interviews in Pilot Study 2

Patients in the second pilot study were asked to take part in a semistructured interview to explore their perspectives on the app, its intended purpose, and app usage. Patients were purposefully selected to form a varied group that included patients who frequently used the app, patients who discontinued use during the study, and patients who did not use the app more than once. The recruitment of patients continued until data saturation. One team member (BS) conducted telephone interviews (15 minutes) in November and December 2018. BS was not previously known to the patients and was not involved in the feasibility studies. Patients gave verbal consent for audio recording. Patients' experiences of using the app were explored following a 7-question interview guide (Multimedia Appendix 2). The questions were in part derived from themes in the mobile app rating scale and in part through discussion between authors BS and WB [25]. Questions were intended to guide the conversation, rather than to be prescriptive. The interviewer responded to patients' comments and encouraged them to talk freely to maximize informative comments. All interviews were audiotaped and transcribed (BS). Patients' perspectives on the app, app usage, and its intended purpose were thematically coded. The coding and thematic analysis were performed by BS; subsequently, 2 investigators (BS/WB) discussed the data. Illustrative comments were selected to illustrate the patients' perspectives and the identified barriers and promoters of usage.

App Development

The development and evaluation of the app were carried out in 3 distinct phases according to the Medical Research Council guidance for developing and evaluating complex interventions [26]. The 3 phases were as follows: (1) setting design requirements, building the prototype, and the first evaluation, (2) improvement of the prototype and re-evaluation, (3) further improvement of the app and a randomized controlled trial. Phase 3 has been described previously [6].

Design of the Prototype

The prototype was developed in 2016. As recommended [14], this was done by a collaboration of patients (enthusiastic volunteers), nurses, rheumatologists, and information technology experts (Brightfish Ltd). The following design requirements were set.

1. Integration of a validated PRO.
2. Short weekly 5-minute questionnaires.
3. High usability and user satisfaction.
4. Multiplatform (native iPhone, native Android, and web-based operating systems).
5. Provision of helpful information for patients about RA.
6. Integration with the electronic medical record.

A prototype MijnReuma Reade app was built by an information technology company (Figure 1). This prototype met design requirements 1-5. As a validated PRO, the multidimensional RAPID3-HAQ-II was chosen by the study team [27]. In the app, all the domains of disease activity are displayed in illustrative graphs over time [28,29]. BrightFish developed the interface to be easy to use and intuitive. Before the initiation of the pilot study, we performed a small pretest. The goal was to explore areas of confusion and areas to improve user experience. Fifteen volunteers completed the questionnaire in the app, while being observed by a rheumatologist (WB) and an information technology expert. No areas of confusion or problems that required immediate repair were noted; therefore, we concluded that the app could be used in the first pilot study. After the first pilot study, a new phase of development took place. First, we shortened the questionnaire after pilot study 1 to meet the 5-minute requirement. Second, the app was integrated with the electronic medical record. Patients were now able to see their laboratory results and appointments. Furthermore, the filled out questionnaires were now visible in the patients' medical files at Reade. This version of the app was used in the second pilot study.

Figure 1. The MijnReuma Reade App prototype. A. The activity module where due questionnaires are found. B. The dashboard module that displays several disease outcomes over time. C. The dossier module that displays the numerical answers given to the different questionnaires. D. The information module that provides information on the app and rheumatoid arthritis. English translation ("Dutch translation"); walking test ("Looptest''); disease activity ("ziekte-activiteit''); pain score ("pijn score'').

Looptest
22 dagen geleden
Duration: 4 minuten
Complete by: 18-03-2018

Ziekteactiviteit
22 dagen geleden
Duration: 4 minuten
Complete by: 18-03-2018

Pijnscore
22 dagen geleden
Duration: 3 minuten
Complete by: 18-03-2018

Pijnscore
zaterdag 18-11-2017 om 07:10
Uitkomst: 28 / 48 (lager is beter)

Ziekteactiviteit
zaterdag 18-11-2017 om 07:08
Uitkomst: 6.3 / 10
(ziekteactiviteit, lager is beter)
Functioneren: 5 / 10
Pijn: 7 / 10
Ziekte- en
gezondheidsproblemen: 7 / 10
Ochtendstijfheid: 60 minuten
Abnormale moeheid: 8 / 10

Voor wie is de ReumaMeter?
Hoe werkt de ReumaMeter?
Hoe kan ik mijn informatie delen?
Hoe kan ik mijn mening over de app geven?
Waar kan ik meer informatie over reuma vinden?
Hoe zit het met mijn privacy?
Reade
Disclaimer

Results

Patient Characteristics

For pilot study 1 and 2, 42 and 27 patients signed informed consent, respectively; 24 of the 27 patients in the second pilot study had also participated in the first pilot study. Patient characteristics are summarized in Table 1. During the first pilot study (n=42), 5 patients dropped out (12%), leaving 37 patients. The reasons for dropout were as follows: never downloaded or used the app (n=2) and technical problems with (n=1) or without (n=2) direct relationship to the app (n=2). Of the 37 patients who completed the first pilot study, 31 patients filled the questionnaire to evaluate the app, while 6 patients did not respond after several reminders. Three patients did not provide their app ID in the questionnaire; the app ID was necessary to request the usage statistics from the software company. Thus, we analyzed the app usage of 28 patients. In the second pilot study, 2 patients never installed the app, 1 decided not to participate after consenting, and 5 did not complete the final questionnaire, leaving 19 patients for analysis.

Table 1. Patient characteristics.

Patient characteristics	Pilot study 1, n=42	Pilot study 2, n=27
Age (years), mean (SD)	54 (13)	52 (11)
Females, n (%)	36 (86)	21 (78)
Baseline disease activity score in 28 joints, mean (SD)	2.88 (1.28)	2.6 (1.48)
Disease duration (years), median (25th percentile, 75th percentile)	9 (4,13)	7 (3,8)
Biological use (yes), n (%)	27 (64)	16 (59)

Primary Outcomes

The primary outcomes are summarized in Table 2. Overall, the app was rated with satisfaction scores of 8.0 (IQR 7.0-9.0) and 7.0 (IQR 6.0-8.0) in the first and second pilot study, respectively. In the first pilot study, the NPS of the app was –9 (9/31 [29%] promoters, 10/31 [32%] passives, and 39% [12/31] detractors); in the second pilot study, the NPS was neutral (37% [7/19] promoters, 26% [5/19] passives, and 37% [7/19] detractors). The completion rates of the weekly in-app questionnaires declined over time in both pilot studies. In the first and second pilot study, the completion rates declined from 100% (28/28) and 78% (21/27) in week 1 to 61% (17/28) and 37% (10/27) in week 4, respectively.

Table 2. Primary outcomes of the pilot studies.

Outcomes	Pilot study 1	Pilot study 2
Overall satisfaction score, median (25th percentile, 75th percentile)[a]	8 (7,9)	7 (6,8)
Net promoter score[b]		
Total score	–9	0
Promoters, n (%)	9 (29)	7 (37)
Detractors, n (%)	12 (39)	7 (37)
Usability		
System usability score, mean (SD)[c]	76 (15)	71 (20)
Usage[d]		
Week 1, n (%)	28 (100)	21 (78)
Week 2, n (%)	26 (93)	11 (41)
Week 3, n (%)	21 (75)	11 (41)
Week 4, n (%)	17 (61)	10 (37)

[a] Scale of 1-10. The higher the score, the higher the satisfaction.

[b] Pilot study 1, n=31; Pilot study 2, n=19.

[c] Scale of 0-100.

[d] Percentage of weekly questionnaires that were completed in the app. Pilot study 1, n=28; Pilot study 2, n=27.

Secondary Outcomes

Qualitative Outcomes of Pilot Study 1

Patient opinions on the feedback statements have been shown in a heat map (Multimedia Appendix 3). In the open feedback fields, several patients reported that the HAQ-II was too long (over 5 minutes), which meant that it did not meet the set design requirements. No other issues with the app were reported. Patients indicated that the graphs (displaying outcomes over time) were “useful” and that “the interface was clear.”

Qualitative Outcomes of Pilot Study 2: Semistructured Interviews

In general, the app was described as “clear,” “easy to use,” and “user friendly.” Patients acknowledged that the app had the potential to improve insight in disease activity over time and that it could help to reduce the burden of unnecessary outpatient clinic visits in time. Usage of the app varied between the patients. When asked to state reasons for not using the app, the following barriers for app usage were identified: technical problems, internal resistance (respondent fatigue, the app reminded them of their disease), and a lack of symptoms. We also identified 3 promoters for app usage: experiencing more grip on the disease, better communication with the physician, and an increase in disease activity. It can be noted that symptoms anecdotally play a modulating role in usage, as more symptoms induce usage whereas a lack of symptoms functions as a barrier for usage. A total of 5 illustrative quotes were chosen, which are presented in Table 3.

To optimize the app, several patients indicated that they desired an open field to disclose some notes with their submitted questionnaires, as they sometimes felt that the questionnaire did not fully capture their symptoms or that symptoms might be caused by something else. Other desires were a medication alarm/reminder, touch ID to log in, more graphs to display outcomes over time, a two-way chat function, or a change in questionnaires. Conflicting opinions were given regarding the addition of game-like elements to the app. Some opinions were positive such as “good, if it helps to me to fill out more questionnaires,” and “fun, if I can win something,” while some opinions indicated that the patients did not see any point in the addition of game-like elements, such as “I do not see additional value” or “not interesting.”

Table 3. Illustrative quotes of the patients.

Identified barriers and promoters	Indicative quote	Patients with a similar quote (n)
Grip on disease and better communication with physician	*…Improves interaction with my doctor, as the complaints I have had in the past month are now clearer.*	5
Disease activity	*…When my pain relapses, I would be more inclined to fill out the questionnaire.*	5
Technical problems	*…Technical problems prevented me from further usage.*	4
Respondent fatigue	*…It is the same (questionnaire) every time.*	4
App reminds patients of their disease	*…When I fill out the questionnaire, it makes me feel like a patient, I prefer not to feel like a patient this often.*	3

Discussion

Summary

This study shows the design, development, and evaluation of a smartphone app that allows patients with RA to monitor their disease activity off-site. This app was developed in line with the recommendations by the European League Against Rheumatism taskforce for development of mHealth apps, which were published after the current pilot studies were performed [30]. The pilot studies showed promising satisfaction (overall) and usability ratings; however, the app usage rates remain a challenge. Furthermore, patients indicated that they agreed with self-monitoring to be able to better allocate clinical consultations according to need.

The overarching aim of the app is to reduce the frequency of clinic visits if the self-monitored disease activity is low, thereby reducing the health care burden for patients, and healthcare costs.We believe that the app is ready to evaluate these anticipated benefits in a randomized controlled trial, as the overall satisfaction and usability ratings were very promising. The NPS showed less positive results, with a negative and a neutral score, which may indicate that patients would not likely recommend the app to others. The discrepancy between the NPS and the overall satisfaction rating may be caused by the cultural differences in scoring. The Dutch or the Europeans tend to give less extreme scores compared to the Americans, and the NPS originated in the United States [31]. If 8 was also considered a promoter score instead of a neutral score and 6 as a neutral score instead of a negative score, both pilot studies would have had a positive NPS rating. The positive NPS rating would better match the overall satisfaction rating. We believe that the proposed implementation strategy is also supported by patients because patients in this study and in previous research studies acknowledge that apps could assist allocation of clinic visits according to need [32]. Furthermore, they approved of self-monitoring (27/31, 87%) and would like to skip hospital visits if the self-monitored disease activity is low (25/31, 81%). There were no concerns with regard to data privacy and security with this app, and a majority of the patients intended to keep using this app in the future.

Declining adherence is a challenge with our app and for medical apps in general. In any eHealth trial, a substantial proportion of the users drop out before completion or stop using the app [33-35]. The frequency of usage was previously evaluated in 2 apps for patients with RA; the median completion rates were 91% of the daily questionnaires over 3 months and 79% of the daily questionnaires over 6 months [36,37]. Our completion rates were lower; this could be (partly) due to the difference in the intended usage frequency (daily versus weekly). One review shows that more frequent intended usage predicts better adherence [33]. For now, it is unclear how often a patient has to be monitored to better target consultation according to need. Hypothetically, if one questionnaire per month would be needed, it might be recommendable to set the intended usage to once a week to make sure that sufficient questionnaires are collected. Even considering the limited usage, we did collect at least one questionnaire per patient. If we get at least one questionnaire per patient per month for a year, we will still have 4 times more updates on their disease activity than when patients visit the outpatient clinic every 3 months. In the qualitative part of our study, we reported several factors that could play a role in the declining usage, including a lack of symptoms, technical barriers, and respondent fatigue, which are endorsed by previous research [32]. Possible ways to increase usage would include providing shorter questionnaires or adaptive questionnaires, improving persuasive and gamified app designs, adding reminder notifications, and limiting technical problems [33,38,39]. Furthermore, as patients reported that more disease activity stimulated usage, it is possible that patients mainly use the app in case of impending flares. This could mean that although usage is low, no flares are missed. This hypothesis should be further examined in larger observational studies.

Strengths

We performed 2 pilot studies with different qualitative and quantitative approaches to evaluate the app. This optimized our understanding of the patients' perspectives toward the app and its purpose and gave insights into the overall functioning of the app. We think these data provide meaningful insights to aspiring medical app designers and rheumatologists who are considering to prescribe apps to specific patient populations. Furthermore, the overall strengths of our project are patient involvement in all stages of the app development and integration of the app with the existing Reade electronic medical record. Ultimately, we have developed a mobile app that facilitates easy data entry for patients, and visualization of that data for both patients and physicians. The repetitive collection of PROs with the app combined with statistics in the patients’ existing electronic medical record has enormous research potential. This has been recognized before, but this integration is often not accomplished [14,40,41].

Limitations

As these were pilot studies, several limitations are present. First, the app is only available for patients of Reade, which limits generalizability. To improve this, we have, as a starting point, made our prototype available for other designers and health care centers. This will help others create a similar app. Second, it is possible that patients with enthusiasm for eHealth were more likely to participate. Therefore, it may be possible that the volunteers had above average technical skills and motivation to use the app. This warrants larger observational studies and controlled experiments in the future. Third, we cannot preclude that patients provided favorable feedback to the investigators. We did try to minimize this limitation by performing semistructured interviews and pilot studies with different researchers so that both had no previous relationships with the patients. Fourth, the semistructured interviews were rather short; however, after 9 interviews, no new opinions and data arose. We feel we have covered the most important opinions and experiences with patients. However, it could be possible that with longer interviews, more data would have been gathered. The last limitation is that patients who did not install the app were not included in the final questionnaire of the first pilot study—this may have led to an overestimation of the positive effects. To collect valuable information on the nonusers, we did purposefully include that specific group in the semistructured interviews to examine their barriers for adherence.

Conclusion

Two pilot studies demonstrated that self-monitoring RA disease activity with the MijnReuma Reade app is feasible in terms of overall (patient) satisfaction and usability; however, the app usage rates remain a challenge. Patients acknowledged that the app had the potential to help them self-monitor their own disease so that they could reduce their frequency of clinic visits in case of low disease activity.

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Authors' Contributions

SR and WB performed the pilot studies. BS and JW analyzed the data and wrote and edited the manuscript. All other authors were involved in the design of the study, the development of the app, and editing of the manuscript.

Conflicts of Interest

FSC is CMIO at Brightfish Ltd, the company that developed the MijnReuma Reade app.

Multimedia Appendix 1
Statements of patients' perspectives.
[DOCX File , 14 KB - formative_v4i9e20165_app1.docx]

Multimedia Appendix 2
Interview guide.
[DOCX File , 13 KB - formative_v4i9e20165_app2.docx]

Multimedia Appendix 3
Heatmap of the patients' perspectives.
[DOCX File , 25 KB - formative_v4i9e20165_app3.docx]

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Abbreviations

HAQ: Health Assessment Questionnaire
mHealth: mobile health
NPS: Net Promoter Score
PRO: patient-reported outcome
RAPID3: Routine Assessment of Patient Index Data 3

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Original Paper

Natural Language Processing Tools for Assessing Progress and Outcome of Two Veteran Populations: Cohort Study From a Novel Online Intervention for Posttraumatic Growth

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Abstract

Background: Over 100 million Americans lack affordable access to behavioral health care. Among these, military veterans are an especially vulnerable population. Military veterans require unique behavioral health services that can address military experiences and challenges transitioning to the civilian sector. Real-world programs to help veterans successfully transition to civilian life must build a sense of community, have the ability to scale, and be able to reach the many veterans who cannot or will not access care. Digitally based behavioral health initiatives have emerged within the past few years to improve this access to care. Our novel behavioral health intervention teaches mindfulness-based cognitive behavioral therapy and narrative therapy using peer support groups as guides, with human-facilitated asynchronous online discussions. Our study applies natural language processing (NLP) analytics to assess effectiveness of our online intervention in order to test whether NLP may provide insights and detect nuances of personal change and growth that are not currently captured by subjective symptom measures.

Objective: This paper aims to study the value of NLP analytics in assessing progress and outcomes among combat veterans and military sexual assault survivors participating in novel online interventions for posttraumatic growth.

Methods: IBM Watson and Linguistic Inquiry and Word Count tools were applied to the narrative writings of combat veterans and survivors of military sexual trauma who participated in novel online peer-supported group therapies for posttraumatic growth. Participants watched videos, practiced skills such as mindfulness meditation, told their stories through narrative writing, and participated in asynchronous, facilitated online discussions with peers. The writings, including online postings, by the 16 participants who completed the program were analyzed after completion of the program.

Results: Our results suggest that NLP can provide valuable insights on shifts in personality traits, personal values, needs, and emotional tone in an evaluation of our novel online behavioral health interventions. Emotional tone analysis demonstrated significant decreases in fear and anxiety, sadness, and disgust, as well as increases in joy. Significant effects were found for personal values and needs, such as needing or desiring closeness and helping others, and for personality traits of openness, conscientiousness, extroversion, agreeableness, and neuroticism (ie, emotional range). Participants also demonstrated increases in authenticity and clout (confidence) of expression. NLP results were generally supported by qualitative observations and analysis, structured data, and course feedback.

Conclusions: The aggregate of results in our study suggest that our behavioral health intervention was effective and that NLP can provide valuable insights on shifts in personality traits, personal values, and needs, as well as measure changes in emotional tone. NLP's sensitivity to changes in emotional tone, values, and personality strengths suggests the efficacy of NLP as a leading indicator of treatment progress.

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KEYWORDS

natural language analysis; emotional tone; personality; values; PTSD; military sexual trauma; online interventions; internet-based cognitive behavioral therapy; narrative therapy; mindfulness

Introduction

The lifetime risk of acquiring a mental illness diagnosis is 50%, yet over 100 million Americans lack affordable access to effective behavioral health care [1]. The economic costs of untreated mental illness are estimated in the hundreds of billions of dollars per year [2]. American military veterans are an especially vulnerable population. Up to 18% of Operation Enduring Freedom/Operation Iraqi Freedom veterans have posttraumatic stress disorder, and 25% have depression [3,4]. Furthermore, up to 41% of women and 4% of men are subjected to military sexual trauma, including sexual violence, sexual coercion, and severe and persistent sexual harassment [5]. It is estimated that 1.5 million of the 5.5 million veterans seen in US Department of Veterans Affairs (VA) hospitals in 2016 had a mental health diagnosis, and lack of access to mental health care is believed to contribute significantly to the high rate of suicide among US veterans, which tragically remains at 20 lives lost per day [6]. It is believed that at least half of veterans who need mental health care do not get the care they need, and more than half of those who would benefit from mental health care are unaware they need it [7].

With or without a mental health diagnosis, most returning veterans struggle with the transition to civilian life, suffering painful and sometimes debilitating symptoms even if they do not meet full criteria for a diagnosis [8]. One factor that exacerbates the difficulties of transition is the sense of profound loss created by being disconnected from the military community [9,10]. For example, veterans transition from almost never being alone to feeling all alone, leaving a life with a clearly established identity, culture, mission, purpose, and ever-present peer support to suddenly having to reinvent themselves. As a result, they tend to isolate [11] and consequently typically believe they are the only ones who feel this way. It can lead to loss of meaning and purpose, resulting from the stark contrast of going from high-intensity deployment, where every decision matters, to civilian life, where decisions seem much more trivial if they matter at all. The failure to address the special needs of veterans may explain why, sadly, real-world completion rates for in-person VA-approved therapies for posttraumatic stress disorder (PTSD) are 2% [12].

Real-world programs to help veterans successfully transition to civilian life must reach the many veterans who cannot or will not access care. These programs must have the ability to scale, as there is a shortage of services available to veterans, and they must address the loneliness that veterans experience while helping them reestablish their sense of mission, purpose, and connectedness. Therefore, successful interventions must also build a sense of community.

In an effort to expand access to care, digitally based behavioral health initiatives have emerged within the past few years. Most mental illnesses, including anxiety, depression, PTSD, and addiction, are effectively treated by cognitive behavioral therapy (CBT) [13]. The knowledge base of CBT best practices lends itself to scale. Internet delivery of CBT via therapist-mediated video chat and mixtures of online therapy sessions with email homework assignments are as effective as in-person therapies [14-18]. However, while improving reach, these approaches offer little or no scale [19]. Completely automated, open access, self-paced internet protocols offer scale, but have very low completion rates of around 1% [20,21]. Guided self-help, where clinicians offer support via brief phone calls or emails, have completion rates of 50% or higher and outcomes equal to in-person therapies [17]. Such interventions, however, rely heavily on the contacts between research associates and research participants, and the actual level of guidance provided is not usually discussed in the methodologies of these studies. Furthermore, few trauma-focused intervention protocols incorporate peer or social support, which has been identified as a protective factor against onset of PTSD and an integral part of recovery [22]. Additionally, an overlooked aspect of recovery from trauma is incorporation of military values. Personal accountability and group accountability are highly valued characteristics in military culture [23], yet rarely used in the treatment of veterans. Our novel behavioral health intervention teaches mindfulness-based CBT and narrative therapy using peer support groups as guides, with human-facilitated asynchronous online discussions. Our intervention attempts to address the aforementioned difficulties of online treatment—those of scale, lack of social support, and heavy reliance on clinical contact—while incorporating group accountability values that resonate with veterans.

Historically, the standard of assessing efficacy of a therapeutic intervention has been through administration of subjective symptom measures at various time points (usually pretreatment and posttreatment) [24-26]. These measures generate quantitative scores that become structured data [27]. Our online intervention, by virtue of administering written narrative and CBT exercises, generated large amounts of unstructured qualitative data that, in the course of successive weekly sessions, was longitudinal. Unstructured, qualitative data, while not generally the standard of intervention evaluation, may contain insights and nuances of personal change that are not captured by subjective symptom measures. Furthermore, data collection for posttreatment evaluation tends to suffer lower completion rates; thus, ground truth information about intervention effectiveness can be lost. The technological advancement of natural language processing (NLP) provides opportunities to generate insights in narrative- and CBT-based interventions by examining participants' own language. In fact, use of NLP is a practice in the artificial intelligence (AI) field for attempting to cultivate emotional intelligence in conversational robotics [28]. Validity studies have shown that NLP reliably predicts personality characteristics, personal needs, and values, and monitors emotional tone and style of communication [29,30]. NLP offers the promise of enhancing scale by giving participants immediate feedback while providing clinicians with real-time, actionable observations. At the same time, NLP supplies researchers the data needed to assess the impact of the behavioral health intervention.

The purpose of our study was to evaluate the feasibility and utility of NLP in evaluating change in a small pilot study of 2 veteran populations who completed 2 novel online behavioral health interventions.

Methods

Participants

A total of 23 participants were recruited for 2 studies of veterans, the Next Mission (NM) program and Women Warriors (WW) program. A total of 13 participants enrolled in the 14-week NM program, and 10 enrolled in the 8-week WW program. Inclusion criteria for the study were: (1) must be a military veteran, (2) must be aged 18 or older, (3) must speak English, (4) must be able to access the internet regularly, and (5) for the WW program, must be a woman. In the NM program, 11 of the 13 (85%) participants were men, while the WW program consisted of all (10/10, 100%) female participants. In total, 16 participants completed the courses, 9 in the NM program and 7 in the WW program.

Procedures

Participants were recruited via Facebook and LinkedIn ads and could sign up on a mobile, laptop, or desktop device of their choice. Recruitment was conducted over several months until enough participants were able to form cohorts for each course. The recruitment messages attempted to account for potential stigma by focusing on building resiliency skills and promoting posttraumatic growth rather than treating mental illness. Participants were informed that they would be helping others in their group while also getting help for themselves.

Participants were also incentivized by the opportunity to earn University of California college credits for their work, although only 3 of 16 (19%) participants took advantage. Participants understood that the program was fully compliant to the Health Insurance Portability and Accountability Act (HIPAA) and that they could choose to participate anonymously. However, they also had the option of revealing their identity to the group at any time they wished during the course. Both programs, which we also refer to as courses, were entitled "Stress, Resiliency and Post Traumatic Growth." The constellation of the groups was generationally diverse and allowed older veterans to connect with younger veterans**.**

In each program, participants watched videos teaching principles of CBT, narrative therapy, behavioral activation, and mindfulness meditation. They submitted written homework, including journal entries and thought and mood logs, and participated in asynchronous discussions, all within a HIPAA-secure environment. Approximately 90 minutes of online class time and one hour per week of homework was completed by each participant. The asynchronous discussions were facilitated and monitored by a licensed, doctoral-level therapist. Of note, facilitators for the WW group were female. The content for the programs was created in various commercially available proprietary applications by faculty members in the Department of Psychiatry of a US University Medical Center and then assembled into the NM and WW programs and delivered on a commercially available proprietary platform.

Measures

Linguistic Inquiry and Word Count

Linguistic Inquiry and Word Count (LIWC) is software designed to analyze word use within written text. It calculates the percentage of usage for sets of words, arranging them in 80 linguistic categories and generating output statistics for each of the categories [31,32]. LIWC uses a proprietary set of algorithms to produce 4 summary variables from the data: analytical thinking, clout, authenticity, and emotional tone [33]. Analytical thinking measures the degree to which words are used that suggest logical and analytic thinking patterns. Clout measures the characteristic of speaking from the perspective of high expertise and confidence. Authenticity measures the characteristic of more honest, personal, and self-disclosing language. Emotional tone measures the characteristic of expressing more positive emotions in an upbeat style and expressing less anxiety, sadness and hostility. LIWC has been shown across numerous studies to have internal consistency and validity [34].

IBM Watson Personality Insights

IBM Watson is a computer system that uses artificial intelligence to interpret unstructured data within natural language. IBM Watson's Personality Insights is programmed to analyze natural language input and provide outputs of personality characteristics based on 3 models [35]: (1) the Big Five personality traits (openness, conscientiousness, extroversion, agreeability, and neuroticism) [36], (2) personal needs, and (3) personal values. Personal needs describe 12 dimensions of personality aspects that are likely to resonate with the participant [37]: excitement, harmony, curiosity, ideal, closeness, self-expression, liberty, love, practicality, stability, challenge, and structure. Personal values [38] describe 5 types of values that are important to an individual and likely to influence decision-making behavior [39]: helping others, tradition, life pleasure, achievement, and openness to change. Outputs generated from Personality Insights are likelihood ratios between 0 and 1 and are data driven, meaning an output for a variable is only produced if detected. A variable with a score above 0.5 indicates a greater than average tendency for the characteristic to be true [40]. Table 1 lists the definitions of detected levels of needs and values.

Table 1. Definitions of personal needs and values outputs.[a]

Characteristic	Description
Needs	
Excitement	Emphasizes importance of getting out and living life, oriented toward having fun
Harmony	Appreciation for other people, their viewpoints, or feelings
Curiosity	Seeking discovery and desire for personal growth
Ideal	Wanting perfection and seeking sense of community
Closeness	Valuing connectedness with others
Self-expression	Emphasizes the importance of expressing oneself and asserting individual identities
Liberty	Have a desire for fashion and new things, as well as the need for escape and freedom
Love	Valuing social contact, either one-to-one or one-to-many
Practicality	Having a desire to accomplish things, a desire for skill and efficiency, including physical expression and experience
Stability	Valuing sensibility, equivalence, and balance
Challenge	Having desire to succeed and take on challenges
Structure	Exhibit a grounded trait and a desire to hold things together. They need things to be well organized and under control
Values	
Helping others	Showing concern for the welfare and interests of others
Tradition	Emphasizes self-restriction, order, and resistance to change
Life pleasure	Seek pleasure and sensuous gratification for themselves
Achievement	Seek personal success for themselves
Excitement	Emphasize independent action, thought, and feeling, as well as a readiness for new experiences

[a] Table content was taken and aggregated from IBM Watson Personality Insights [29].

IBM Watson Tone Analyzer

IBM Watson Tone Analyzer is an artificial intelligence–enabled text analysis tool produced by IBM Watson that uses AI to infer emotional tone through written text. Tone Analyzer is based on psycholinguistics theory and examines how day-to-day word usage correlates to manifest emotions [30], based on the International Survey on Emotion Antecedents and Reactions [41] data set. Tone Analyzer has undergone studies for consistency and validity against human analysis of emotion and shown no statistically significant difference between human-labelled emotion of text and Tone Analyzer analysis of emotional tone [30]. Tone Analyzer–generated data outputs of the 5 basic emotions enabled us to evaluate the presence of 5 basic emotions: anger, disgust, fear, joy, and sadness [42].

Qualitative Observations and Questionnaires

Participants reported feedback from the course and filled out structured subjective symptom questionnaires. Structured data were not analyzed quantitatively in comparison with NLP due to variations of sample size and low completion rates. As such, quantitative changes in structured data were observed qualitatively. Facilitators also reported subjective qualitative observations of participant progress. Structured measures included the Positive States of Mind Scale (PSOM) [43], Posttraumatic Growth Inventory (PTGI) [44], PTSD checklist for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (PCL-5) [45], Patient Health Questionnaires (PHQs) [46], Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWS) [47], and the Brief Coping Orientation to Problems Experienced (COPE) [48].

Statistical Analysis

Participants' writing samples and online posts were analyzed using the LIWC [33], IBM Watson's Personality Insights [49], and Tone Analyzer [50]. Detection scores (NLP outputs) were generated as outputs, upon which we conducted a pretest-posttest analysis of these language attributes at the beginning and end of each course. Analysis was conducted in IBM SPSS Statistics (version 26). Initially, repeated-measures 1-tailed *t* tests were run and effect sizes were calculated using Cohen *d*. However, to reduce the risk of type I statistical error from multiple *t* tests, variables were grouped into 4 multivariate categories: (1) LIWC variables, (2) personality trait variables, (3) personality values and needs variables, and (4) emotional tone variables. Omnibus testing in the form of repeated-measures multivariate analysis of variance (rMANOVA) was conducted with Bonferroni correction [51]. Effect sizes were calculated as partial η^2 [52] and Cohen *d* effect sizes were retained from *t* tests.

Results

Overview

In total, 16 of the 23 (70%) participants completed the courses and 15 were able to have their unstructured data analyzed. Results of all rMANOVA analyses on NLP outputs are summarized in Table 2.

Table 2. Results of natural language analysis for personality traits, values, emotional tone, and Linguistic Inquiry and Word Count for treatment groups of Next Mission combat veterans and Women Warriors military sexual assault survivors.[a]

Characteristic	NM[b] combat veterans (n=9)				WW[c] military sexual assault survivors (n=6)			
	F test[d] (*df*)	Cohen *d*	*P* value	Effect size (partial η^2)	*F* test[d] (*df*)	Cohen *d*	*P* value	Effect size (partial η^2)
Personality traits								
Openness	6.372 (1,8)	1.34	.04	0.443	9.740 (1,5)	1.47	.03	0.661
Agreeableness	10.305 (1,8)	1.77	.01	0.777	12.211 (1,5)	1.68	.02	0.709
Extroversion	12.446 (1,8)	1.52	.001	0.609	7.105 (1,5)	–1.58	.045	0.587
Conscientiousness	27.923 (1,8)	–2.83	.001	0.563	1.929 (1,5)	–0.53	.22	0.278
Emotional range	15.473 (1,8)	–1.74	.004	0.659	1.1014 (1,5)	0.58	.36	0.169
Values and needs[e]								
Curiosity	3.227 (1,8)	0.84	.11	0.287	5.971 (1,5)	1.44	.06	0.544
Harmony	7.787 (1,8)	1.42	.02	0.493	N/A[f]	N/A	N/A	N/A
Structure	1.865 (1,8)	–0.44	.21	0.189	2.784 (1,5)	0.87	.16	0.358
Closeness	17.672 (1,8)	2.23	.003	0.688	10.006 (1,5)	1.23	.03	0.667
Stability	6.518 (1,8)	1.49	.03	0.449	N/A	N/A	N/A	N/A
Helping others	21.715 (1,8)	2.06	.002	0.731	3.077 (1,5)	0.35	.14	0.381
Excitement	23.635 (1,8)	2.34	.001	0.747	0.391 (1,5)	0.15	.56	0.072
Life pleasure	18.926 (1,8)	1.92	.002	0.703	8.511 (1,5)	1.30	.03	0.630
Tradition	9.005 (1,8)	–1.54	.02	0.530	1.238 (1,5)	0.12	.32	0.198
Achievement	9.414 (1,8)	1.01	.02	0.541	7.294 (1,5)	1.28	.04	0.593
Love	N/A	N/A	N/A	N/A	13.474 (1,5)	1.58	.01	0.729
Ideal	N/A	N/A	N/A	N/A	3.173 (1,5)	1.03	.14	0.388
Emotional tone								
Sadness	10.852 (1,8)	–1.01	.01	0.576	1.164 (1,6)	–0.20	.33	0.283
Disgust	7.660 (1,8)	–1.25	.02	0.489	1.413 (1,5)	–0.74	.29	0.220
Joy	11.017 (1,8)	1.81	.01	0.579	1.977 (1,5)	0.84	.22	0.283
Fear	0.114 (1,8)	–0.17	.74	0.014	4.365 (1,5)	–0.80	.09	0.466
Anger	0.542 (1,8)	–0.32	.48	0.063	0.518 (1,5)	–0.40	.50	0.094
LIWC[g] analysis								
Analytical thinking	0.229 (1,8)	0.20	.65	0.028	0.094 (1,5)	–0.12	.77	0.018
Authenticity	7.326 (1,8)	0.92	.03	0.478	5.457 (1,5)	0.37	.07	0.522
Clout	8.651 (1,8)	0.90	.02	0.520	7.920 (1,5)	1.47	.04	0.613
Emotional tone	6.016 (1,8)	0.92	.04	0.429	4.597 (1,5)	1.17	.09	0.479

[a] N=15.

[b] NM: Next Mission.

[c] WW: Women Warriors.

[d] *F* values reported are from repeated-measures multivariate analysis of variance (rMANOVA), with effect sizes calculated using both Cohen *d* from repeated-measures *t* tests and partial η^2 from rMANOVA tests. Significance calculated from rMANOVA test with Bonferroni correction.

[e] For each program group, 10 identified values were outputted by IBM Watson Personality Insights based on highest density, thus differ slightly between programs.

[f] N/A: not applicable.

[g] LIWC: Linguistic Inquiry and Word Count.

NM Program

A total of 9 of the 13 (70%) Next Mission participants completed the course and were able to have their unstructured data analyzed. Results of analysis on NLP data were grouped into 4 outcome variable groups: (1) personality traits, (2) personal values and needs, (3) emotional tone, and (4) LIWC. Results from rMANOVA were reported as univariate analyses. Cohen *d* effect sizes from initial *t* tests were retained and reported.

Analysis of Personality Traits

Participants showed significant increases in openness ($F_{1,8}$=6.37; *d*=1.34; *P*=.03; partial η^2=0.44), agreeableness ($F_{1,8}$=10.3; *d*=1.77; *P*=.01; partial η^2=0.78), and extroversion ($F_{1,8}$=12.46; *d*=1.52; *P*=.02; partial η^2=0.609), while conscientiousness ($F_{1,8}$=27.92; *d*=–2.83; *P*=.001; partial η^2=0.563) and emotional range ($F_{1,8}$=15.47; *d*=–1.74; *P*=.01; partial η^2=0.659) significantly decreased.

Analysis of Personal Values and Needs

Participants showed significant increases in the values and needs of helping others ($F_{1,8}$=21.72; *d*=1.98; *P*=.002; partial η^2=0.73), closeness ($F_{1,8}$=17.67; *d*=2.23; *P*=.003; partial η^2=0.69), excitement ($F_{1,8}$=23.63, *d*=2.34; *P*=.001; partial η^2=0.75), life pleasure ($F_{1,8}$=18.93; *d*=1.92; *P*=.01; partial η^2=0.70), harmony ($F_{1,8}$=7.79; *d*=1.42; *P*=.01; partial η^2=0.493), achievement ($F_{1,8}$=9.41; *d*=1.01; *P*=.05; partial η^2=0.54), and stability ($F_{1,8}$=6.52; *d*=1.98; *P*=.02; partial η^2=0.45). Furthermore, participants showed a significant decrease in valuing tradition ($F_{1,8}$=9.01; *d*=–1.53; *P*=.03; partial η^2=0.53).

Curiosity ($F_{1,8}$=3.23; *d*=0.84; *P*=.24; partial η^2=0.28) increased but was not statistically significant. Likewise, structure ($F_{1,8}$=1.87; *d*=–0.44; *P*=.10; partial η^2=0.19) decreased but was not statistically significant.

Analysis of Emotional Tone

Participants showed significant decreases in sadness ($F_{1,8}$=10.85; *d*=–1.01; *P*=.01; partial η^2=0.58) and disgust ($F_{1,8}$=7.66; *d*=–1.25; *P*=.02; partial η^2=0.49), while joy significantly increased ($F_{1,8}$=11.02; *d*=1.81; *P*=.01; partial η^2=0.58).

Anger ($F_{1,8}$=0.54, *d*=–0.32; *P*=.24; partial η^2=0.06) and fear ($F_{1,8}$=0.11; *d* =–0.17; *P*=.37; partial η^2=0.01) decreased but were not statistically significant.

LIWC Analysis

The application of LIWC tools showed significant improvement in authenticity, clout, and emotional tone. Authenticity ($F_{1,8}$=7.33; *d*=0.92; *P*=.01; partial η^2=0.48) improved by 49%. Clout ($F_{1,8}$=8.65; *d*=0.90; *P*=.01; partial η^2=0.52) increased by 80%. Emotional tone ($F_{1,8}$=6.02; *d*=0.92; *P*=.02; partial η^2=0.43) improved by 51%. However, analytical thinking did not show significant change ($F_{1,8}$=0.23; *d*=0.20; *P*=.65; partial η^2=0.03).

Qualitative Observations

Observations were derived from structured data completed by 3 of the participants (results found in Table 2). The PTGI showed a general increase in the domains of relating to others, new possibilities, personal strength, and appreciation for life. The PSOM indicated no overall changes but did show an increase from all 3 participants in responsible caretaking. Course feedback included comments such as:

> *The site made me feel calm and cared for. It made me feel like people were looking out for me and that I had a network of resources and people if I needed.*
>
> *I got my laughter back.*

WW Military Sexual Assault Survivors

In total, 7 of the 10 (70%) Women Warriors participants completed the course. Of these, 6 WW participants produced sufficient narrative to have their unstructured data analyzed. Results of analysis of unstructured data were grouped into 4 outcome variable groups: (1) personality traits, (2) personal values and needs, (3) emotional tone, and (4) LIWC. Results from rMANOVA were reported as univariate analyses. Cohen *d* effect sizes from initial *t* tests were retained and reported.

Analysis of Personality Traits

Participants showed significant increases in personality traits of openness ($F_{1,5}$=9.74; *d*=1.47; *P*=.01; partial η^2=0.66) and agreeableness ($F_{1,5}$=12.21; *d*=1.68; *P*=.01; partial η^2=0.71), while showing significant decreases in extraversion ($F_{1,5}$=7.11; *d*=–1.58; *P*=.04; partial η^2=0.59).

Conscientiousness ($F_{1,5}$=1.93; *d*=–0.53; *P*=.22; partial η^2=0.28) decreased and emotional range ($F_{1,5}$=1.10; *d*=0.58; *P*=.36; partial η^2=0.17) increased but these were not statistically significant.

Analysis of Personal Values and Needs

Participants showed significant increases in the personal values and needs of closeness ($F_{1,5}$=10.01; *d*=1.23; *P*=.03; partial η^2=0.67), love ($F_{1,5}$=13.47; *d*=1.58; *P*=.01; partial η^2=0.73), life pleasure ($F_{1,5}$=8.51; *d*=1.30; *P*=.02; partial η^2=0.63), curiosity ($F_{1,5}$=5.97; *d*=1.44; *P*=.03; partial η^2=0.54), and achievement ($F_{1,5}$=13.47; *d*=1.28; *P*=.02; partial η^2=0.73).

The values and needs domains of helping others ($F_{1,5}$=3.10; *d*=0.35; *P*=.07; partial η^2=0.38), stimulation ($F_{1,5}$=0.39; *d*=0.15; *P*=.28; partial η^2=0.07), tradition ($F_{1,5}$=1.24; *d*=0.12; *P*=.16; partial η^2=0.20), structure ($F_{1,5}$=2.78; *d*=0.87; *P*=.08; partial η^2=0.36), and idealism ($F_{1,5}$=3.17; *d*=1.03; *P*=.07; partial η^2=0.39) generally increased but were not statistically significant.

Analysis of Emotional Tone

None of the differences of emotional tone were statistically significant. Fear ($F_{1,5}$=4.37; d=–0.8; P=.09; partial η^2=0.47), disgust ($F_{1,5}$=1.41; d=–0.74; P=.14; partial η^2=0.22), and sadness ($F_{1,6}$=1.16; d=–0.2; P=.16; partial η^2=0.28) generally decreased, while joy ($F_{1,5}$=1.98; d=0.84; P=.11; partial η^2=0.28) generally increased.

LIWC Analysis

The application of LIWC tools showed significant improvement in clout ($F_{1,5}$=7.92; d=1.47; P=.02; partial η^2=0.61), which increased by 56%. Although not significant, emotional tone ($F_{1,5}$=4.60; d=1.17; P=.08; partial η^2=0.48) improved by 24%, and authenticity ($F_{1,5}$=5.46; d=0.37; P=.07; partial η^2=0.52) improved by 9.3%. Analytical thinking did not show significant change ($F_{1,5}$=0.09; d=–0.12; P=.77; partial η^2=0.02).

Qualitative Observations

Qualitative observations of structured data (results found in Table 3) were generally consistent with anecdotal reports from participants and facilitators. There were 7 participants who completed structured measures. The PHQ-15 showed general decreases in somatization levels, from moderately severe to minimal. The Brief COPE showed a general increase in acceptance, decreased denial, increases in getting support and asking advice, and increased feelings of hope (ie, not giving up). Of the 7 participants, 5 showed less anxiety (generalized anxiety disorder 7-item checklist) and 4 showed improvement in depression (PHQ-9). Results of the PCL-5 did not show overall improvement, but 2 of the 7 participants showed substantially reduced symptoms scores, while 3 others recorded no change. PTGI did not show overall improvement, but 4 participants showed a general improvement in relating to others and participation in life. Observations of the SWEMWS were mixed, as 2 participants improved and 5 remained the same. Course feedback included comments such as:

> *I believe [course facilitator] when you say WE WILL get to the place of balance and peace. I returned home and I feel better than I have in a long time. I still have challenges and I know it's a day to day journey, but I ACTUALLY feel stronger…I'm honestly still in shock. I didn't think recovery would ever be a word used to describe me, but now I'm believing it.*
>
> *The good thing that came from this week's assignment was I found that I found support that I didn't realize that I had from sources I never would've thought.*
>
> *[The course platform] made me feel calm and cared for. It made me feel like people were looking out for me and that I had a network of resources and people if I needed.*

Table 3. Averages and change scores for treatment groups of Next Mission combat veterans and Women Warriors military sexual assault survivors.

Assessment	NM[a] combat veterans (n=3)			WW[b] military sexual assault survivors (n=7)		
	Pretest, mean	Posttest, mean	Difference score[c], mean	Pretest, mean	Posttest, mean	Difference score[c], mean
Posttraumatic Growth Inventory (PTGI)	47.3	58.7	11.4	66.6	60.6	–6.0
PTGI-I: relating to others	10.7	17.0	6.3	21.0	18.6	–2.4
PTGI-II: new possibilities	13.0	14.7	1.7	17.0	1.7	–15.3
PTGI-III: personal strength	11.7	12.7	1.0	14.6	10.6	–4.0
PTGI-IV: spiritual change	3.0	3.7	0.7	2.6	2.7	0.1
PTGI-V: appreciation of life	9.0	10.7	1.7	8.6	8.7	0.1
SWEMWS[d]	N/A[e]	N/A	N/A	21.1	22.2	1.1
Brief COPE[f]	N/A	N/A	N/A	36.3	30.3	–6.0
Active coping	N/A	N/A	N/A	3.1	2.6	–0.5
Positive reframing	N/A	N/A	N/A	3.3	2.9	–0.4
Plan	N/A	N/A	N/A	3.6	2	–1.6
Emotional support	N/A	N/A	N/A	2.6	3	0.4
Self-distraction	N/A	N/A	N/A	3.3	2.7	–0.6
Vent	N/A	N/A	N/A	2.9	2.1	–0.8
Behavioral disengagement	N/A	N/A	N/A	1.9	0.7	–1.2
Acceptance	N/A	N/A	N/A	1.9	3.4	1.5
Humor	N/A	N/A	N/A	2.9	1.9	–1.0
Religion	N/A	N/A	N/A	3.1	2.3	–0.8
Instrumental support	N/A	N/A	N/A	2.3	3.6	1.3
Denial	N/A	N/A	N/A	0.9	0.4	–0.5
Substance use	N/A	N/A	N/A	1.1	0.9	–0.2
Self-blame	N/A	N/A	N/A	2.0	1.8	–0.2
PCL-5[g]	N/A	N/A	N/A	57.6	60.9	3.3
PHQ[h]-15	N/A	N/A	N/A	13.6	10.9	–2.7
PHQ-9	N/A	N/A	N/A	13.4	10.7	–2.7
GAD-7[i]	N/A	N/A	N/A	11.4	8.3	–3.1
PSOMS[j]	9.0	9.0	0.0	N/A	N/A	N/A
Focused attention	1.7	1.7	0.0	N/A	N/A	N/A
Productivity	2.0	1.3	–0.7	N/A	N/A	N/A
Responsible caretaking	1.0	2.0	1.0	N/A	N/A	N/A
Restful repose	0.7	1.3	0.6	N/A	N/A	N/A
Sensuous pleasure	2.0	1.0	–1.0	N/A	N/A	N/A
Sharing	1.7	1.7	0.0	N/A	N/A	N/A

[a] NM: Next Mission.

[b] WW: Women Warriors.

[c] Differences in scores were used for qualitative observation. Differences in scores were not calculated for significance due to variation in completion and sample size.

[d] SWEMWS: Short Warwick-Edinburgh Mental Well-Being Scale.

[e] N/A: not applicable.

[f] COPE: Coping Orientation to Problems Experienced.

[g] PCL-5: PTSD checklist for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

[h] PHQ: Patient Health Questionnaire.

[i] GAD-7: generalized anxiety disorder 7-item checklist.

[j] PSOMS: Positive States of Mind Scale (n=10).

Discussion

Principal Findings

The purpose of our study was to evaluate the feasibility and utility of NLP in evaluating change in a small pilot study of 2 veteran populations who completed 2 novel online behavioral health interventions. Our aggregate results suggest that NLP can provide valuable insights on shifts in personality traits, personal values, and needs, as well as measure changes in emotional tone, in an evaluation of our novel online behavioral health interventions. The process of our participant recruitment suggests additional support for our findings. Recruitment was conducted over several months until critical mass was obtained for a cohort, with participants waiting variable amounts of time until start of the courses. Participants, regardless of waiting time, began the courses with similar symptom profiles. However, although our effect sizes are large, our small sample size must be considered in the interpretation of our results. Additionally, although it is reasonable to conclude that the large effect sizes seen are the result of our intervention, a limitation of our study was that we were unable to account for potential confounds by comparison with a control group. Thus, we cannot say with absolute certainty whether the effects seen were due to our intervention or additional factors. Future studies should seek to replicate the effects found in our pilot study with a control or comparison group, accounting for potential confounds.

In general, results of NLP mirrored qualitative reports and feedback from participants and facilitators on the efficacy of these interventions. Furthermore, our study suggests that NLP may detect participant change with a greater sensitivity than that of subjective symptom measures. We note that checklists do not tell stories—only stories do. A common clinical observation is the phenomenon in treatment of depression or anxiety wherein an individual’s loved ones or a clinician will often notice change in the individual before the individual become self-aware of the change [53,54]. In a similar manner, natural language analysis may provide an indication that change is occurring through the person’s own written text before there is meta-recognition of change and before such change is detectable using subjective symptom measures.

Findings such as decreased fear, sadness, disgust, and emotional range (neuroticism) with increased joy are consistent with posttraumatic growth and specifically tend to be associated with resilience. A common phenomenon in combat veterans is survivor’s guilt, more conventionally termed moral injury [55]. The nature of combat is such that it lends itself to situations that are morally ambiguous or unclear, potentially culminating in significant moral conflict after the fact. The constructs of moral injury and PTSD overlap, although they have characteristics that differentiate them [56]. A key component of moral injury is the presence of guilt or shame as a result of a real or perceived transgression [55]. From an evolutionary psychology perspective on emotions, guilt and shame are considered derivatives of the emotion of disgust [57]. Furthermore, there is evidence that elevated levels of disgust are associated with increases in intrusive thoughts of trauma [58] and with posttraumatic stress symptoms in general [59]. There is further evidence to suggest that inclusion in a supportive community of individuals with shared experiences is known to reduce feelings of guilt and shame while increasing feelings of acceptance and belonging [60]. Hence, the results of our study may suggest that reductions in the emotion of disgust could correlate with reductions in guilt and shame and could subsequently correspond to symptom change in PTSD. Although there is indication of this effect from our findings, further exploration and replication is required.

A noteworthy finding of our study is revealed by the consistent increases in closeness, love, and life pleasure in WW military sexual assault survivors. PTSD research indicates that these domains are severely impacted by trauma in general and sexual assault in particular [61]. In fact, one of the main treatment targets for cognitive processing therapy of PTSD is reduced ability to trust [62], which is associated with negatively impacting closeness and intimacy. In sexual assault survivors, intimacy and closeness can become significantly more difficult in the wake of the trauma, especially when combined with other sequelae of PTSD symptoms [63,64]. The findings of our study suggest that this intervention is helpful in fostering an enhanced ability to become close and intimate, and indeed to rely on others for social support. A potential explanation is that the medium in which survivors of trauma interact, asynchronously through the web, provides a sense of psychological safety that enables taking healthy risks to interact with others. In other words, the interaction can feel safe because it removes potential external and environmental triggers, which can be physiologically and cognitively destabilizing in the moment. Additionally, knowing that social support is a significant protective factor for PTSD [22], the participants in our study could find additional psychological safety in knowing that the other members of the group had been through a similar experience. In fact, it is already established that support groups can be efficacious [65], but in populations with PTSD, avoidance can be a significant obstacle to treatment [66]. It suggests that a slow gradual approach to social interaction through a technological medium can produce significant changes in the ability to experience closeness and intimacy, as well as in needing and valuing others. Finally, we believe there is therapeutic value inherent in the task of writing about one’s adverse experiences [67].

There is tentative evidence to suggest that the personality trait of conscientiousness is related to hypervigilance in decision making [68]. Thus, our findings may suggest that hypervigilance, a cardinal symptom of PTSD, may reduce in tandem with reduced conscientiousness. It is quite possible that on subjective symptom measures, individuals may not realize reductions in hypervigilance due to their identification as someone who is “always on guard,” a concept that has overlap and is consistent with military cultural values. However, additional research is needed to establish a clear association between the constructs of conscientiousness and hypervigilance.

A possible explanation for increased need for stability (eg, a consumer who consistently likes the same choice in a product, not a variety of choices) is that as veterans connect and create community with each other, there may be a reflection back to shared military values. Stability and regimen are a hallmark of military culture [23]. In fact, one participant reported via course feedback that "the good thing that came from this week's assignment was I found that I found support that I didn't realize that I had from sources I never would've thought."

Further studies are needed and are underway to determine whether a higher rate of completion of subjective symptom measures will correspond to changes found with NLP. These studies are also needed to determine whether NLP changes will accurately predict future changes in subjective symptom measures.

We recognize that with the attributes being measured by these tools, aggregating data is not always the best way to assess whether the impact of an intervention on an individual is positive, negative, or neutral. For example, authenticity and confidence in expression are generally understood in terms of "the more the better," whereas for attributes like conscientiousness, the desired outcome would be more for someone who is irresponsible and less for someone who is overly obsessive or rigid. Future research should focus on evaluating these online behavioral health interventions with larger samples across different populations while also measuring effectiveness in comparing natural language analytics to conventional evaluation methods.

A limitation of our study is that the generalizability is impacted by small sample sizes and the lack of a control group. Thus, we are unable to confirm whether results are due to the online intervention or another unidentified factor or set of factors. Furthermore, despite a growing number of validation studies, NLP is not widely accepted or implemented as a reliable indicator of therapeutic change. Thus, further validation studies that establish convergent and discriminant validity with therapeutic outcomes are warranted. An additional limitation of our study is that we were unable to statistically compare outputs from NLP to validated structured measures. The extant validation literature suggests that attempts at finding convergence of NLP with self-report measures of personality have produced mixed results. This could be due to the fact that NLP tends to measure both latent and explicit emotional tone and personality, whereas self-report measures are solely reliant on the perception of the individual. As a result, both methods have accrued criticism for being affected by bias [69]. However, the two methods may not measure the same construct, but different constructs from differing perspectives. Additionally, although there is initial evidence that NLP outputs can be predictors of consumer behavior [70], there is not yet certainty that those variables are predictors of therapeutic or behavioral change or that they impact psychosocial outcomes. On the other hand, symptom reduction measures have a better representation and acceptance as predictors of therapeutic and behavioral change within the extant literature. Thus, future studies should attempt to replicate our findings using NLP with larger sample sizes of veterans and construct a study design in such a way that NLP can be evaluated as a predictor of psychosocial outcomes.

Conclusions and Implications

Our interventions were impactful on attributes detected in writing, and the results of NLP provided tentative yet potentially valuable and provocative insights. By quantifying and aggregating these attributes, we have gained insights about which areas of emotional functioning are responsive to our intervention. By looking at individual analyses, we can readily see how each participant is progressing, for example by noting reduced emotional expression in someone who was emotionally dysregulated and increased emotional expression in another participant who was initially emotionally constricted. The use of natural language analytics tools opens up a completely new area of scientific inquiry. We are getting closer to entirely replicating what happens in in-person psychotherapy. We can now provide the benefit of both symptom checklists and patient narratives to expert clinicians who know how to interpret the data for clinical decision making and to researchers who can determine the impact and value of any given behavioral health intervention. We believe that using AI powered by natural language analytics will enable the creation of effective therapy bots that will assist facilitators and sustain participant engagement, as this intervention is scaled to make it accessible to everyone, anytime, anywhere. We also believe that using NLP applied to behavioral health interventions and other clinical situations creates an entirely new field of medical informatics.

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Authors' Contributions

All authors reviewed and edited the manuscript and approved of the final draft.

Conflicts of Interest

KN has a household interest in Tiatros Inc. KN is an advisor to Tiatros compensated by stock options. DWK is a project-based contractor with Tiatros Inc. WK is an employee of IBM. AG is an employee of IBM.

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Abbreviations

AI: artificial intelligence
CBT: cognitive behavioral therapy

COPE: Coping Orientation to Problems Experienced
HIPAA: Health Insurance Portability and Accountability Act
LIWC: Linguistic Inquiry and Word Count
NLP: natural language processing
NM: Next Mission
PCL-5: PTSD checklist for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
PHQ: Patient Health Questionnaire
PSOM: Positive States of Mind Scale
PTGI: Posttraumatic Growth Inventory
PTSD: posttraumatic stress disorder
rMANOVA: repeated-measures multivariate analysis of variance
SWEMWS: Short Warwick-Edinburgh Mental Well-Being Scale
VA: US Department of Veterans Affairs
WW: Women Warriors

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Original Paper

Evaluating the Relationship Between Fitbit Sleep Data and Self-Reported Mood, Sleep, and Environmental Contextual Factors in Healthy Adults: Pilot Observational Cohort Study

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Abstract

Background: Mental health disorders can disrupt a person's sleep, resulting in lower quality of life. Early identification and referral to mental health services are critical for active duty service members returning from forward-deployed missions. Although technologies like wearable computing devices have the potential to help address this problem, research on the role of technologies like Fitbit in mental health services is in its infancy.

Objective: If Fitbit proves to be an appropriate clinical tool in a military setting, it could provide potential cost savings, improve clinician access to patient data, and create real-time treatment options for the greater active duty service member population. The purpose of this study was to determine if the Fitbit device can be used to identify indicators of mental health disorders by measuring the relationship between Fitbit sleep data, self-reported mood, and environmental contextual factors that may disrupt sleep.

Methods: This observational cohort study was conducted at the Madigan Army Medical Center. The study included 17 healthy adults who wore a Fitbit Flex for 2 weeks and completed a daily self-reported mood and sleep log. Daily Fitbit data were obtained for each participant. Contextual factors were collected with interim and postintervention surveys. This study had 3 specific aims: (1) Determine the correlation between daily Fitbit sleep data and daily self-reported sleep, (2) Determine the correlation between number of waking events and self-reported mood, and (3) Explore the qualitative relationships between Fitbit waking events and self-reported contextual factors for sleep.

Results: There was no significant difference in the scores for the pre-intevention Pittsburg Sleep Quality Index (PSQI; mean 5.88 points, SD 3.71 points) and postintervention PSQI (mean 5.33 points, SD 2.83 points). The Wilcoxon signed-ranks test showed that the difference between the pre-intervention PSQI and postintervention PSQI survey data was not statistically significant (Z=0.751, *P*=.05). The Spearman correlation between Fitbit sleep time and self-reported sleep time was moderate (r=0.643, *P*=.005). The Spearman correlation between number of waking events and self-reported mood was weak (r=0.354, *P*=.163). Top contextual factors disrupting sleep were "pain," "noises," and "worries." A subanalysis of participants reporting "worries" found evidence of potential stress resilience and outliers in waking events.

Conclusions: Findings contribute valuable evidence on the strength of the Fitbit Flex device as a proxy that is consistent with self-reported sleep data. Mood data alone do not predict number of waking events. Mood and Fitbit data combined with further screening tools may be able to identify markers of underlying mental health disease.

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KEYWORDS

Fitbit; sleep; healthy; mood; context; waking

Introduction

Anxiety, depression, and post-traumatic stress disorder (PTSD) are increasingly common types of mental health disorders in the United States. Mental health disorders can cause significant reduction in function and quality of life [1].While mental health disease is prevalent throughout the United States, it affects a disproportionately large proportion of the active duty service member (ADSM) population. In 2013, 20% of ADSM had a mental health disease, with the Army showing the highest prevalence of mental health disease, at 30% [2]. Routine screening and early referral for mental health disorders can help improve quality of life for ADSM [3]. Since it is known that treatment is effective, the key to better serving ADSM is early identification of underlying mental health disorders.

There is a well-defined relationship between mental health disorders, such as anxiety, depression, and PTSD, and sleep disturbances [4]. Up to 90% of patients with major depressive disorder have sleep disturbances [5]. Patients with generalized anxiety disorder have double the risk of having sleep disturbances as compared to healthy controls [6]. A majority of patients with PTSD suffer from sleep disturbances [7]. Sleep disturbances due to underlying mental health conditions can be measured using contextual factors such as fear, worry, or life stressors.

Personal fitness devices are wearable sensors (usually worn on the wrist) that allow for direct tracking of biometric data. Devices such as the Fitbit are light, portable, and inexpensive and can obtain passive sleep data [8]. These trackers have been used by both the Army and Navy to promote health and are ubiquitous in the ADSM population [9]. Specifically, Fitbit has been found to be a valid method of obtaining sleep metrics compared to the gold standard polysomnography (PSG) [10-12]. Fitbits have also been found to positively correlate with patient-reported outcomes such as sleep and step count [13]. Fitbit has an intradevice reliability of 96.5%-99.1% for measuring sleep efficiency and total sleep time compared with the gold standard of PSG in a study of 24 healthy volunteers [10]. Another study compared the Fitbit Flex, the same device used in this study, against PSG and found a correlation of 97.4% for total sleep time in good sleepers and 88.6% for participants with insomnia [14].

Many studies have measured total sleep time, time awake, and number of waking events but have not investigated causes for why the waking events happened [15]. A study of 22 participants using the SleepTight tracking algorithm to evaluate contextual factors such as caffeine and exercise did not show a statistically significant correlation with good, neutral, or poor sleep over a month [16]. Another study also attempted to explore the relationship between sleep and contextual factors with 12 participants looking at Fitbit data over 2 weeks compared with an online sleep tool called Sleep Explorer [15]. The most common reasons for increased number of waking events were spouses, children, pets, garbage trucks, and alcohol [15]. An additional study by the same author found that the total time slept and number of waking events most strongly correlated with the participants' experience of sleep [17]. Finally, a small study of 10 participants looking at Fitbit Alta sleep metrics and self-reported sleep diaries found a positive correlation between the 2 measures [18]. None of these studies attempted to explore the relationship between self-reported mood, sleep, and contextual factors as markers of early mental health disorders.

Although Fitbit has been found to be a valid instrument for measuring sleep data, it has not been used to evaluate potential underlying mental health disorders. The paucity of data creates an opportunity to design research studies to fill current gaps in the literature.

This study aimed to evaluate if Fitbit sleep data can be validated as reliable compared with self-reported sleep and mood. If Fitbit can be found to be a reliable device that can uncover early markers for mental health disorders, then Fitbit could be used as a screening tool to identify early markers of mental stress in different populations such as ADSM. No analysis in the literature has attempted to address the following 3 aims: (1) Determine the correlation between daily Fitbit minutes slept and daily self-reported sleep data, (2) Determine the correlation between Fitbit number of waking events and self-reported mood, and (3) Explore qualitative relationships between Fitbit waking events and self-reported contextual factors for sleep.

Methods

This observational cohort study evaluated the relationship among Fitbit sleep data (hours and waking events), self-reported mood, self-reported sleep (hours and waking events), and self-reported environmental contextual factors that impact sleep in a convenience sample of healthy, working, adult ADSM participants over a 2-week period at the Madigan Army Medical Center. Healthy participants were defined as not having primary uncontrolled insomnia, obstructive sleep apnea, hyperthyroidism, or cardiac dysrhythmia. Inclusion criteria consisted of voluntary participation in the study and having a functioning Fitbit. Exclusion criteria included having a pre-existing uncontrolled primary sleep disorder, uncontrolled obstructive sleep apnea, uncontrolled thyroid disease, dysrhythmias, or nonfunctioning Fitbit. Exclusion criteria were based on studies with a similar design [15].

Participants wore the Fitbit Flex for the 2-week data collection period. Data were collected from participants at 3 time points: pre-intervention, during the intervention, and postintervention.

Participants completed pre-intervention and postintervention sleep surveys using the Pittsburg Sleep Quality Index (PSQI) [19]. Participants completed daily mood and sleep logs using the National Institute of Mental Health's Life Chart Method (NIMH LCM) [20]. At the end of the first week of data collection and at the end of the 2-week period, participants completed the Clinical Interview Schedule-Revised (CIS-R) [21] as a measure of contextual factors for sleep.

Aim 1. Determine the Correlation Between Daily Fitbit Sleep Data and Daily Self-Reported Sleep

The relationship between daily Fitbit minutes slept and daily self-reported number of hours slept was assessed using Spearman correlation analysis. Spearman correlation analysis was used to compare ordinal self-reported sleep to measured Fitbit sleep. As a quality check, the pre-intervention PSQI and postintervention PSQI scores were compared using the Wilcoxon signed rank test to ensure no change in pre-intervention and postintervention sleep habits during the 2-week interval. The Wilcoxon signed ranked test was used to compare ordinal values from the pre-intervention and postintervention PSQI surveys.

Aim 2. Determine the Correlation Between Number of Fitbit Waking Events and Self-Reported Mood

The NIMH LCM was used to track self-reported mood with a daily log of the number of hours slept and a presleep mood assessment on a rating scale from –3 (lowest) to +3 (highest). The relationship between daily Fitbit number of waking events and daily self-reported presleep mood were assessed with the Spearman correlation.

Aim 3. Explore Qualitative Relationships Between Fitbit Waking Events and Self-Reported Contextual Factors for Sleep

Contextual factors contributing to disruptive sleep were obtained using survey data from the PSQI and CIS-R. Both surveys allow for participants to pick from a list of common sleep disturbances as well as manually write in other contextual factors. These open-ended responses were analyzed and sorted into groups based on similarity to identify specific contextual factors that were disruptive to participant sleep.

Results

A total of 17 participants (P1-P17) completed the study (Table 1). No self-reported data were excluded.

Table 1. Participant demographic profile (n=17).

Age bracket (years)	Number of participants	Number of men	Number of women
31-35	1	1	0
36-40	2	0	2
41-45	4	3	1
46-50	3	2	1
51-55	3	3	0
56-60	4	4	0

As seen in Table 1, the demographic analysis shows that participants were in the working age range, and the sample was approximately three-fourths male and one-fourth female. No significant demographic differences were seen.

Table 2 summarizes the survey and Fitbit sleep data. Disrupted sleep habits were reported by 5 participants (P2, P5, P11, P13, and P16), with both pre-intervention and postintervention PSQI sleep scores >5. These scores could be a sign of possible underlying conditions giving rise to disrupted sleep patterns. Contextual factors reported on the CIS-R by those participants indicate situational factors that contributed to disruptive sleep.

Each participant with high pre-intervention and postintervention PSQI sleep scores indicating poor sleep reported situational confounding factors in the CIS-R survey (Table 2).

There was no significant difference in the mean scores for the pre-intervention PSQI (5.88, SD 3.71) and postintervention PSQI (5.33, SD 2.83). The Wilcoxon signed-ranks test showed that the difference between the pre-intervention PSQI and postintervention PSQI survey data was not statistically significant (Z=0.751, *P*=.05). Thus, participants' self-reported sleep habits remained stable during the study period.

Table 2. Fitbit-reported data versus participant self-reported survey data.

Variables	Results
Fitbit hours slept, mean (SD)	6.50 (0.95)
Self-reported hours slept, mean (SD)	6.38 (0.80)
Fitbit waking events, mean (SD)	1.79 (1.05)
Self-reported mood (–3 to +3), mean (SD)	0.67 (1.01)
Pre-intervention PSQI[a], mean (SD)	5.53 (2.83)
Postintervention PSQI, mean (SD)	5.88 (3.71)
Interim CIS-R[b] contextual factors, n	
Noises	2
Pain	2
Worries	4
Other	9
Postintervention CIS-R contextual factors, n	
Noises	3
Pain	3
Shift work/late nights	3
Worries	2
Other	6

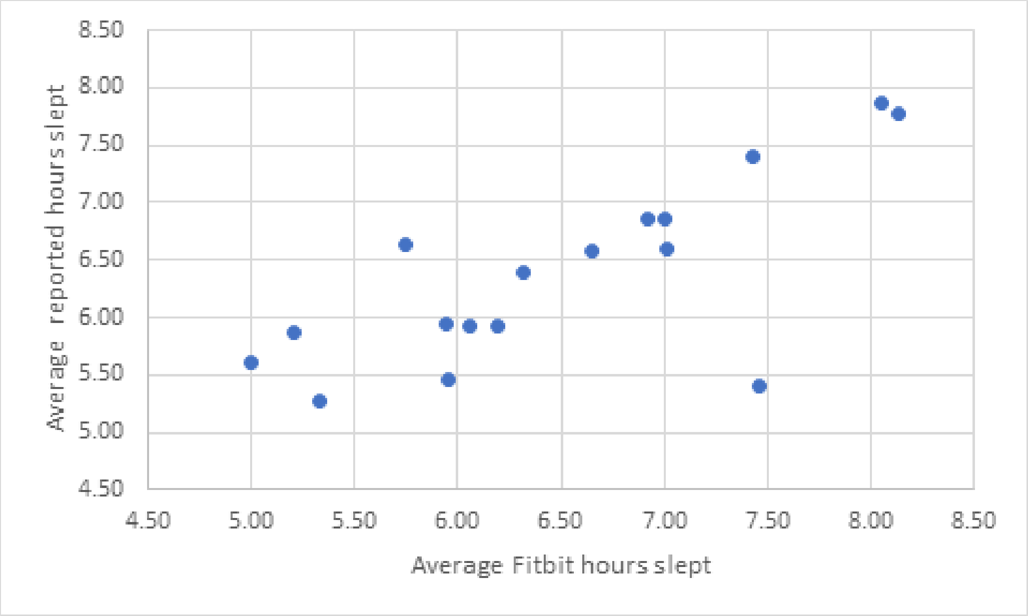
[a] PSQI: Pittsburg Sleep Quality Index.

[b] CIS-R: Clinical Interview Schedule-Revised.

Aim 1: Comparison of Self-Reported Sleep Versus Fitbit Sleep

Figure 1 compares Fitbit sleep time and self-reported sleep time. The population mean of Fitbit average hours slept was 6.49 hours (SD 0.95 hours), which was close to the participant self-reported mean of average hours slept of 6.38 hours (SD 0.80 hours). The Spearman correlation between Fitbit sleep time and self-reported sleep time was moderate (r=0.643, *P*=.005) [22].

Figure 1. Average sleep recorded by Fitbit compared with average self-reported sleep (n=17).



Aim 2: Comparison of Self-Reported Mood Versus Fitbit Waking Events

The average number of Fitbit waking events was 1.79 (SD 1.05). The average self-reported mood was 0.67 (SD 1.00). Figure 2 shows no clear linear relationship between self-reported mood and number of waking events. This lack of relationship between waking events and self-reported mood is confirmed by the weak correlation between number of waking events and self-reported mood (r=0.354, *P*=.163).

Figure 2. Average number of waking events compared with average self-reported mood (n=17).

Aim 3: Exploring the Relationship Between the Number of Waking Events and Contextual Factors

Qualitative analysis of the interim and post CIS-R data from Table 2 resulted in 4 categories of contextual factors: noises, pain, shift work/late nights, and worries. P9, P12, and P13 reported "noises" were the main reason to wake up at night. "Noises" and "shift work/late nights" provide additional environmental context for waking events, while "pain" provides an additional physical context for waking events. The subcategories of "worries" provide additional mental health context for waking events.

A subset of participants was evaluated to further explore "worries" as a mental health marker of stress. The correlations between the number of waking events and mood were analyzed for this subset of participants and are shown in Figure 3.

Figure 3. Mood compared with number of waking events for the subcategory of the contextual factor "worries".

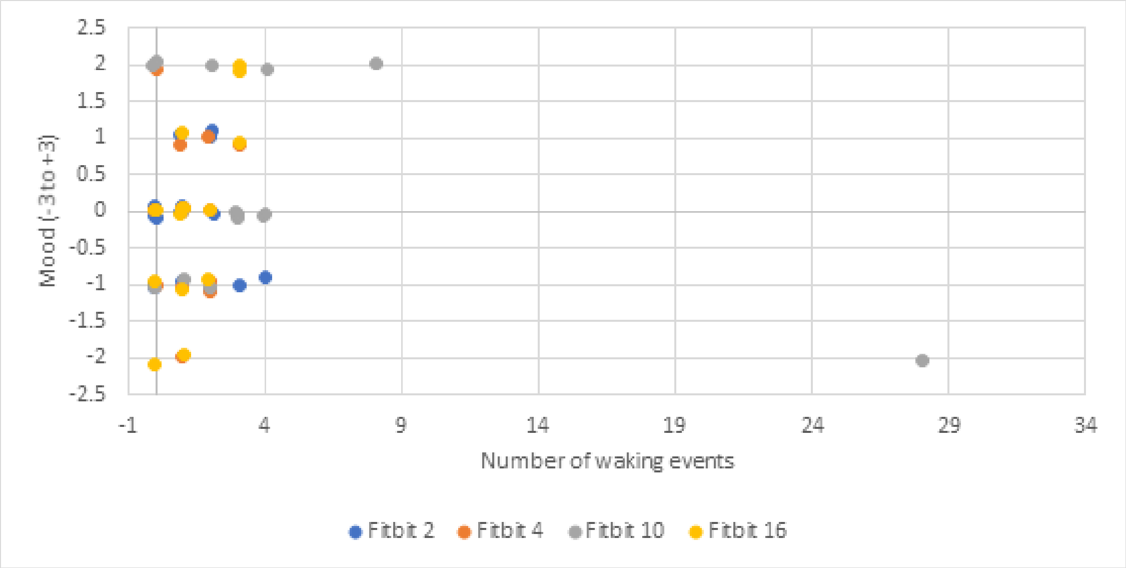


Figure 3 shows the relationship between number of waking events and presleep mood for the subcategories of "worries." The mental resilience of this population is seen in the relationship between high mood and an increased number of waking events. The outlier may indicate a potential marker of mental stress and possibly an underlying mental health disorder.

Discussion

There was no statistical difference in the pre-intervention PSQI and postintervention PSQI scores. This indicates that sleep habits were stable, even with the use of a Fitbit. Additionally, Fitbit hours slept correlated well with self-reported hours slept. This finding for Aim 1 indicates that the Fitbit Flex functioned effectively as a feasible tool for measuring participants' self-reported sleep and could be reliably used for further testing in future populations. The unique contribution of Aim 1 is that it showed a correlation between self-reported sleep and measured sleep in a population of healthy, working-age individuals at the Madigan Army Medical Center. Previous literature has shown a positive correlation between self-reported sleep and mood in the general population suing PSG and actigraphy. However, no study has aimed to confirm the correlation between self-reported sleep and mood in a healthy, working age population in the military health system. Confirming that this correlation exists provides the foundation for trusting Fitbit data as a reliable tool for measuring sleep and serves as a baseline to explore other parameters such as number of waking events and presleep mood.

Aim 2 attempted to determine whether mood can be used as a marker for detecting underlying mental health disorders. The idea being that if someone has anxiety, depression, PTSD, or another mental health disorder, this will be observed as a negative mood prior to going to bed, and the Fitbit will be able to capture this negative mood as an increased number of waking events. However, although there was a moderate correlation for Aim 1, as measured using the Spearman coefficient, the correlation for Aim 2 was weak.

This finding of a weak correlation between number of waking events and presleep mood indicates that self-reported mood does not correlate with increased waking events in this population. This indicates that presleep mood is not a reliable marker for detecting early markers of mental health disorders. However, given the lack of variability in the population data, this cohort may be used a potential baseline for future testing.

Additionally, 2 unintended findings occurred while investigating Aim 2. Since this was a healthy population without underlying mental health disorders and no significant mood or waking event relationship was found, this population can be used as a baseline for measuring normal population data. This can be helpful for future studies looking at different mood, sleep, and contextual factors.

Interestingly, several participants reported a higher mood with an increased number of waking events. One potential explanation of this is the sample population itself. The study participants were healthy adults serving in an Armed Forces environment. This cohort may have had naturally positive attitudes, becoming energized during times of stress. For this group, waking events do not increase with a negative presleep mood possibly due to the mental resilience and positive stress response of this population under stressful conditions. This study's findings could help to screen populations for stress-resilient personnel by further testing using the Fitbit device, mood, and contextual factors in similar populations. These findings may also be of significance for use as baseline in healthy, working-age, military-associated populations. Further testing with the ADSM population could attempt to screen for less adaptive stress responses that show a correlation between negative mood and increased waking events.

Finally, for Aim 3, the contextual factors disrupting sleep varied by participant and lifestyle context. Specific common disturbances identified were "noises," "pain," "shift work/late nights," and "worries." "Pain" and "worries" may indicate underlying physical and mental stress. A subanalysis performed with data from these participants found outliers in the number of waking events. Although the aggregate population data did not show a correlation between mood and waking events, at the individual level, a potential correlation may exist as identified by P10's increased number of waking events and self-report of "worries." Future studies may use an additional dedicated mental health screening tool such as the Patient Health Questionnaire (PHQ-9), which may reveal a relationship between mood and waking events that Aim 2 did not show.

Limitations

There are several limitations to this study. First, the sample size was small, consisting of 17 participants. However, this sample size is consistent with similar studies [15]. Further testing with a larger sample size may be needed to generalize findings to the ADSM population.

Second, the NIMH LCM is used primarily to track the effectiveness of treatments in patients with bipolar disease. Here, it was used to track daily mood, although its intended purpose is to track the severity of bipolar over a period of a month. Since mood data were collected from self-reported surveys, recall bias may have affected the accuracy of these results. Future studies may consider obtaining longitudinal mood data rather than a single mood value.

Third, both the PSQI and CIS-R contain questions asking participants to describe contextual factors that may disrupt sleep over a 30-day period. Participants were asked to report contextual factors for 2 weeks only. Since portions of the PSQI and CIS-R were adapted for a shorter study period, this may limit their validity.

Fourth, since this study first focused on healthy participants prior to being conducted in patients with known pathology, only a few mood scores were found in the –1 to –3 region. This may limit the ability to find a linear relationship in an unobserved area. Future studies may address this by evaluating patients with known underlying mental health disease.

Finally, the Fitbit Flex is one of the oldest Fitbit models. A newer Fitbit model may correlate better with presleep mood. Newer models may include more sensitive methods for detecting REM sleep and may also be more sensitive in determining the number of waking events.

Despite these limitations, this study has a number of strengths. The Fitbit was shown to be a reliable device for measuring sleep. Fitbit waking data and presleep mood data serve as a baseline for future studies. Finally, the combination of Fitbit data and survey data can identify outliers in subgroups that can be evaluated for mental health disorders with further screening tools. Further screening in this subgroup of participants with an additional dedicated mental health survey such as the PHQ-9 may be able to reveal underlying mental health disorders.

Conclusions

Since both mental health disorders and Fitbits are prevalent in the ADSM population, personal fitness trackers may be able to capture patient-generated data for clinically meaningful outcomes. The purpose of this study was to evaluate the relationship between Fitbit sleep data, self-reported mood, and contextual factors that may disrupt sleep to determine if the Fitbit device can be used to identify early markers of mental health disorders. The findings contribute valuable evidence on the strength of the Fitbit Flex as a proxy that is consistent with self-reported sleep data. Low mood was not found to correlate with an increased number of waking events. Increased mood was observed when there was an increased number of waking events, indicating that this population may exhibit a stress resilience not seen in the general population, which future work should investigate. Additionally, the subgroup analysis indicated that this population can be used as a baseline to identify outliers in the characteristics of a healthy Department of Defense population's sleep and mood patterns. Finally, using the Fitbit in combination with mood and contextual surveys may identify outliers that can be further screened with a dedicated mental health screening tool such as the PHQ-9.

Conflicts of Interest

None declared.

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Abbreviations

ADSM: active duty service member
CIS-R: Clinical Interview Schedule-Revised
NIMH LCM: National Institute of Mental Health’s Life Chart Method
PHQ-9: Patient Health Questionnaire
PSG: polysomnography
PSQI: Pittsburg Sleep Quality Index
PTSD: post-traumatic stress disorder

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Original Paper

EHealth Literacy in UK Teenagers and Young Adults: Exploration of Predictors and Factor Structure of the eHealth Literacy Scale (eHEALS)

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Abstract

Background: Increasingly, teenagers and young adults (TYAs) seek out health information online; however, it is not clear whether they possess electronic health (eHealth) literacy, defined as “the ability to select, appraise, and utilize good quality health information from the internet.” A number of factors are included in the Lily model proposed by Norman and Skinner underpinning the development of eHealth literacy. It is important to understand which elements may influence the development of eHealth literacy in young people, as the current generation will continue to “Google it” when faced with a health problem throughout their lives.

Objective: The objectives of this study are to explore potential factors influencing young people’s eHealth literacy and explore the underlying constructs of the eHealth Literacy Scale (eHEALS) in a population of UK university students.

Methods: A total of 188 undergraduate psychology students from a large UK University were recruited as an opportunity sample. Of these, 88.8% (167/188) of participants were female with a mean age of 20.13 (SD 2.16) years and the majority were White British (159/188, 84.6%). Employing a cross-sectional design TYAs completed the following measures exploring eHealth literacy (eHEALS): Irrational Health Belief Scale; Newest Vital Sign (NVS), a measure of functional health literacy; Need for Cognition Scale, a preference for effortful cognitive activity; and General Self-Efficacy (GSE) Scale, exploring personal agency and confidence. The eHEALS was also subject to exploratory factor analysis (EFA), for which in addition to the total variance explained, the scree plot, eigenvalues, and factor loadings were assessed to verify the structure.

Results: eHEALS and GSE were significantly positively correlated (r=0.28, P<.001) and hierarchical linear modeling revealed GSE as the significant predictor of scores on the eHEALS ($F_{1,186}$=16.16, P<.001, R^2=0.08), accounting for 8.0% of the variance. Other notable relationships were GSE and need for cognition (NFC) were also positively correlated (r=0.33, P<.001), and NFC and irrational health beliefs were significantly negatively correlated (r=–.14, P=.03). Using Spearman correlations, GSE and NVS (r_s=0.14, P=.04) and NFC and NVS (r_s=0.19, P=.003) were positively correlated. An EFA revealed the scale to be stable and identified a 2-factor structure related to information acquisition and information application.

Conclusions: This is the first study in the UK to explore relationships between these key variables and verify the structure of the eHEALS in a TYA population in the UK. The findings that self-efficacy has a major influence firmly consolidate its status as fundamental to the development of eHealth literacy. Future studies will explore the influence of body image and the development of eHealth literacy in more diverse TYA populations.

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KEYWORDS

eHealth literacy; irrational health beliefs; predictors; self-efficacy; teenagers and young adults; need for cognition; exploratory factor analysis

Introduction

Background

Almost all young adults in the UK are shown to be recent internet users [1] with teenagers present online for over 6 hours a day [2]. Indeed, most young adults consider the internet a valid source of health information [3,4] and compared with "digital immigrants," "digital natives" (ie, those who have grown up in the digital age) seek out more health information electronically [5]. While the internet has transformed and widened access to health information, there has been concern about the quality of electronic health (eHealth) resources [6,7] and indeed whether people can select good quality health information on the internet. Undoubtedly, increasing the health literacy of populations is now seen as essential and is fast becoming a global challenge [8]. In England, 15% of adults are classed as functionally illiterate [9] and 32 million adults in the United States are unable to read [10]. However, successfully accessing eHealth resources goes beyond functional literacy skills and requires "eHealth literacy," defined as the ability to "seek out, find, evaluate and appraise, integrate, and apply what is gained in electronic environments toward solving a health problem" ([11], p. 2).

Young People and eHealth Literacy

Intuitively one would assume that young people as "digital natives" would be competent users of the technology they have been brought up with; however, this is not always the case [12]. Equally they are not always capable users of eHealth resources [13]. This lack of competency and fundamental concerns around the extent of misinformation in eHealth resources [14] have the potential to impact public health in terms of individual health outcomes and unnecessary burdens on health care systems [15]. Therefore, it is important to know whether young people can discern if the information gained from eHealth resources is of good quality and appropriate to their needs. To this end, Norman and Skinner [16] have developed a measure of perceived eHealth literacy—the "eHealth Literacy Scale" (eHEALS). Good reliability and validity from the eHEALS are demonstrated in young people in the United States [17] and the measure has been successfully translated into several languages [18-20]. Thus, if we are to successfully measure eHealth literacy, it is also important to understand factors that may influence the perceived ability of teenagers and young adults (TYAs) to successfully navigate internet-provided health resources. This is particularly crucial as this is the first generation to have grown up with access to eHealth resources and will continue to "Google it" when faced with a health problem throughout their lives. Therefore, it is important to gain a deeper understanding of what factors potentially influence eHealth literacy in young people. Norman and Skinner [11] propose that eHealth literacy is underpinned by a set of complex skills depicted by the 6-factor Lily model. The model proposes the following 6 overlapping literacies that determine and influence eHealth literacy: traditional literacy, health literacy, information literacy, scientific literacy, media literacy, and computer literacy. Here we explore putative variables which could enable the exploration of eHealth literacy and the 6-factor Lily model in young adults today.

Potential Factors Influencing eHealth Literacy

Functional Health Literacy

One of the fundamental variables underpinning the Lily model is functional health literacy (FHL; ie, the literacy and numeracy skills required to read and understand health information). FHL is an essential skill in navigating health information and pivotal to successful engagement with health resources over the internet. Recent studies have shown that there is a relationship between FHL and eHealth literacy; higher scores in FHL were correlated with higher scores on the eHEALS in a sample of Italian adults [21]. Until recently we have had few reliable and valid ways to measure FHL in the UK. However, the Newest Vital Sign (NVS), a new measure of FHL, has recently been adapted [22] and validated against the Test of Functional Health Literacy in Adults (TOFHLA) in the UK [23], thus enabling an exploration of a potential relationship between FHL and eHealth literacy in the TYA population in the UK.

Need for Cognition

Norman and Skinner cite Feuerstein [24] who describes media literacy as successful navigation for those who develop metacognitive reflective strategies to enable them to reflect, reason, and discern media information. As such, media literacy has been adopted as an important component of the Lily model. Although not all those who use the media have the same level of cognitive facility, we often differ in our willingness to engage in cognitive activity to aid our understanding. Need for cognition (NFC) is an individual difference which can be described as "people's tendency to engage in, and enjoy, effortful cognitive activity" ([25], p. 130). Those with high NFC enjoy problem solving, actively search for information, and reflect on the findings [26]. By contrast, those with low NFC avoid problem solving and rely on others to process and present information (eg, celebrities or powerful others). In terms of internet use, NFC is positively correlated with all internet activities involving cognitive thought [27], and also linked to cancer screening uptake such that matching health messages to information-processing styles improved mammography attendance at 6 months in high NFC women [28]. More recently NFC was explored in relation to eHealth literacy in US university students, establishing a positive relationship between high NFC and eHEALS scores, and showing those with high NFC scores would be more likely to seek out health information online [29]. Thus, it seems a natural progression to explore whether this relationship between NFC and eHEALS exists in a UK university sample.

Irrational Health Beliefs

However, it is not only cognitive capacity which underpins success in processing and utilizing health information. Generally, it is assumed that health and scientific information are processed rationally. However, some (particularly people with anxiety) have "irrational health beliefs" (IHBs) which can be explained by the cognitive–behavioral model of hypochondriasis [30,31]. People with IHBs believe serious illness to be more prevalent than it is, believe fast action health input is imperative, and fear disastrous health outcomes (if not treated) [32]. This irrationality can have a dramatic influence on young peoples' information literacy and their use and interpretation of health information and decision making (eg, in not adequately responding to the real costs and benefits of alcohol consumption) [33]. Certainly, it was found that people with higher IHBs have poorer health and are less likely to adhere to treatments [34,35]. Clearly, this could be problematic for seeking health information via the internet and using this appropriately. Indeed, this "worried and wired" combination has recently been shown to be detrimental where individual levels of health anxiety have negatively influenced the relationship between online health information seeking and health care utilization [36]. Thus, in terms of influencing the health, science, and media literacy of young people, IHB is a concept worthy of study.

Self-Efficacy

Underpinning the previously mentioned components of the Lily model, Norman and Skinner state that electronic health literacy is born out of social cognitive theory proposed by Bandura [37], with self-efficacy (SE) being a major component [38]. SE is defined as "beliefs in one's capabilities to mobilize the motivation, cognitive resources, and courses of action needed to meet given situational demands" ([39], p. 408). High SE [40] is related to engaging and maintaining healthy behaviors, and is a key component of most major health models [41]. SE is viewed as the factor to bridge the intention–behavior gap, the most eagerly pursued link of health behavior change. SE is pivotal to seeking out information and acting appropriately on it via the internet and is likely to improve the likelihood of utilizing the resources successfully [42]. Therefore, measuring young people's general levels of self-efficacy (GSE) is an important factor to explore in relation to perceived eHealth literacy.

The putative factors we have reviewed here all relate to young people's experiences of help seeking via the internet and consequent health behavior. Further, these factors reflect the overlapping literacies of the Lily model proposed by Norman and Skinner [11], namely, health literacy, information literacy, scientific literacy, media literacy, and computer literacy.

With regard to the scale to measure eHealth literacy (eHEALS) [16], this been evaluated with young adults and baby boomers in the United States, whereas in the UK and New Zealand this has been evaluated only in the latter [43]. Therefore, it would be prudent to also conduct an exploratory construct analysis on the eHEALS in a UK TYA population.

Aims

The primary aim was to explore whether factors potentially underpinning the 6 facets of the Lily model [11] (including NVS [FHL], IHBs, NFC, and GSE) are associated with and are significant predictors of eHealth literacy in young people measured by the eHEALS [16].

A secondary aim was to explore the underlying constructs of the eHEALS using an exploratory factor analysis (EFA) in a sample of university students in the UK.

Methods

Participants

Participants (n=188) were undergraduate psychology students from a UK University recruited via opportunity sampling in research methods sessions. Of these, 167 participants were female (88.8%), with a mean age of 20.13 (SD 2.16) years. The majority of participants identified their ethnicity as White British 159/188 (84.6%) and said that English was the main language spoken at home (181/188, 96.3%). Other participants described their ethnicity as Mixed 4/188 (2.1%); Pakistani, Indian, or Asian 13/188 (6.9%); any other White background 2/188 (1.1%); or Black 2/188 (1.1%). The majority were unmarried 182/188 (96.8%) and living in shared accommodation 122/188 (64.9%). Most participants 139/188 (73.9%) had not seen a health professional in the past 2 weeks. Of those that had, most had seen a general practitioner (family doctor; n=26) or a physiotherapist (n=4).

Materials

eHealth Literacy Scale (eHEALS)

The eHEALS [16] is an 8-item measure of eHealth literacy, and has an internal consistency (Cronbach α) of .88. An example question is "I know **how to use** the Internet to answer my questions about health." The responses range from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating a higher level of eHealth literacy.

Newest Vital Sign (NVS)

The NVS [22,23] is a measure of FHL, and has an internal consistency (Cronbach α) of .70. It includes a maximum of 7 questions, in which participants answer questions (involving calculations) relating to the nutritional information label on a tub of ice cream. The responses to questions are scored as either correct or incorrect and range from 0 to 6, with higher scores indicating higher levels of FHL.

Need for Cognition Scale

The Need for Cognition Scale [44] is an 18-item measure which assesses a tendency to enjoy and engage in effortful cognitive activity. It has an internal consistency (Cronbach α) of .88, suggesting good reliability. An example question is "I really enjoy a task that involves coming up with new solutions to problems". Items are scored from –4 (very strong disagreement) to 4 (very strong agreement), with higher scores signaling greater NFC.

Irrational Health Belief Scale

The Irrational Health Belief Scale [45] is a 20-item scale assessing the tendency to appraise health-related information in an irrational manner, and has an internal consistency (Cronbach α) of .90. It includes a series of vignettes to which participants have to rate their perceived response from a 5-point scale ranging from 1 (Not at all like I would think) to 5 (Almost exactly like I would think). For example, "Your doctor recommends a new medication for an ongoing health problem and indicates that about 10% of patients experience unpleasant side effects from the medicine. You think to yourself, 'If anyone is going to have side effects, it's going to be me'." Scores are summed, with higher scores relating to higher IHBs.

General Self-Efficacy (GSE) Scale

The General Self-Efficacy (GSE) [46] scale is a 10-item measure, which captures the extent to which individuals are optimistic about their ability to cope with challenging situations, and has an internal consistency (Cronbach α) of .90. An example question is "I can always manage to solve difficult problems if I try hard enough." The measure has Likert scale scoring, with responses ranging from 1 (not at all true) to 4 (exactly true). The answers are summed, with total scores ranging from 10 to 40. A higher score indicates greater SE.

Procedure

Ethical approval from the Leeds Beckett Psychology Ethics Committee was granted on December 12, 2017 (number: PH/AW/121217). Participants took part in this study in order to generate data for them to analyze in a research methods module, and gave informed consent for these data to be used in further research. All measures were programmed into Qualtrics, a web-based survey tool, and participants completed these in-exam conditions during research methods sessions over the course of 1 week in March 2018.

Data Analysis

All data analyses were conducted using IBM SPSS Statistics (version 26). Internal consistency of the scales was examined using the Cronbach alpha coefficient. The psychometric properties of the eHEALS in a UK sample were explored using EFA. We initially examined correlations between all key variables. We had theoretical grounds to suggest that GSE would be a significant predictor of eHealth literacy, therefore a hierarchical multiple regression was performed by entering GSE first and then examining the impact of NFC, IHBs, NVS, and GSE on the outcome variable eHEALS. For the NVS, 18% of the data were missing, therefore mean scores were inputted; missing data were <0.01% for other variables.

Data assumption tests were performed prior to conducting the linear regression, including Cook distance, collinearity, variance inflation factor, Durbin–Watson, and homoscedasticity. To test for normality, skewness and kurtosis values were computed prior to correlation analysis.

An EFA was used to examine the eHEALS structural validity on the 8 data item set (N=188 cases). The minimum recommended sample size to conduct an EFA is 100 [47] and if factors emerge with 4 or more loadings over 0.6, then this would be deemed reliable regardless of sample size [48]. In addition to the total variance explained, the scree plot, eigenvalues, and component loadings were assessed to verify the factor structure of the eHEALS in this population.

Results

Descriptive statistics for all key variables are presented in Table 1. All data met the requirements for parametric testing, with skewness and kurtosis values between +2.0 and –2.0 [49], with the exception of the NVS which was negatively skewed (as expected in an educated undergraduate sample). After a verbal consultation with a colleague (G. Rowlands, London South Bank University, personal communication), the decision was made not to transform the NVS data, as this has not been done using this measure before. Therefore, a Spearman nonparametric correlation coefficient (ρ) was employed for the NVS, thus elsewhere the NVS results should be interpreted with caution.

Table 1. Descriptive statistics and internal consistency for key variables.

Measure	N	Range	Mean (SD)	Cronbach α
Electronic Health Literacy Scale	188	12-40	29.46 (4.91)	.84
Newest Vital Sign	154	2-6	5.44 (0.94)	.60
General Self-Efficacy Scale	188	20-40	29.78 (3.84)	.80
Irrational Health Belief Scale	188	18-64	31.30 (9.12)	.85
Need for Cognition Scale	188	23-85	7.02 (18.97)	.90

Correlations between key variables are presented in Table 2. The main finding of interest is the significant positive correlation between eHEALS and GSE (r=0.28, P<.001). No other significant relationships were noted between eHEALS and other key variables. The GSE and NFC scores were also positively correlated (r=0.33, P<.001), and NFC and IHBs were significantly negatively correlated (r=–0.14, P=.03). Using Spearman correlations, GSE and NVS (r_s=0.14, P=.04) and NFC and NVS (r_s=0.19, P=.003) were positively correlated.

Table 2. Correlation coefficients for key variables[a].

Measure	1	2	3	4	5
1. Electronic Health Literacy Scale	—[b]	0.02	0.28[c]	–0.11	0.11
2. Newest Vital Sign	0.07	—	0.14	–0.08	0.20[c]
3. General Self-Efficacy Scale	0.28[c]	0.80	—	–0.14[d]	0.33[c]
4. Irrational Health Belief Scale	–0.11	–0.18[d]	–0.14	—	–0.14[d]
5. Need for Cognition Scale	0.11	0.19[c]	0.33[c]	–0.14[d]	—

[a] All correlations are Pearson with the exception of NVS where Spearman was performed.

[b] Not applicable.

[c] Correlation is significant at the 0.01 level.

[d] Correlation is significant at the 0.05 level.

All assumptions of the regression analysis were met, and a hierarchical procedure was performed to assess if the variables GSE, NVS, IHB, and NFC could predict eHealth literacy measured by the eHEALS. GSE was entered first into the model (Model 1) and this explained a significant proportion (8.0%) of the variance in eHealth literacy ($F_{1,186}$=16.16, P<.001, R^2=0.08). Model 2 (including GSE, NFC, IHB, and NVS) explained a nonsignificant 0.6% increase in the variance ($F_{4,183}$=4.30, P=.80, R^2=0.086). Together, both models explained 8.6% of the total variance. Table 3 shows that only GSE was a significant predictor in each model. The internal consistency of most scales was good (ie, ≤0.80), excluding the NVS, for which this was 0.60.

Table 3. Beta coefficients, standard errors (SEs), standardized betas, and significance value for each model and predictors therein.

Factors	β coefficient	SE β	Standardized β	*P*
Constant	18.71	2.70	—[a]	<.001
General self-efficacy (Model 1)	0.36	0.90	.28	<.001[b]
Constant	20.84	3.71	—	<.001
General self-efficacy (Model 2)	0.34	0.09	.27	<.001[b]
Need for Cognition	0.00	0.02	.00	.93
Irrational Health Beliefs	–0.04	0.03	–.08	.28
Newest Vital Sign	–0.07	0.32	–.01	.83

[a] Not applicable.

[b] Significant at the 0.01 level.

Using principal axis factoring an EFA was conducted on the 8 items with varimax rotation. The Kaiser–Meyer–Olkin measure verified sampling adequacy at 0.80 above the minimum criterion of 0.50, and all Kaiser–Meyer–Olkin values for individual items were 0.65 or more. The Bartlett test of sphericity was also significant at P<.001. All items on the eHEALS correlated significantly at P=.001. A determinant value of 0.023, which is greater than the required value (ie, >0.00001), revealing collinearity levels, was not detrimental to the analysis, and thus, no items were removed.

The eHEALS performed well in terms of psychometrics in this sample (Table 4): we calculated a Cronbach α value of .84 for the total eHEALS score, whereas for factors 1 and 2 this was .90 and .77, respectively, but when removing item 8, which had a coefficient of less than 4, the Cronbach α for factor 2 increased to .80. However, almost one-third scored the maximum on the eHEALS overall (Table 4).

Table 4. Descriptive statistics, floor, and ceiling effects for eHEALS[a] overall and its factors 1 and 2.

Measure	Mean (SD)	Floor effect (% of min score)	Ceiling effects (% max score)
eHEALS	29.46 (4.91)	16.48	28.12
Factor 1: Information acquisition	11.46 (0.80)	2.65	10.11
Factor 2: Information application	19.07 (1.00)	13.82	17.70

[a] eHEALS: Electronic Health Literacy Scale.

The scree plot confirmed that two factors had Eigen values over the Kaiser criterion of 1 and together explained 64.6% of the variance. Table 5 shows the results of the EFA, suggesting that factor 1 (items 1-3) represents information acquisition and factor 2 (4-8) information application.

Table 5. Summary of the exploratory factor analysis on the eHEALS[a].

Items on the eHEALS	Factor 1 (acquisition)	Factor 2 (application)
1. I know where to find helpful health resources on the Internet	.91	
2. I know how to find helpful health resources on the Internet	.78	
3. I know what health resources are available on the Internet	.72	
4. I know how to use the health information I find on the Internet to help me		.74
5. I know how to use the Internet to answer my questions about health		.63
6. I feel confident in using information from the Internet to make health decisions		.63
7. I have the skills I need to evaluate the health resources I find on the Internet		.62
8. I can tell high quality health resources from low quality health resources on the Internet		.32
Eigen values	4.0	1.2
Percentage of variance	49.4	15.1

[a] eHEALS: Electronic Health Literacy Scale.

Discussion

Principal Findings

In this exploratory study we have been the first to investigate relationships and potential predictors of key variables influencing eHealth literacy sample of UK University students. A highly significant positive relationship was found between eHEALS and GSE scores, but eHealth literacy did not significantly correlate with any other factor. However, significant positive correlations between NFC and the NVS, and between NFC and GSE were demonstrated as well as a significant negative association between NFC and IHB. Our secondary aim was to explore the underlying construct of the eHEALS in a UK TYA sample using EFA, where we found 2 underlying factors within the scale related to information *acquisition* and information *application*.

Despite the expected negatively skewed distribution indicating higher scores on the NVS in our student sample, FHL measured by the NVS was not found to be a significant predictor of eHealth literacy. Previously Del Giudice and colleagues [21] demonstrated large associations between functional and eHealth literacy; however, in their study, FHL was not directly measured but rather assumed (as a proxy measure) based on studying or working in the health sector (eg, physicians, nurses, and allied health professions). Further, Del Giudice et al [21] found that for older and better educated participants eHEALS scores were higher. Our sample comprised psychology students (a health-focused subject), but perhaps the younger age of our sample (mean age 20) could have been an influencing factor in the lack of significant association with the eHEALS scores.

In line with the literature, those who scored highly in our sample on the NVS (a test of functional literacy) also scored highly on the NFC scale. This suggests an overlap between these 2 variables in that someone who prefers effortful cognitive activity would be more likely to score highly on a functional literacy test [26]. Our findings do not support the health literacy aspect of the Lily model in terms of demonstrating a relationship between functional and eHealth literacy. However, the expected negatively skewed scores in this educated sample and the internal consistency of .60 of this scale would suggest proceeding with caution in interpretation of our findings. In future studies it may be useful to explore FHL with the NVS in a more diverse population of young people who are either unemployed or who have not had a university education, as there is an urgent need to explore the factors driving FHL in *all* young people [50] to enable successful health promotion strategies.

The significant negative association between NFC and IHBs was as predicted, as IHBs are usually strongly held and people displaying IHBs have a limited need or desire to acquire new information to challenge or inform these beliefs [32]. Although counterintuitively, this did not transfer into a tangible negative association with eHealth literacy.

Self-Efficacy

SE has been shown to be a pivotal component in the adoption and execution of healthy behaviors [51], and that it being a significant predictor of eHealth literacy would seem entirely plausible. Previously, internet SE was deemed to play a key role in the process of using the internet to acquire health information [52]. With this in mind it may be useful to explore the relationship between eHealth literacy and a measure of health-related SE (eg, [53]). Using a dedicated health SE measure may have accounted for more variance in the model and therefore may be a greater predictor. Interestingly, others have argued that the eHEALS actually measures SE rather than eHealth literacy [29]; indeed, the question prefixes (eg, “I know how to” and “I have the skills to”) would seem to tap into confidence and SE rather than assess performance. Perhaps, implementation of internet skills could not be predicted from high eHEALS scores, suggesting an incongruence between perceived and actual eHealth literacy [54]. We echo the thoughts of Britt and Hatten [29] who call for the relationship between SE and eHealth literacy to be fully explored.

Need for Cognition

We found a lack of significant correlation and predictive impact of NFC on the outcome variable (eHEALS) in contrast to the US study of young university students in which an association between the 2 variables was demonstrated [29]. It is useful to try to explain the reasons for failure to replicate these findings in a UK sample. The mean eHEALS scores and standard deviations were very similar in this study and the one conducted in the United States [29], and both samples were of a similar age. However, the US study had a larger sample yielding greater power to detect significant associations. Moreover, our UK sample produced higher NFC scores than participants in the US study, but the latter did not provide information on the types of courses the students were enrolled in. Conceivably, the type of course influenced the results, as Del Giudice and colleagues [21] found that participants' exposure to health-related study was associated with higher eHealth literacy scores.

Scale Structure

Previously the eHEALS was thought to be a unidimensional scale [16,17]; however, in the UK a confirmatory factor analysis and structured equation modeling in a large study with baby boomers in the United States, UK, and New Zealand (born between 1946 and 1954) found the eHEALS to have 3 distinct scales related to the Lily model [43]. They found items 1 and 2 related to awareness, items 3-5 related to skills to access resources, and items 6-8 evaluation of resources (self-efficacy). The authors recognize that more work needs to be done, particularly in other age groups to verify the 3-factor structure. Our findings that the eHEALS related to 2 distinct constructs, namely, information *acquisition* (items 1-3) and information *application* (items 4-8), concur with those of Soellner et al [55], who found the 2-factor structure to be more compelling than a single one. However, we would recommend continuing to explore the construct validity of the scale in different populations.

Limitations

This was a cross-sectional design and as such only measured eHealth literacy at one time point, although it may be more revealing to measure this longitudinally to explore temporal changes and responses to changing circumstance (eg, an individual's own health concerns). The skewed distribution of the NVS data and low internal consistency ensure that we proceed with caution and thus cannot conclusively state that FHL does not influence eHealth literacy in a UK TYA population. However, we also must question "Does perceived eHealth literacy (as measured by the eHEALS) translate into competent performance on the internet to gain health information?" Others have also found that the expected strong positive relationships between eHEALS scores and internet performance were absent [53]. This suggests that future studies should also focus on measuring practical internet tasks along with perceived eHealth literacy as a comprehensive measurement of true eHealth literacy.

In this study, because GSE only accounted for a small proportion of variance in our predictive model, we must speculate that alternative, more potent predictors of eHealth literacy exist. Gilstad [56] has proposed further aspects to eHealth literacy, thereby expanding the Lily model proposed by Norman and Skinner [11]. Four additional aspects to the Lily model were proposed: bodily experience, procedural literacy, contextual and cultural literacy, and communicative expertise. These additional factors are particularly pertinent to young people as they navigate seeking health information online, particularly knowledge of the norms, values, rules, and regulations in social situations (contextual and cultural literacy) and bodily experience (the ability to identify a health problem in one's own body). A recent work [57] demonstrated that delayed help seeking for potential breast cancer in females was associated with dissatisfaction with their breasts. Given that body dissatisfaction increases for both males and females as they transition to young adulthood [58], it would be interesting to explore whether body dissatisfaction could impact on their eHealth literacy.

Conclusion

We are reassured that NHS England [59] is working toward improving health literacy to reduce health inequalities, and perhaps there should be a greater directive to expand this initiative to include eHealth literacy. eHealth literacy should not be seen as a static state, but rather as a dynamic evolving skill set that will develop over time and in response to individual need and circumstance [11]. This would seem a logical step forward to serve digitally native young people as these are the generation that will "Google it" for health information into adulthood.

In conclusion, this is the first study in the UK to explore relationships between these key variables in a TYA population, and to perform EFA on the eHEALS with a TYA sample in the UK. As such, we can confirm the stability of the scale. The findings that SE has a major influence on eHealth literacy should consolidate its status as underpinning the Lily model, and as a fundamental starting point from where eHealth literacy is developed and understood. Future studies will explore physical and mental health status, health SE, and body image as potential predictors of eHealth literacy in more diverse TYA populations.

Conflicts of Interest

None declared.

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Abbreviations

EFA: exploratory factor analysis
eHEALS: Electronic Health Literacy Scale
FHL: functional health literacy
GSE: general self-efficacy
IHB: irrational health belief
NFC: need for cognition
NVS: Newest Vital Sign
SE: self-efficacy
TOFHLA: Test of Functional Health Literacy in Adults
TYAs: teenagers and young adults

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Original Paper

Phone Calls to Retain Research Participants and Determinants of Reachability in an African Setting: Observational Study

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Abstract

Background: Long-term retention of research participants in studies is challenging. In research in sub-Saharan Africa, phone calls are the most frequently used method to distantly engage with participants.

Objective: We aimed to get insight into the effectiveness of phone calls to retain contact with participants and evaluated determinants of reachability.

Methods: A cross-sectional study was performed using the databases of two randomized controlled trials investigating different kinds of antiretroviral therapy in HIV-positive patients. One trial finished in 2018 (study 1), and the other finished in 2015 (study 2). A random sample size of 200 participants per study was obtained. There were up to 3 phone numbers available per participant collected during the studies. Participants received a maximum of 3 phone calls on every available number on different days and at different times. Voicemails were left, and emails sent wherever possible. We documented how many calls were answered, who answered, as well as after how many attempts participants were reached. To further increase our understanding of reachability, we conducted a short questionnaire assessing factors contributing to reachability. The study was approved by the Research Ethics Committee of the University of Witwatersrand, Johannesburg, South Africa (reference number M1811107).

Results: In our sample size of n=200 per study, study 1, with a median time of 11 months since the last visit at the research site, had a response rate of 70.5% (141/200) participants while study 2, with a median duration of 55 months since the last visit, had a response rate of 50.0% (100/200; *P*<.001). In study 1, 61.5% (123/200) of calls were answered directly by the participant while this was 36.0% (72/200) in study 2 (*P*=.003). The likelihood of reaching a participant decreased with time (odds ratio [OR] 0.73, 95% CI 0.63 to 0.84) for every year since the last face-to-face visit. Having more phone numbers per participant increased reachability (OR 2.32, 95% CI 1.24 to 4.36 for 2 phone numbers and OR 3.03, 95% CI 1.48 to 6.22 for 3 phone numbers compared with 1 number). A total of 141 of 241 reached participants responded to the questionnaire. Of the 93 participants who had changed phone numbers, 5% (50/93) had changed numbers because their phone was stolen. The most preferred method of being contacted was direct calling (128/141) with participants naming this method followed by WhatsApp (69/141).

Conclusions: Time since last visit and the number of phone numbers listed were the only determinants of reachability. Longer follow-up time is accompanied with a decrease in reachability by phone while more listed phone numbers increases the likelihood that someone can be reached.

Trial Registration: ClinicalTrials.gov NCT02671383; https://clinicaltrials.gov/ct2/show/NCT02671383 and ClinicalTrials.gov NCT02670772; https://clinicaltrials.gov/ct2/show/NCT02670772

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KEYWORDS

retention; loss to follow-up; phone; mobile phones; HIV; ART; South Africa

Introduction

Mobile phone use has global penetration, making it accepted as an effective method to reach patients and participants during follow-up in research over the past years [1-3]. In South Africa, 97% of households have access to a mobile phone [4]. However, experience has shown that reachability and accessibility by phone is challenging due to changes of phone numbers. Theft and loss of phones are common, with approximately 40% of participants in a study in Durban, South Africa, reporting that they lost a previously owned phone [5]. These factors result in a loss of connection with the participant and loss to follow-up.

Studies in low- and middle-income settings suffer from low rates of retention. One study in Togo including 16,617 HIV-positive patients showed that 7% were lost to follow-up after initiation of treatment after 6 months. In another study, of 13,726 participants whose phone number was listed, 80% were not reachable on the known phone number [6]. In a study in Cote d’Ivoire of patients on antiretroviral therapy (ART), an attempt was made to trace approximately 7000 patients through telephone calls who were lost to follow-up. Of these, only 40% of the patients could be contacted [7].

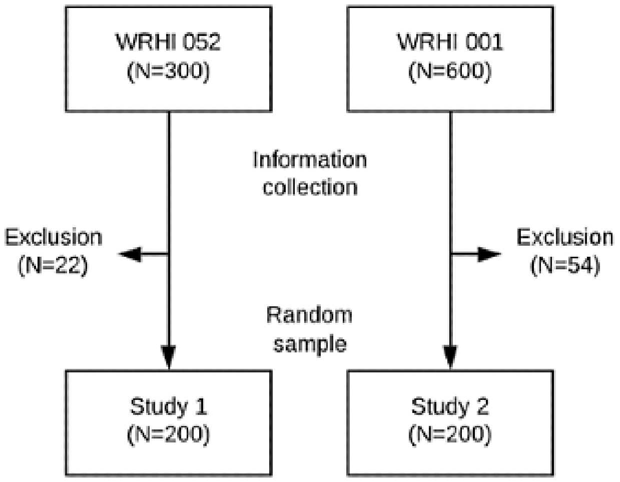
These studies raise concern about the effectiveness of telephonic follow-up as the primary method for contact and retention. There are few studies investigating the effectiveness of the use of phone numbers for follow-up in research. Insight into the frequency of nonreachability of participants and the relation with follow-up time and participant characteristics will help to develop more targeted strategies and novel ways to facilitate maintaining contact with participants in long-term follow-up studies in the future. Hence, in this study we aimed to get insight into the use of phone numbers to retain contact with participants in a study setting and evaluated determinants of reachability using a reachability questionnaire.

Methods

Study Population

A cross-sectional study was conducted using the databases of two completed randomized controlled trials with participants diagnosed with HIV receiving ART, study 1: WRHI 052 [8] [NCT02671383] and study 2: WRHI 001 [9] [NCT02670772] (only patients recruited at the South African site were eligible for this study). The trial methods are published elsewhere [8,9]. The participants’ contact details were updated at every study visit for both trials. The latest available contact information files were used in this study. All participants in both studies consented for the use of their information and the option to be contacted for further research. Participants were excluded from this study when there were no phone numbers listed, the participant withdrew from one of the studies, or the participant was known to be deceased. Exclusion for no phone numbers listed and known deceased status resulted in 22 exclusions in study 1 and 54 exclusions in study 2. Sampling was done using the contact sheets of both studies including all participants that came for a final follow-up visit. In April 2019, a random sample of 200 participants per study was obtained (Figure 1).

Figure 1. Flowchart of sample selection.



The study was approved by the Human Research Ethics Committee of the University of Witwatersrand (reference number M1811107). Participation was voluntary, and informed consent was obtained verbally after explaining the study using an information sheet and answering any questions. This verbal consent was recorded using Skype for Business recording manager and securely stored digitally.

Study Design

During the period April to June 2019, participants were contacted by phone by a single researcher. When someone answered the phone, the participant was identified by name and date of birth. Data were collected and managed using Research Electronic Data Capture (REDCap) [10]. When not reached on the first attempt, each participant was called on each available phone number to a maximum of 3 times. A participant with 3 listed phone numbers who did not answer would, therefore, be called 9 times in total. The first call attempt was made in the afternoon between 13:00 and 16:00, the second call in the morning between 9:00 and 12:00. Both calls were made from Monday to Friday. The third call was made on a Saturday between 9:00 and 16:00. No repeat calls were made on the same day, Sundays, and public holidays. If a participant did not answer after the third round, a voicemail would be left on all numbers, if this option was available, with the request to call back. Furthermore, if an email address was available a message would be sent after the third attempt on every number with a request to return the call or send an email indicating what number should be used and what time would be best for a phone call. A person could either be reached or not reached; the criteria for labeling reached or not reached can be found in Textbox 1.

Textbox 1. Criteria for labeling reached or not reached.

Reached:

- Participant answered the phone, responded to voicemail, or responded to email
- Someone else (friend and/or family) answered the phone and would be able to get a message to the participant

Not reached:

- No response after three calls, voicemail, and email
- Someone else (friend and/or family) responded but would not be able to get a message to the participant

If someone else (friend and/or family) answered, this person was specifically asked if it would be possible to send the participant a message. If the phone was answered and the participant was identified, the reason for the call was explained and informed consent was obtained verbally through the phone. If the participant was fluent in English, a study-specific questionnaire was administered. In case a participant picked up the phone but was unable to complete the questionnaire due to time constraints, an additional 3 calls were made at a time that suited the participant to attempt questionnaire completion. If the participant did not answer the phone anymore, the questionnaire could not be completed but the participant was still labeled as reached.

Questionnaire

The aim of the questionnaire (Multimedia Appendix 1) was to edit or complement the available personal information and gain more information about the reachability of the participant. The questionnaire consisted of 8 questions with subquestions to clarify a given answer. The questionnaire took around 5 to 10 minutes to complete. The questionnaire was piloted prior to data collection. The following information was checked and amended if necessary: city of residence, country of origin, and tribe or race of the participant. Assessment of reachability was completed by evaluating if all listed phone numbers were still correct and active. Phone numbers were determined to be correct when a participant or someone knowing the participant answered. Phone numbers were determined to be incorrect when the phone number was out of service or the person that answered the phone did not know the participant. The phone number status unknown was given if phone numbers were active and reachable although the phone was not answered; these phone numbers could not be identified as correct or incorrect. The following information was obtained: how many phone numbers does the participant currently have in use and why, how long has the participant been using the current phone number, has the phone number been changed and the reasons for changing phone numbers, use of email and reachability by email, and use of WhatsApp and reachability by WhatsApp. Last, the participant was asked what the best method to contact the participant would be.

Statistical Analysis

Statistical analysis was done using SPSS Statistics version 25.0 (IBM Corporation). A $P<.05$ was considered statistically significant. Baseline characteristics were presented as means with standard deviation or as medians with interquartile ranges (IQR) in case of nonnormally distributed data. To test for differences between study 1 and study 2, an independent *t* test was used for continuous and dichotomous variables and a chi-square test was used for categorical variables. Logistic regression was used to test the effect of variables on reachability, and results were presented using odds ratios (OR) with 95% confidence intervals and *P* values. Confounders considered for reachability were age, gender, country of origin, and number of available phone numbers. Factors with a $P<.20$ in univariable analysis were included in multivariable analysis.

Results

In total, 400 participants were called and included in this analysis. In study 1, the mean time since last visit was 0.89 (SD 0.64) years, and for study 2 this was 4.58 (SD 0.41) years ($P<.001$). The average age was significantly different between groups as participants in study 1 were on average 3.95 years older ($P<.001$). Gender and country of origin were evenly distributed between the studies. City of residence ($P=.007$) and tribe or race ($P=.002$) were both significantly different between groups with more participants residing in Johannesburg and more participants from the Zulu race in study 1 and more participants from the Ndebele race in study 2. Participants in study 1 had fewer phone numbers listed per participant. The average number of phone numbers in study 1 was 1.88 (SD 0.67) versus 2.70 (SD 0.53) in study 2 ($P<.001$). Baseline characteristics are shown in Table 1.

In total, 915 phone numbers were called for the 400 participants, and 60.3% (241/400) of participants answered the phone during the 3 rounds of calling. This outcome was significantly different between studies with a response rate of 70.5% (141/200) for study 1 and 50.0% (100/200) for study 2 (*P*<.001). Of the 241 participants who answered, after division in calling rounds, most of the participants were reached in round 1 (176/241), with decreasing numbers for rounds 2 (42/241) and 3 (23/241) with a significant difference between study 1 and study 2 (*P*<.001; Table 2).

After 3 rounds of calls, 71 voicemails were left using every phone number with voicemail available of the remaining 159 participants. Moreover, an email was sent to 15 participants that had not answered and had an email address available. Of the 71 voicemails, 2 participants returned the call, but no response was received by email.

Time since last visit was significantly associated (*P*<.001) with a decreased chance of answering the phone in univariable analysis with an OR 0.794 (95% 0.713-0.885) for each additional year (Table 3).

When the answered calls were disaggregated by participant answering the phone, someone else (friend and/or family) answering, or no answer, in study 1, 61.5% (123/200) were answered by the participant while this was 36.0% (72/200) in study 2 (*P*=.003; Figure 2).

Table 1. Study population characteristics.

Characteristics	Participants	Study 1 (n=200)	Study 2 (n=200)	*P* value
Age in years, mean (SD)	400	43.84 (8.1)	39.89 (7.5)	<.001
Gender, female, n (%)	400	135 (67.5)	119 (59.5)	.10
City of residence, Johannesburg, n (%)	141	79 (86.8)	42 (84)	.007
Country of origin, n (%)	399	200	199	.19
South Africa	234	127 (63.5)	107 (53.8)	N/A[a]
Zimbabwe	147	65 (32.5)	82 (41.2)	N/A
Other	18	8 (4)	10 (5)	N/A
Tribe or race, n (%)	137	88	49	.002
Zulu	48	35 (39.8)	13 (26.5)	N/A
Ndebele	37	17 (19.3)	20 (40.8)	N/A
Others	52	36 (40.9)	16 (32.7)	N/A
Time since enrollment in years, mean (SD)	400	2.37 (0.27)	6.16 (0.37)	<.001
Time since last visit in years, mean (SD)	400	0.89 (0.64)	4.58 (0.41)	<.001
Listed phone numbers, n (%)	400	200	200	<.001
1	65	58 (29.0)	7 (3.5)	N/A
2	155	109 (54.5)	46 (23)	N/A
3	180	33 (16.5)	147 (73.5)	N/A

[a] N/A: not applicable.

Table 2. Phone call results.

Outcomes	Participants	Study 1 (n=200)	Study 2 (n=200)	*P* value
Answered phone in total, yes, n (%)	241 (60.3)	141 (70.5)	100 (50.0)	<.001
Answered phone in calling round, n (%)				<.001[a]
Round 1	176 (73.0)	107 (75.9)	69 (69.0)	N/A[b]
Round 2	42 (17.4)	24 (17.0)	18 (18.0)	N/A
Round 3	23 (9.5)	10 (7.1)	13 (13.0)	N/A
Reachability, n (%)				.003
Participant	195 (48.8)	123 (61.5)	72 (36.0)	N/A
Someone else, friend, and/or family	46 (11.5)	18 (9.0)	28 (14.0)	N/A
Unanswered	159 (39.8)	59 (29.5)	100 (50.0)	N/A

[a] Probability calculated using a chi-square test for the difference in answers between study 1 and 2 for all rounds.

[b] N/A: not applicable.

Table 3. Univariable and multivariable analysis of phone answering.

Characteristics	Univariable OR[a] (95% CI)[b]	*P* value	Multivariable OR (95% CI)[b]	*P* value
Time since last visit	0.794 (0.713 to 0.885)	<.001	0.728 (0.631 to 0.839)	.001
Age	1.026 (1.000 to 1.053)	.047	1.018 (0.990 to 1.045)	.21
Gender, male	1.257 (0.826 to 1.912)	.29	N/A[c]	N/A
Country of origin				
South Africa	Ref[d]	N/A	N/A	N/A
Non-South Africa	0.010 (–0.092 to 0.111)	.85	N/A	N/A
Number of phone numbers				
1	Ref	N/A	N/A	N/A
2	1.650 (0.915 to 2.975)	.10	2.321 (1.236 to 4.358)	.009
3	1.173 (0.663 to 2.075)	.58	3.038 (1.484 to 6.221)	.002

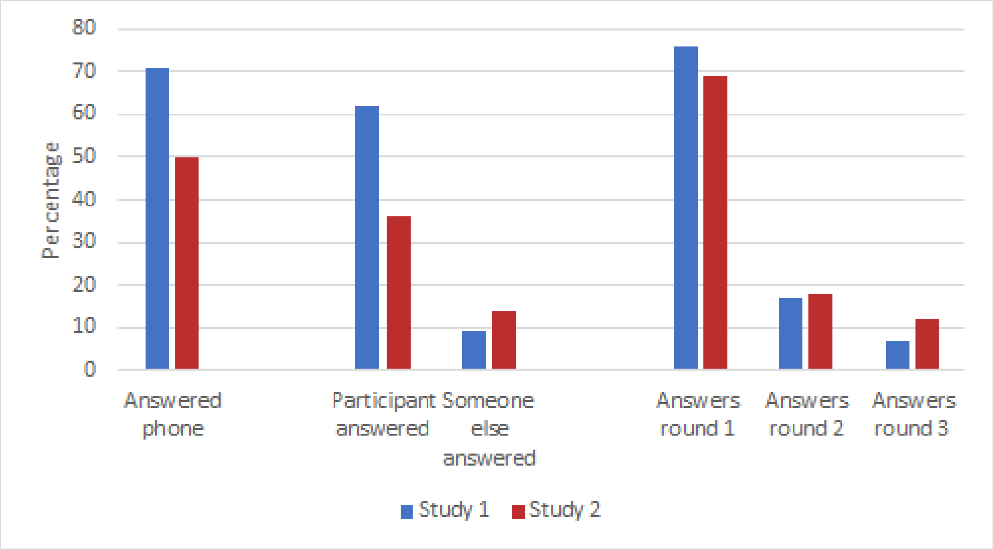
[a] OR: odds ratio.

[b] Calculated using logistic regression.

[c] N/A: not applicable.

[d] Ref: reference.

Figure 2. Reachability comparison between study 1 and study 2.



Additional adjustment for age and number of phone numbers strengthened the relation between years since last visit and reachability (OR 0.728, 95% CI 0.631 to 0.839).

The number of phone numbers listed was associated with answering the phone. Two phone numbers listed increases the odds of the participant answering the phone by OR 2.321 (95% CI 1.236 to 4.358), and three phone numbers listed increased odds by OR 3.038 (95% CI 1.484 to 6.221) with *P*=.009 and *P*=.002, respectively, compared with only having one phone number listed. Age, gender, and country of origin were not significantly related to reachability.

Of the participants who answered the phone, 72.3% (141/195) allowed the questionnaire to be completed. The other participants did not want to complete the questionnaire or they were not fluent enough in English to understand the questions.

Of all the listed phone numbers, 65.4% (598/915) could be identified as either correct (383/915, 41.9%) or incorrect (215/915, 23.5%). Of the questionnaires taken, 36.2% (51/141) of participants reported using more than one phone number. The median time the questionnaire participant had been using the reached phone number was 9 (IQR 5.75-11) years. Participants often changed their number, with 64.6% (93/144) of the participants reporting having ever changed their phone number with the main reason for a change in phone number being theft of the phone, reported by 53.8% (50/93) of participants. Only 36.2% (51/141) reported having an email address and being easily reachable through it, 84.4% (119/141) reported having WhatsApp and being easily reachable on it. Of the 141 participants, 128 said the best method of connecting with them would be calling directly, followed by WhatsApp with 69 participants (Table 4).

Table 4. Questionnaire results.

Questionnaire outcomes	Participants, n (%)
Questionnaires taken, n (%)	141
Study 1 (n=200)	92 (46.0)
Study 2 (n=200)	51 (25.5)
Phone numbers called (1-3 numbers per participant)	915
Correct[a], n (%)	383 (41.9)
Incorrect[b], n (%)	215 (23.5)
Unknown[c], n (%)	317 (34.6)
Use of more than 1 phone number, n (%)	51 (36.2)
Time using current phone in years, median (IQR)[d]	9 (5.75-11)
Reasons for change—phone stolen, n (%)	50 (53.8)
Email user and reachable, n (%)	51 (36.2)
WhatsApp user and reachable, n (%)	119 (84.4)
Best method to reach (>1 answer possible), n	
Calling	128
WhatsApp	69
SMS[e]	25
Email	11

[a] Status correct was given when a participant or someone knowing the participant answered.

[b] Status incorrect was given when the phone number was out of service or the person who answered the phone did not know the participant.

[c] Status unknown was given if phone numbers were active and reachable, but the phone was not answered; these phone numbers could not be identified as correct or incorrect.

[d] IQR: interquartile range.

[e] SMS: short message service.

Discussion

Principal Findings

In our study of 400 participants with varying time since the last visit to the study site, we could only subsequently reach 60.3% (241/400). None of the sociodemographic factors that were investigated showed a relation to reachability. Time since last visit and the number of phone numbers listed were the only determinants of reachability. This is the first study we are aware of that assesses the use of phone calls to stay in contact with participants in an urban African setting and how to increase reachability with these phone numbers. Phone calls are widely implemented and yet sparsely investigated.

Literature on determinants of and guidelines for retention in follow-up is scarce, but there is literature on retention percentages over time in HIV/ART studies. In a cohort study in HIV-positive patients on ART in South Africa, the incidence rate of loss to follow-up increases with time with 81.8% retention after 2 years and 54.7% retention at 5 years [11]. A systematic review of 33 patient cohorts from numerous HIV studies in sub-Saharan Africa showed that the mean retention rates were 79%, 75%, and 62% at 6, 12, and 24 months after enrollment, respectively. At 2 years, the best program retained 85% and the worst 46% [12]. Our study showed a reachability rate of 71% at 2.4 years and 50% at 6.2 years since time of enrollment. The reachability in our study is above average when compared with loss to follow-up in other studies. This might have been due to the extensive attempts to reach our participants including multiple phone calls at different times. Our questionnaire reveals a high percentage of incorrect phone numbers. Although no literature was found on the effect of the number of phone numbers per participant on reachability rate, our study shows that reachability could potentially be increased by collecting more than one phone number and by updating phone numbers at every possible occasion.

The vast majority of people who could be reached indicated a willingness to be reached via WhatsApp. WhatsApp could be an effective way to increase retention in follow-up because of the simplicity, low cost, and high percentage of users [13]. Currently, there are numerous dedicated apps that have been developed and investigated to contact participants through (push) messages to their phones [14,15]. Privacy guidelines are required for further implementation of these dedicated apps or even WhatsApp in the health care and research settings.

Limitations

Our study comes with some limitations. We could only conduct the questionnaire if people answered the phone. Therefore, we have no information on participants who were nonreachable, and this group is crucial to better understand reasons for loss to follow-up and ways to increase retention. A second group that is underrepresented in our study is the non-English speaking group. They could not participate in the questionnaire, even though this group might have different opinions on reachability and what is important to stay in follow-up. Another limitation was related to the person who answered the call. If someone else (friend and/or family) answered but was unsure about the availability of giving a message to the participant, the call would be registered as not answered. Strengths of this study are the systematic method to evaluate phone numbers to retain participants in follow-up, the relatively large sample size, and the investigation for factors that contribute to loss to follow-up.

Conclusion

Time since the last face-to-face visit is the main determinant for loss to follow-up in research projects in an urban African setting, while participants having more than one phone number increases the likelihood of staying in touch. The high frequency of incorrect and/or unidentified phone numbers indicates that every contact session with the participant should be used to verify and amend the available phone numbers. To further enhance reachability, the potential of WhatsApp or dedicated phone apps should be explored. Although WhatsApp was recommended as a preferred method of contact, second to phone calls, more research needs to be done to investigate what communication method is preferred by participants who did not respond to phone calls.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Connect Reachability Questionnaire.
[DOCX File , 15 KB - formative_v4i9e19138_app1.docx]

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Abbreviations

ART: antiretroviral therapy
IQR: interquartile range
OR: odds ratio
REDCap: Research Electronic Data Capture

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Original Paper

Message Appeals on an Instagram Account Promoting Seat Belt Use That Attract Adolescents and Young Adults: Elaboration-Likelihood Perspective Study

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Abstract

Background: Adolescents and young adults demonstrate the highest rate of unrestrained motor vehicle fatalities, making the promotion of seat belt restraint a priority for public health practitioners. Because social media use among adolescents and young adults has proliferated in recent years, it is critical to explore how to use this tool to promote seat belt use among this population. Social media posts can contain various types of information within each post and this information can be communicated using different modalities.

Objective: In this study, based on the elaboration likelihood model, we aimed to examine how adolescents and young adults reacted to different appeals in various components of posts in the pilot of a promotion intervention on the Instagram *BuckleUp4Life* account.

Methods: Using thematic analysis, we examined different appeals in 3 components (photo, text, and caption) of 199 posts in *BuckleUp4Life* and compared the number of likes for different appeals.

Results: We found that 6 appeals were used in the posts: rational, ego, social, fun, positive emotional, and fear appeals. The results of our study showed that in photos, fun appeals were the most popular. Rational and positive emotional appeals were the most appealing in text and captions. Regardless of the location of the components (photo, text, or captions), rational appeal was the most popular appeal.

Conclusions: Based on the findings of our study, we recommend that public health practitioners utilize fun photos with rational and positive emotional appeals in text and captions rather than fear or social appeals, when promoting seat belt use through social media, especially Instagram.

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KEYWORDS

rational appeal; ego appeal; social appeal; fun appeal; positive emotional appeal; fear appeal; social media; youth; adolescents; health information; car safety

Introduction

Background

Despite improvements in vehicle safety, motor vehicle crashes remain a major public health concern and a leading cause of death in the United States (Centers for Disease Control and Prevention) [1]. While there has been an overall increase in seat belt restraint use, accompanied by a decrease in unrestrained fatalities, 49% of motor vehicle fatalities involve unrestrained occupants (National Center for Statistics and Analysis) [2]. Additionally, adolescents and young adults represent the largest proportion of unrestrained fatalities [2]. As motor vehicle crashes and fatalities continue to be a significant health concern among adolescents and young adults, social media platforms may provide an effective means to promote motor vehicle safety (National Highway Traffic Safety Administration) [3].

Most teenagers in the United States between the ages of 13 years and 17 years report using social media sites such as YouTube (85%), Instagram (72%), Snapchat (69%), Facebook (32%), and Twitter (32%) [4]. These levels of social media use among teenagers have led health organizations and health care professionals to recognize that social media sites are viable platforms for public health communication and for adopting new communication channels for health promotion interventions [5,6]. Several research studies have shown how professionals have used social media, particularly Facebook [7] and Twitter [8], for health communication in different public health fields. For example, researchers have examined how social media sites have been used to promote physical activity [8-10], diabetes awareness, and mental health [11]. However, no researchers, to our knowledge, have examined how social media sites are or could be used as a health intervention to promote seat belt use.

While social media posts can potentially be used to promote seat belt use among adolescents and young adults, it is still unclear what kinds of persuasive appeals in this new medium are most effective at attracting the young generation. Previous research has examined the appeals of mass media [12] and websites [13] in road safety communication campaigns. Guttman [13] examined persuasive appeals in over 300 road safety health communication campaigns from 41 countries, mainly on websites of road safety organizations. Guttman categorized 5 main types of persuasive appeals, namely, appealing to reason, appealing to “negative” and “positive” emotions, the threat of enforcement, and the use of humor.

According to the elaboration likelihood model (ELM), there are 2 routes by which outside messages influence and persuade an individual: the central and peripheral routes of persuasion [14]. The central route describes the perception of a message that health educators think about (ie, elaborate upon) more thoroughly compared to the peripheral route, in which less thought occurs at a lower elaboration level. Rational appeal, one of Guttman’s categories of persuasive appeals, requires the audience to go through the central route, which focuses on the content and arguments of the message [13]. The ELM asserts that people are more likely to process information through a central route when the information requires reasoning or thorough understanding [14]. The ELM shows that people can be attracted to peripheral cues or appeals such as liking, consensus, or credibility, rather than the content or the argument of the message [14]. The “negative” and “positive” emotions, the threat of enforcement, and the use of humor in Guttman’s categorization can peripherally persuade an audience [13]. For example, the National Cancer Institute reported in as early as 2004 that positive emotional appeals were better accepted when viewers comprehended the action portrayed in the message and that health communication campaigns should avoid high degrees of fear arousal, unless the fear is easily resolvable [15]. In addition, the use of humor could attract an audience to a particular content because enjoyment is one of the main reasons people use social networking sites [16].

According to Witte et al [17], people consider fear as either a motivator or an inhibitor for behavioral change depending on their perceptions of the risks and their willingness to change the situation or their behaviors. Some have recommended that health communication campaigns avoid high degrees of fear arousal unless the fear is easily resolvable [15]. However, very few research studies have examined different appeals about seat belt use promotion on Instagram. Furthermore, only few studies have explored the appeals that attract the young audience on Instagram.

Of the main social media sites, Instagram is one platform in which one can use both the central and peripheral routes of persuasion [18]. Instagram is a web-based social networking site that allows users to share photos and videos with texts directly. On Instagram, users can post images or videos permanently on their profile or as stories, which disappear from users’ profiles, feeds, and direct inboxes after 24 hours. Instagram posts can serve to inform, entertain, or express an opinion [18]. Appeals in both the central and peripheral routes can be presented in one or more of these 3 components of a post: photo, text, and caption. Additionally, Instagram users may publicly display their reactions to other user’s content by “liking” a post or commenting on a post.

The *BuckleUp4Life* account on Instagram was created for a pilot Instagram intervention promoting the use of seat belts among high school adolescents and young adults [19]. It was developed in the fall of 2014 with approximately 1000 followers, and this account included high school adolescents and young adults by the end of 2015. This account was open to the public with a hashtag #SeatbeltSelfie. This site was promoted by a group of 20 undergraduate nursing students who inputted 1-3 daily posts that resulted in an average of 19 likes per day in the *BuckleUp4Life* Instagram account. Working with the injury prevention program in the Level 1 trauma department of a local hospital, the nursing students used 3 high school health fairs to advertise the *BuckleUp4Life* Instagram account. The high school adolescents and nursing students could also invite their friends to follow the account. Thus, the followers of this account were not limited to high school adolescents and undergraduate nursing students. This pilot health communication intervention provided an opportunity to observe the persuasive appeals that the nursing students used to collect data on the audience reactions to the different appeals about seat belt use promotion.

Research Questions

Our research examined the types of persuasive appeals used by the *BuckleUp4Life* Instagram account and how those appeals were received by the audience.

Our first research question (RQ1) was as follows: What are the different types of persuasive appeals in different components (photo, text, and caption) of the posts in the *BuckleUp4Life* Instagram account?

Our second question (RQ2) was as follows: Are the distributions of the types of appeals different among different components (photo, text, and caption) in the posts in the *BuckleUp4Life* Instagram account?

Our third research question (RQ3) was as follows: What is the relationship between the different appeals and the number of likes in the different components of the post (photo, caption, and text)?

The fourth research question (RQ4) was as follows: What are the differences in the number of likes among the different appeals, regardless of the components of the posts?

Methods

We used thematic analysis [20] to code the appeals that appeared in each component (photo, text, and caption) of 199 posts occurring between September 2014 and September 2015 in the *BuckleUp4Life* Instagram account [21]. Thematic analysis was used to pinpoint, examine, and record patterns of meaning (or “theme”) within each post. Additionally, we recorded the number of likes for each appeal in each component of the posts on Instagram.

To ensure rater accuracy and coding reliability, 2 public health students used 5 rounds of coding with 49 posts to obtain a consensus on the component’s appeal categories. The first author met with the 2 raters to discuss the disagreement and reconcile them in each round of coding and revised the coding scheme accordingly. To test interrater reliability, we independently coded 49 posts by indicating “yes” or “no” to each appeal identified on 3 aspects of a post: photo, text, and caption. Holsti tests indicated an interrater reliability of 77%-95% for the 5 rounds of coding. After the interrater reliability reached a satisfactory level (>0.80) for each appeal, 2 research principals coded the 199 posts.

We used descriptive statistics to examine the distribution of the number of likes each appeal received for the 3 post components (photo, text, and caption; RQ2). Because the number of likes for each characteristic were not normally distributed, we used Mann-Whitney *U* tests to compare the mean number of likes for each element within the same component to the mean number of likes of all the remaining cases (RQ3). We examined the similarity of the histogram distribution of any 2 pairs of elements entering a test prior to the Mann-Whitney *U* test. We aggregated the same characteristic across 3 aspects, examined the normality and outliers for the number of likes, and compared all the characteristics for their mean number of likes by using one-way analysis of variance (RQ4). We set the alpha at .05 and used SPSS 25 (IBM Corp) for all statistical analyses.

Results

Analysis of RQ1 and RQ2

We identified 6 main appeals used in the different components of the posts in the *BuckleUp4Life* Instagram account: rational, ego, social, fun, positive emotional, and fear (Table 1).

Rational appeal: We identified the rational appeal as using logical reasoning or the central route of persuasion to provide justification for seat belt use. We found 4 rational appeals in photos, 38 in text, and 52 in captions.

Ego appeal: Instagram users can post selfies while wearing seat belts and share their own seat belt wearing experience. We identified ego appeal as selfies (self/group images taken by an individual in the photo) and any information bolstering of self-image of wearing a seat belt. We found 55 selfie appeals in photos, 8 in texts, and 9 in captions.

Positive emotional appeal: We identified positive emotional appeals as showing or promising positive emotions, promise of acceptance, love, or related rewards. We found 10 positive emotional appeals in photos, 26 in text, and 27 in captions.

Fun appeal: We included humor, sarcasm, jokes, excitement, and entertainment as fun appeals. For example, we identified cartoon characters and toys as fun appeals primarily because of their entertainment characteristics. We found 42 fun appeals in photos, 18 in texts, and 6 in captions.

Fear appeal: We identified fear appeal as any information that could evoke fear. We identified 8 fear appeals in photos, 12 in texts, and 9 in captions.

Social appeal: We defined any collective actions, including social events and gatherings for seat belt use promotion, as social appeals. Appeals to social value cater to solidarity or collective actions. Collective actions, including social events, demonstrate social support in an offline setting. We found 34 social appeals in photos, 17 in texts, and 20 in captions.

Table 1. Association between the number of likes and appeals in different components of the Instagram posts (N=199).

Components, appeals, and likes	n (%), Values	Mean	*U* (Mann-Whitney)	*P* value
Photo				
Fun			1641	.001
Yes	42 (21.1)	19		
No	157 (78.9)	35		
Fear			668.5	.56
Yes	8 (4.1)	23		
No	191 (95.9)	32		
Rational			177	.06
Yes	4 (2.1)	59		
No	195 (97.9)	31		
Social			646.5	.001
Yes	34 (17.1)	13		
No	165 (82.9)	35		
Positive emotions			913	.88
Yes	10 (5.1)	24		
No	189 (94.9)	32		
Ego			3236.5	.05
Yes	55 (27.6)	25		
No	144 (72.4)	34		
None			2261.5	.001
Yes	80 (40.2)	43		
No	119 (59.8)	23		
Text				
Fun			1507.5	.63
Yes	18 (9.1)	39		
No	181 (90.9)	30		
Fear			840	.15
Yes	12 (6.1)	34		
No	187 (93.9)	31		
Rational			1965.5	.001
Yes	38 (19.1)	40		
No	161 (80.9)	29		
Social			536	.001
Yes	17 (8.5)	14		
No	182 (91.5)	33		
Positive emotions			1425	.003
Yes	26 (13.1)	41		
No	173 (86.9)	30		
Ego			657	.52
Yes	8 (4.1)	21		
No	191 (95.9)	32		
None			3966.5	.02

Components, appeals, and likes	n (%), Values	Mean	*U* (Mann-Whitney)	*P* value
Yes	92 (46.2)	27		
No	107 (53.8)	35		
Caption				
Fun			366.5	.13
Yes	6 (3.1)	43		
No	193 (96.9)	31		
Fear			665	.27
Yes	9 (4.5)	31		
No	190 (95.5)	31		
Rational			2596.5	.001
Yes	52 (26.1)	38		
No	147 (73.9)	29		
Social			857.5	.001
Yes	20 (10.1)	16		
No	179 (89.9)	33		
Positive emotions			1495.5	.003
Yes	27 (13.6)	39		
No	172 (86.4)	30		
Ego			604	.14
Yes	9 (4.5)	18		
No	190 (95.5)	32		
None			3760	.009
Yes	85 (42.7)	29		
No	114 (57.3)	33		

Analysis of RQ3

People liked some *BuckleUp4Life* posts much more than the others, with the number of likes per post ranging from 7 to 158. We found that for appeals in photos, fun demonstrated a significantly positive association with the number of likes (Table 1, *P*<.001). For appeals in text and in captions, rational and positive emotional appeals had significantly positive associations with the number of likes (*P*<.001). Social appeal had a significantly negative association with the number of likes for photos and captions (*P*<.001) (Table 1).

Analysis of RQ4

To examine the differences in the number of likes among the different appeals regardless of their locations in different components of the posts (RQ4), we averaged the number of likes for each appeal across the 3 components (photo, text, and caption). We found a significant difference in the number of likes across the 6 appeals (F=8.537, *P*=.01). Tukey's honest significant difference postdoc testing revealed that the number of likes for social appeal was significantly lower than that for fear, ego, positive emotional, and rational appeals (*P*=.04, *P*=.02, *P*=.01, and *P*=.01, respectively). The number of likes for fun was significantly lower than that for positive emotional and rational appeals (*P*=.02). The number of likes for fear was significantly lower than that for rational appeal (*P*=.05). The number of likes for ego appeals was significantly lower than that for positive emotional and rational appeals (*P*=.01, Table 2).

Table 2. Comparison of the mean number of likes among the different appeals in Instagram posts.

Type of appeal (mean number of likes)	Social (4.9)	Fun (8.1)	Fear (9.1)	Ego (10.7)	Positive emotional (12.9)	Rational (15.4)
Social (4.9)						
d[a]	0	3.2	4.2	5.8	8.0	10.5
P value[b]	—[c]	.16	.04	.02	.001	.001
Fun (8.1)						
d	—	0	1.0	2.6	4.8	7.3
P value	—	—	.89	>.99	.051	.02
Fear (9.1)						
d	—	—	0	1.6	3.8	6.3
P value	—	—	—	.81	.82	.051
Ego (10.7)						
d	—	—	—	0	2.2	4.7
P value	—	—	—	—	.03	.006
Positive emotional (12.9)						
d	—	—	—	—	0	2.5
P value	—	—	—	—	—	>.99
Rational (15.4)						
d	—	—	—	—	—	0
P value	—	—	—	—	—	—

[a] One-way analysis of variance test was performed. “d” values are the differences between the mean number of likes among the different appeals.

[b] *P* values were obtained from Tukey posthoc test.

[c] Not applicable.

Discussion

Principal Results

The posts on *BuckleUp4Life* Instagram account used 6 main appeals within 3 components of each post (photo, text, and caption): rational, ego, social, fun, positive emotional, and fear. Most of these appeals were consistent with Guttman’s identification of 5 main appeals found mostly on the websites of road safety organizations [13]. Specifically, the rational appeal identified in this study is similar to Guttman’s appealing to reason. Similarly, the positive emotional appeal identified in this study is consistent with Guttman’s categorization of positive emotional appeals with regard to what people were concerned about including compassion, empathy, and caring [13]. Moreover, the fun appeal identified in this study is similar to Guttman’s use of humor appeal, but our study broadened this category to include sarcasm, jokes, excitement, and entertainment [13]. The fear appeal identified in our study is similar to Guttman’s threat of enforcement [13].

We identified 2 appeals in the *BuckleUp4Life* Instagram account that were not similarly identified in Guttman: ego and social appeals. The ego appeal is unique to Instagram because this social media platform is user-generated and thus different from traditional mass media [13]. Users can post their own photos and report their own seat belt wearing status. Social appeal may also be unique to social media, and thus not identified in Guttman’s study because people use social networking sites to connect with each other for social purposes [13]. Furthermore, social networking sites have been found to provide social support for other health behaviors such as physical activity [10].

There was a wide range in the number of likes per post (7-158), suggesting that in viewing and responding to posts, the audience as a group either greatly liked or did not like a post. Additionally, the *BuckleUp4Life* Instagram program demonstrated that high school students preferred rational appeals over fun, fear, social, positive emotional, and ego appeals, regardless of whether the appeal was imbedded within a photo, text, or caption. In particular, rational appeals presented within the text, either through captions or superimposed on a photo, were more likely to yield likes than those posts that did not have a rational appeal. Because the *BuckleUp4Life* Instagram audience was high school adolescents and young adults, this young population may need more information to make decisions [14]. Thus, rational appeal was more attractive to our young audience as they went through the central route of information processing when viewing a post.

Peripheral route appeals also attracted the *BuckleUp4Life* Instagram audience. Positive emotional appeals in text or captions received significantly more likes than post components that did not have positive emotional appeals. Our findings may be due to students' positive emotions toward seat belt use in terms of their acceptance of the behavior. Our study confirmed that positive emotional appeals are attractive to adolescents and young adults in terms of seat belt use promotion. Positive emotional appeals received more likes than fun appeals, regardless of the location in an Instagram post. Fun appeals were more likely to receive likes in photos than in texts and in captions. Furthermore, our findings suggest that fun appeal is easily achievable through pictures that do not directly relate to people wearing seat belts. For example, a picture of a stuffed bear in a car wearing a seat belt received many likes. Fun appeal uses humor to entertain and helps viewers overcome their reluctance in viewing safety messages.

In contrast, the peripheral route ego appeal was not popular among the audience, as people preferred fun photos to selfies depicting individuals wearing seat belts. This could be because the posts were not generated by people that the audience knew. Ego appeal might be more effective within their own Instagram networks rather than on a public Instagram account such as *BuckleUp4Life*.

Social appeal was the least popular of the 8 appeals identified in this study. Social gatherings and events to promote seat belt use might not be of interest to this population, as individuals in this young population may consider seat belt use a personal decision that is easy and that does not require social support in the way that other health behaviors such as physical activity require [10]. Social appeal might not have influenced likes because the audience may not know the people who posted the information about a particular social gathering and thus, they felt less engaged with the social appeals.

We found that our audience did not like fear appeals. Witte et al [17] suggested that young people may not perceive the risks involved in not using a seat belt and thus, may fail to see fear as a motivator to change their behavior. Therefore, our finding that fear appeals were not significantly associated with likes may be due to the age range of our subjects.

Applications

The goal of this study was to investigate ways in which health educators can use Instagram as an effective health communication channel. This study demonstrated that rational appeals were more effective than other appeals in garnering the positive attention of high school students when promoting seat belt use. These findings have implications for health communication practitioners who utilize social media sites as a means of promoting injury prevention. In future interventions that use Instagram to promote seat belt use, we recommend the use of rational appeals irrespective of the component of the post (photo, text, or caption) and use of fun photos with rational and positive emotional appeals rather than photos with fear or social appeals.

This study further confirmed that social media, especially Instagram, can be an effective tool to communicate the importance of using a seat belt to high school adolescents and young adults. In contrast with traditional mass media or institutional websites, Instagram allows users to generate their own content. For example, Instagram users in the *BuckleUp4Life* account generated creative photos with fun appeals such as a teddy bear or a dog wearing a seat belt. Future interventions can let adolescents and young adults create their own fun photos to promote seat belt use. Although ego and social appeals were not found to be attractive to the *BuckleUp4Life* Instagram account audience, we should not disregard the possible positive impact of ego and social appeals on audience members' own Instagram account networks. Future interventions can recruit adolescents and young adults to post promotional messages on seat belt use, including seat belt wearing selfies, on Instagram. Interventions for other health topics on Instagram can also apply the different appeals that we found to promote health behaviors among adolescents and young adults.

Limitations and Future Directions

Although this exploratory study was useful in providing insight into the usefulness of specific persuasive appeals, we only examined a limited number of posts (N=199). Furthermore, the sample size was not large enough to examine the limited number of comments besides likes on each post. Additionally, the *BuckleUp4Life* Instagram account was targeted toward high-school adolescents, some of whom were not drivers yet. However, as the web-based account was open to public, nursing students also responded to the posts, making it a mixed audience of high schoolers and nursing students who might have slightly different information processing preferences than high schoolers. Moreover, this account had a low engagement rate of 1.12% and the average interactions per post were 16 likes with 0 comments [22]. Thus, our findings may not be generalizable to a larger population. Future studies employing a large sample size should examine the content of the comments and explore the relationship between the different appeals and the content of the comments targeting adolescent or young adult groups specifically.

Conclusion

This study is one of the first investigations to use a theoretical framework to evaluate how different persuasive appeals of an Instagram post influenced the responses of adolescents and young adults in a pilot seat belt promotion intervention. Our study demonstrates how practitioners should consider using specific persuasive appeals within specific post components when developing a public health intervention. Our findings suggest that in photos, adolescents and young adults prefer fun appeals, while in text and captions, rational and positive emotional appeals are most appealing. Rational appeal was more popular than ego and fear appeals, regardless of the location of the components (photos, text, and captions) in the posts. We recommend that public health practitioners use these results to inform the design and implementation of future public health road safety interventions through social media channels, especially Instagram.

Conflicts of Interest

None declared.

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Abbreviations

ELM: elaboration likelihood model
RQ: research question

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Original Paper

Knowledge and Psychological Stress Related to COVID-19 Among Nursing Staff in a Hospital in China: Cross-Sectional Survey Study

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Abstract

Background: Since December 2019, coronavirus disease (COVID-19) has been rapidly spreading worldwide. Nurses play a key role in fighting this disease and are at risk of COVID-19 infection. Therefore, there is an urgent need to assess the mental health condition of nurses and establish appropriate interventions to reduce the negative psychiatric outcomes of the pandemic.

Objective: The objectives of this study were to evaluate the knowledge and psychological stress related to COVID-19 among nursing staff and to provide evidence of the need for targeted training and psychological intervention.

Methods: This cross-sectional web-based survey study was performed in a class 3 grade A general hospital in a southwest province of China from March 1 to March 15, 2020. A self-designed questionnaire with questions about COVID-19–related prevention and control knowledge and the Triage Assessment Form (TAF) were used to assess nursing staff's knowledge of COVID-19 and their degree of psychological stress, respectively. SPSS 23.0 was applied for statistical analysis of the collected data.

Results: A total of 979 nurses completed the questionnaire. The results showed that the nursing staff provided the fewest correct answers to questions about continuous viral nucleic acid testing specifications (379/979 correct answers, 38.7%), isolation/discharge criteria (539/979 correct answers, 55.1%), and management measures for patients with suspected symptoms (713/979 correct answers, 72.8%). The median total score of the TAF was 7.0 (IQR 5.0-12.0), and there were statistically significant differences in scores between different nursing roles, years of work experience, and hospital departments ($P<.05$).

Conclusions: This study indicated that nursing staff have insufficient knowledge about COVID-19. Meanwhile, although the psychological damage to nurses during the pandemic was found to be low, nurse managers must continue to monitor the mental health of nursing staff and perform timely interventions.

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KEYWORDS

COVID-19; nursing staff; knowledge; psychological stress

Introduction

Since December 2019, increasing numbers of new cases of coronavirus disease (COVID-19) have emerged in Wuhan City, Hubei Province [1]. New cases have also spread in other cities in China as well as in other countries worldwide. In China, the disease has been classified as a Class B infectious disease that requires the same management as a Class A infectious disease [2]. Gene sequencing analysis revealed that the virus is highly homologous to severe acute respiratory syndrome coronavirus (SARS-CoV) found in bats [3]. The incubation period of COVID-19 can be 1 to 14 days but is usually 3 to 7 days. The main route of transmission is through interpersonal respiratory droplets or contact [4]. Early detection, early diagnosis, early isolation, and early treatment have become the most effective measures to limit the transmission of COVID-19. For nurses who are fighting the pandemic on the front line, knowledge about COVID-19 prevention will be important to adopt precise management strategies. Meanwhile, heavy workload, shortage of personal protective equipment, and inadequate support may contribute to different levels of psychological stress [5]. Therefore, the objective of this study is to evaluate nursing staff's knowledge about COVID-19 and their psychological stress.

Methods

Study Design and Participants

This is a cross-sectional survey study. Nurses who had participated in the prevention and control of COVID-19 and were willing to take part in this survey were recruited from a class 3 grade A comprehensive hospital in a southwest province of China from March 1 to 15, 2020. This study was reviewed and approved by the ethics committee of the hospital (reference number: 2020-03), and informed consent was obtained from all participants.

Questionnaire

The questionnaire included 3 parts: general information, knowledge about the prevention and control of COVID-19, and the Triage Assessment Form (TAF) for psychological crisis intervention [6]. General information included age, gender, education, job title, personnel category, and department. The questions regarding knowledge about the prevention and control of COVID-19 were mainly designed based on the *Prevention and Control Plan for COVID-19* [7] issued by the National Health Commission of China; this part consisted of 10 items, 2 of which were multiple-choice questions related to the nurses' amount of patient contact and sources of information about COVID-19 and 8 of which were true or false questions regarding prevention and control strategies for COVID-19. The TAF included three dimensions: emotion, behavior, and knowledge. Each dimension used a 10-point scoring method; "never" scored 1 point and "always" scored 10 points, with a total score of 3 to 30 points. The higher the score, the more severe the mental health damage. The Cronbach α value of the scale was .81.

Survey Distribution

To abide by the principle of informed consent, a unified guideline was used to inform participants of the purpose of this study and its confidentiality measures. A web-based survey (via a questionnaire website platform) was sent to the head nurse of each ward, who was asked to send the survey to other nurses. Participants could complete the questionnaire using a computer or a smartphone that could open a website link or scan a Quick Response code.

Statistical Analysis

SPSS 23.0 (IBM Corporation) was used to analyze the collected data. The binary variables were expressed in the form of percentages. For continuous variables, if they conformed to the normal distribution, the results are presented as mean (SD). Otherwise, they are presented as median (IQR). Univariate analysis was performed using the Wilcoxon rank test or Kruskal-Wallis test. $P<.05$ was considered to indicate a statistically significant difference.

Results

Demographic Characteristics of the Participants

A total of 981 questionnaires were collected in this survey, of which 2 questionnaires were rejected due to imperfect information. Finally, 979 valid questionnaires were obtained, with a questionnaire effectiveness rate of 99.8%. As shown in Table 1, the majority of the nursing staff who participated in the survey were in-service nurses who had a bachelor's degree, held a junior professional title, and had less than 5 years of working experience; the average age of the participants was 29.68 years (SD 7.35).

Table 1. Demographic characteristics of the study participants (N=979).

Characteristic	Value
Age (years), mean (SD)	29.68 (7.4)
≤30	662 (67.6)
>30	317 (32.4)
Gender, n (%)	
Male	45 (4.6)
Female	934 (95.4)
Personnel category, n (%)	
Student nurse	113 (11.5)
Trainee nurse	118 (12.1)
In-service nurse	748 (76.4)
Education level, n (%)	
Technical secondary school	4 (0.4)
Junior college	301 (30.8)
Undergraduate college	668 (68.2)
Postgraduate college	6 (0.6)
Professional title, n (%)	
Nurse practitioner	674 (68.9)
Supervisor nurse	247 (25.2)
Co-chief operator nurse	55 (5.6)
Chief operator nurse	3 (0.3)
Work experience (years)	
<1	203 (20.7)
1-5	263 (26.9)
6-10	284 (29.0)
10-15	92 (9.4)
16-20	47 (4.8)
>20	90 (9.2)
Department	
Emergency	47 (4.8)
Outpatient	51 (5.2)
Respiratory	54 (5.5)
Critical care medicine	48 (4.9)
Infection	9 (0.9)
General ward	437 (44.6)
Other	333 (34.0)

TAF Scores Among Nursing Staff

The median total TAF score of the nursing staff was 7.0 (IQR 5.0-12.0), indicating that the psychological damage suffered by the nursing staff was slight. There were statistically significant differences in the total TAF score and the score of each domain between the different personnel categories, years of work experience, and departments (*P*<.05; Table 2).

Table 2. Status of psychological stress among nursing staff (N=979) based on their Triage Assessment Form scores, median (IQR).

Characteristic	Emotion	Knowledge	Behavior	Total
Age (years)				
≤30	3.0 (2.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	8.0 (5.0-11.3)
>30	3.0 (2.0-5.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	7.0 (4.0-13.0)
z value	–1.387	–0.046	–1.080	–0.356
P value	.17	.96	.28	.72
Gender				
Male	3.0 (1.0-4.0)	2.0 (1.0-3.0)	2.0 (1.0-4.0)	6.0 (3.5-12.0)
Female	3.0 (2.0-4.3)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	7.0 (5.0-12.0)
z value	–1.154	–1.240	–0.990	–1.411
P value	.25	.22	.32	.16
Personnel category				
Student nurse	3.0 (2.0-5.0)	4.0 (2.0-5.0)	3.0 (2.0-5.0)	11.0 (6.0-15.0)
Trainee nurse	3.0 (2.0-4.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	7.5 (5.0-11.0)
In-service nurse	3.0 (2.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-3.0)	7.0 (5.0-12.0)
H value	8.613	24.576	25.796	17.433
P value	.01	<.001	<.001	<.001
Education				
Technical secondary school	2.5 (1.3-3.0)	3.0 (2.3-3.8)	3.0 (1.5-3.8)	8.0 (5.5-10.5)
Junior college	3.0 (2.0-4.5)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	8.0 (5.0-12.0)
Undergraduate college	3.0 (2.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	7.0 (5.0-12.0)
Postgraduate college	4.0 (2.8-5.5)	3.5 (2.5-5.0)	3.0 (2.0-5.0)	10.0 (8.0-15.5)
H value	2.857	2.180	2.961	1.773
P value	.41	.54	.40	.62
Professional title				
Nurse practitioner	3.0 (2.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-3.0)	7.0 (5.0-11.0)
Supervisor nurse	3.0 (2.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	7.0 (4.0-13.0)
Co-chief operator nurse	2.0 (1.0-5.0)	2.0 (1.0-5.0)	2.0 (1.0-4.0)	9.0 (4.0-14.0)
Chief operator nurse	2.0 (2.0-4.0)	6.0 (4.5-7.5)	2.0 (1.5-4.0)	12.0 (9.5-15.0)
H value	1.748	5.022	0.533	2.296
P value	.63	.17	.91	.51
Work experience (years)				
<1	3.0 (2.0-5.0)	3.0 (2.0-5.0)	3.0 (2.0-5.0)	9.0 (5.0-13.0)
1-5	3.0 (2.0-4.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	7.0 (5.0-11.0)
6-10	3.0 (2.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-3.0)	7.0 (5.0-11.0)
10-15	3.0 (2.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	6.0 (4.0-12.0)
16-20	2.0 (1.0-6.0)	2.0 (1.0-4.0)	1.0 (1.0-3.0)	6.0 (4.0-13.0)
>20	3.0 (1.8-5.0)	3.0 (1.0-4.3)	2.0 (1.0-4.0)	9.0 (5.0-13.3)
H value	4.377	18.330	18.516	12.738
P value	.50	.002	.003	.03
Department				
Emergency	4.0 (3.0-5.0)	3.0 (2.0-5.0)	3.0 (2.0-5.0)	10.0 (7.0-13.0)
Outpatient	4.0 (2.0-5.0)	3.0 (2.0-5.0)	3.0 (2.0-5.0)	11.0 (6.0-15.0)

Characteristic	Emotion	Knowledge	Behavior	Total
Respiratory	3.0 (2.0-5.0)	3.0 (1.0-4.0)	3.0 (1.0-4.0)	9.0 (5.8-12.0)
Critical care medicine	3.0 (2.0-4.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	7.0 (4.0-9.8)
Infection	4.0 (2.5-5.5)	4.0 (2.0-6.0)	3.0 (1.5-6.0)	11.0 (6.5-17.0)
General ward	2.0 (2.0-4.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	6.0 (4.0-11.0)
Other	3.0 (2.0-5.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	8.0 (5.0-12.0)
H value	18.734	16.692	14.376	18.042
P value	.01	<.001	<.001	<.001

Status of Nursing Staff Knowledge About COVID-19

In this survey, 34 of the 979 nurses (3.5%) nurses reported that they had a very high degree of contact with patients, 214 (21.9%) reported that they had a high degree of contact with patients, and 731 (74%) reported that they had a moderate degree of contact due to indirect contact with patients. The most common approaches by which the nursing staff accessed relevant knowledge were WeChat, Weibo, and official websites. The nursing staff's knowledge about the prevention and control of COVID-19 reflected that they did not have adequate knowledge of the standards for consecutive viral nucleic acid tests (correct answer rate 379/979, 38.7%), the criteria for release of isolation/discharge (539/979, 55.1%), and the management measures for patients with suspectable symptoms (713/979, 72.8%) (Table 3).

Table 3. Knowledge about prevention and control of COVID-19 among nurses (N=979).

Question	Correct answers, n (%)	Ranking
For people who have been exposed to suspicious cases, but do not have any discomfort at present, how does one deal with them subsequently?	947 (96.7)	1
The first symptom of COVID-19?	915 (93.5)	2
Clinical classification of patients with COVID-19?	906 (92.5)	3
Definition of confirmed cases of COVID-19?	905 (92.4)	4
Which mask has the best protective effect when worn correctly?	793 (81.0)	5
Management measures for occurrence of headache, runny nose, cough, sore throat, and other symptoms?	713 (72.8)	6
What are the criteria for patients to be discharged and released from isolation?	539 (55.1)	7
Sampling time interval between the two consecutive respiratory tract nucleic acid tests?	379 (38.7)	8

Discussion

Principal Findings

Since the early reports of COVID-19 cases in China in late December 2019, the worst pandemic in 100 years has spread worldwide, with approximately 823,626 confirmed cases and over 40,598 deaths as of April 1, 2020 [8]. The World Health Organization has declared the global COVID-19 outbreak to be a public health emergency of international concern [9]. Due to the atypical pneumonia symptoms and long incubation period of COVID-19 as well as its transmission through respiratory droplets, secretions, and contact, prevention and control of the disease are difficult. Nursing staff are fighting the pandemic on the front lines, and knowledge about the prevention and control of COVID-19 is critical to enable them to provide better care for patients and to protect themselves.

The results of this study showed that nursing staff mainly acquire COVID-19–relevant knowledge through new media platforms such as WeChat and Weibo, followed by the official websites of health administrative departments and professional medical organizations. In the Internet era, WeChat, Weibo, and other platforms have become the most popular learning approaches for health professionals due to their advantages such as mobility, portability, fast update speed, and substantial amounts of information [10]. WeChat has become the most commonly used interactive communication tool for medical education [11] and patient management [12]. However, the information disseminated on social media is also highly arbitrary, especially regarding the COVID-19 outbreak, and response to the pandemic on social media has been accompanied by an overabundance of information [13]. Nurses should have the ability to distinguish false information and avoid being misled. In terms of knowledge related to the prevention and control of COVID-19, the rates of correctness of nursing staff's answers to questions about the standards for consecutive pathogen nucleic acid tests, the criteria for release from isolation or discharge, and the management measures for patients with suspectable symptoms were relatively low. Multi-round and multi-sample viral nucleic acid tests are of great significance for supporting etiological diagnosis [14]; however, most nurses were unclear about the time interval required between multiple tests (at least 24 hours). At the same time, because the criteria for release from isolation or discharge of patients are mainly determined by doctors, the enthusiasm of nursing staff for learning relevant knowledge was not high. The management of patients with suspected COVID-19 symptoms has become a key step in prevention and control of the pandemic. Because many clinical symptoms caused by the new coronavirus are similar to those caused by influenza virus, parainfluenza virus, adenovirus, etc., the symptoms of COVID-19 are mainly atypical, with fever as the only typical symptom [15]. If health care professionals are not familiar with the processes to identify and manage patients with suspected COVID-19 symptoms, they are likely to fail to properly manage these patients in a timely manner, leading to further spread of the epidemic. Therefore, nursing staff must also further strengthen their training on the *Prevention and Control Plan for COVID-19* issued by the National Health Commission of China to improve the emergency response ability of nursing staff during this epidemic.

Infectious diseases are classified as public health emergencies and have the systematic characteristics of urgency, wide spread, complicated and changeable disease conditions, and serious harm. When an infectious disease epidemic occurs, it can easily cause anxiety, depression, and other epidemic-related stress reactions along with negative emotions in the public, including medical staff [16,17]. In this study, the TAF was used to evaluate the psychological status of the nursing staff who responded to the survey. The median score was 7.0, reflecting that the psychological damage suffered by the nursing staff was low. However, Lai et al [18] conducted a study involving 1830 heath care workers to assess the magnitude of mental health outcomes in Wuhan City, China. The results indicated that heath care workers, especially nurses, experienced more severe psychological burdens. One possible explanation for this difference from our study is the use of different investigation tools. However, among different personnel types, tenures, and departments, the difference in the scores of each dimension was statistically significant ($P<.05$). The main reason for this result is that nursing students during internship and nurses in standardized training have only just started clinical practice and lack rescue experience for disaster events, including public health emergencies [19,20]. Nursing staff with long tenure, meanwhile, have relatively high levels of psychological preparedness for disasters and already have experience in coping with epidemics, as they have experienced outbreaks of severe acute respiratory syndrome (SARS), avian influenza, H1N1 influenza, and other major infectious diseases. However, due to the extreme shortage of medical protective materials, especially protective clothing and masks, there is still a certain gap in the expectations of frontline departments with high exposure risks; therefore, the psychological damage among nursing staff in frontline departments is relatively high compared with that of nurses in the general department and other departments. It is suggested that all hospitals should strengthen the centralized and unified management of medical protection supplies, establish and use account books, accurately distribute materials, and carefully manage the situation to meet the needs of clinical workers.

Limitations

This study has certain limitations. First, the content and structure of the knowledge questionnaire used in this study are relatively unique, and the reliability and validity of the structure have not been tested; this may affect the credibility of the results and lead to one-sidedness of the survey results. Second, the time period for investigating the psychological status of nursing staff was relatively short; therefore, the impact of the disease on the psychological health of the nursing staff may be underestimated, especially for those in job positions with high degrees of exposure. Finally, the investigation of the psychological status in this study mainly relies on a questionnaire and lacks an overall evaluation method, which may ignore potential influencing factors not included in the scale.

Conclusion

The results of this study showed that nursing staff have insufficient knowledge about COVID-19 and should be retrained to strengthen their ability to manage and cope with the disease. Meanwhile, the nurse respondents showed minimal emotional, cognitive, behavioral, and overall psychological damage, and the impact of the disease on their psychological state was found to be relatively low at present. However, further study is required involving continuous follow-up observation combined with qualitative research to determine the mental health status of nursing staff in a timely manner and to provide a series of interventions.

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Conflicts of Interest

None declared.

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Abbreviations

COVID-19: coronavirus disease
SARS: severe acute respiratory syndrome
SARS-CoV: severe acute respiratory syndrome coronavirus
TAF: Triage Assessment Form

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Original Paper

Evaluation of an Occupational Exercise Training Program for Firefighters: Mixed Methods Pilot Study

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Abstract

Background: Occupational exercise training programs can improve overall health and fitness in firefighters, but evidence beyond clinical and performance outcomes is needed before fire departments invest in and successfully adopt health promotion programs.

Objective: This mixed methods pilot study sought to pair clinical and performance outcomes with participants' qualitative feedback (eg, participants' enjoyment, lifestyle behavior changes, and team structure) with the goal of informing recommendations for future programs.

Methods: Professional firefighters participated in a 14-week occupational exercise training program with assessments conducted pre- and posttraining. Clinical outcomes included weight, BMI, body fat percentage, resting heart rate, systolic blood pressure, and diastolic blood pressure. Performance outcomes included the sharpened Romberg balance test, 1-repetition maximum leg press and bench press, graded exercise test (estimated VO_{2max}), knee range of motion, shoulder flexibility, and hamstring flexibility. Self-administered surveys (Short Form-36, International Physical Activity Questionnaire, Barriers Self-Efficacy Scale, and Barriers to Being Active Quiz) were completed. In 3 private focus groups of 3 to 4 participants, firefighters' experiences in the training program and their health behaviors were explored.

Results: Male firefighters (n=14; age: mean 36.4, SD 2.6 years) completed 20 training sessions. There were no significant changes to weight (P=.20), BMI (P=.15), body fat percentage (P=.16), systolic blood pressure (P=.12), estimated VO_{2max} (P=.34), balance (P=.24), knee range of motion (left: P=.35; right: P=.31), or hamstring flexibility (P=.14). There was a significant decrease in diastolic blood pressure (P=.04) and significant increases in shoulder flexibility (P<.001) and leg press 1-repetition maximum volume (P=.04). Participants reported improvements in overall health, endurance, flexibility, and mood as well as improvements to team environment and health behaviors around the station; however, there was a decline in overcoming barriers to physical activity.

Conclusions: A 14-week program of exercise training in firefighters elicited improvements in clinical, performance, and self-reported physical activity outcomes. This occupational exercise training program for firefighters increased time spent exercising, improved team building, and led to physical and mental health benefits. Results from this pilot study set a broad, informed, and meaningful foundation for future efforts to increase firefighter participation in occupational fitness programs.

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KEYWORDS

firefighters; exercise; mixed methods; qualitative; clinical; performance

Introduction

Heart disease is the number one cause of firefighter fatalities [1] accounting for nearly 50% of all firefighting-related deaths [2,3]. In general, firefighters have high rates of cardiovascular disease risk factors such as hypertension and obesity [4] contributing to their high overall risk of death from heart disease [5]. Not only would an acute event harm the individual, but any health condition that limits a firefighters' performance compromises the safety of colleagues and the community. Poor physical fitness is associated with a higher risk of cardiovascular disease and acute myocardial events [6]. Carrying heavy gear and wearing restrictive clothing in extreme heat while performing the high intensity work of firefighting elicits significant physiological stress which, when paired with poor fitness, can lead to line of duty cardiovascular disease events [7]. Furthermore, poor fitness is associated with socioeconomic consequences due to the benefits awarded to responders who die or are disabled by cardiovascular disease or who are affected by work-related orthopedic problems [8]. Therefore, improving and maintaining overall health and physical fitness is critical to the safety and longevity of firefighters and those they serve.

Any amount of exercise is beneficial in reducing cardiovascular disease risk, reducing all-cause mortality up to 40% [9,10], and emergency personnel who engage in higher levels of physical activity are more physically fit than less active peers [11]. Regular exercise training elicits adaptations that can improve job performance, reduce the risk of cardiovascular events, and prevent musculoskeletal injuries [12-17]. Furthermore, exercise is beneficial for firefighters, significantly improving body fat percentage, aerobic capacity, endurance, strength, and power [18]. High fitness levels are correlated with improved job performance during real and simulated firefighting activities [19-21]. Unfortunately, infrequent physical activity is common in fire service, and most departments do not mandate regular exercise or require that firefighters maintain fitness standards [22].

One means of improving overall health and fitness in firefighters is through the implementation of departmental or occupational fitness programs [22,23]. Indeed, firefighters within departments that incorporate a wellness or fitness program are less likely to be obese, more likely to meet endurance standards for firefighting, more likely to have higher cardiorespiratory fitness, more likely to express higher job satisfaction, and are less likely to smoke or be diagnosed with an anxiety disorder [24]. While the National Fire Protection Association Needs Assessment emphasizes the importance of health and wellness programs, only 30% of departments have such a program [25]. Several investigators have issued a call to action for health and fitness professionals to assist fire departments in implementing programs for firefighters that improve fitness and reduce cardiovascular disease risk factors [26,27].

For firefighter departments to adopt and invest in occupational wellness programs that promote exercise training, evidence of success beyond the exhaustively reported [9-24] clinical and performance outcomes is needed. To date, the comprehensive influence of these programs has not been fully explored including the role of these programs in inciting permanent behavior change or their influence on team structure or building. Indeed, others have noted that exercise patterns are influenced by the culture of fire stations [28], but this has not been explored.

Finally, there still exists a gap in understanding how best to intervene in firefighters' health promotion [28-30], and participant feedback has not been reported within the literature. We evaluate the influence of an occupational fitness program on qualitative outcomes including participants' enjoyment, lifestyle behavior changes, and team structure. To our knowledge, this is the first study to incorporate mixed method analyses of clinical and performance outcomes and firefighters' experiences and feedback.

Methods

Design

This semiexperimental, community-based participatory intervention research pilot study was approved by the institutional review board of West Virginia University (1812386641). Briefly, a local firefighter captain, concerned about the apparent poor physical fitness of the firefighters under his command, approached faculty in the division of Exercise Physiology about implementing an exercise training program within his 3 companies. The investigators (exercise physiology faculty members at West Virginia University), assisted by trained undergraduate exercise physiology student interns, developed and implemented an occupational exercise training program for the firefighters. Clinical, performance, and survey results were collected before and after a 14-week exercise training intervention. At the end of the intervention, the firefighters participated in focus groups to capture impressions of the intervention. While the captain strongly encouraged all firefighters under his directive to participate, enrollment into the research project was voluntary. Written and verbal consent were obtained from all participants.

Intervention

The exercise training program ran from mid-January through mid-April 2019. Due to the firefighters' irregular schedules, training occurred at least once, but usually twice weekly either at the nearest fire station (equipped with a small gym facility) or in the Human Performance Laboratory (a fitness and research facility in the division of exercise physiology) at West Virginia University. Four student interns trained 3 to 4 firefighters each. The student interns developed and prescribed exercises targeted to improving functional outcomes in firefighters (eg, getting in and out of the truck, carrying heavy loads up and down stairs, etc) and which incorporated strength, muscular endurance, cardiovascular, flexibility, and agility exercises.

Participants visited the laboratory for assessments before starting and after completing the 14-week training program. Participants were instructed to arrive in athletic shoes and comfortable clothing as well as to abstain from vigorous exercise for 24 hours and caffeine and tobacco for 4 hours prior to testing. All assessments were conducted pre- and postintervention with the exception of the health history questionnaire, which was completed after consent but before physical assessments.

Assessment Measures

Overview

Before arriving to the laboratory, all participants completed a health history questionnaire to assess information related to disease risk, medication use, and lifestyle behaviors (eg, physical activity, nutrition, stress). Upon arrival, to the laboratory, a resting 12-lead electrocardiogram (ECG) was performed by a trained technician and reviewed by a clinical exercise physiologist for evidence of irregular myocardial contractility or arrhythmia. An experienced technician measured resting seated brachial blood pressure of the right arm using a stethoscope and sphygmomanometer and resting heart rate by palpation at the radial artery. The clinical exercise physiologist reviewed the health history questionnaire and assessment results and followed American College of Sports Medicine safety guidelines to determine whether it was safe for participants to exercise [31]. Any evidence of risk required that the participant follow up with their physician before continuing with preassessments or starting the exercise program.

Anthropometrics

Standing height (±0.1 cm) was measured with a stadiometer, and body weight (±0.1 kg) was measured with a calibrated body mass scale with the participant barefoot and in light clothing. Body mass index (BMI) was calculated from height and weight (kg/m^2). Percentage body fat was measured with air plethysmography using a BodPod (Cosmed USA Inc).

Balance Test

The sharpened Romberg balance test was administered to participants by a trained technician. Participants stood with feet heel-to-toe, arms crossed over their chest, with eyes open for 60 seconds or until the participant moved one or both feet. If the participant successfully completed 60 seconds without moving, the test was repeated with eyes closed.

Strength Measures

Participants warmed up by walking on a treadmill at a self-selected speed before performing lower and upper body maximum strength assessments. Lower body strength was assessed with 1-repetition maximum leg press, and upper body strength was assessed with 1-repetition maximum bench press. For the bench press machine (Body Masters Sports Industries Inc), the handle was lowered to chest level. A repetition began with the handle at the level of the chest with no resistance and was completed when the elbows reached full extension. For the leg press (Body Masters Sports Industries Inc) machine, the participant’s feet were placed on the platform shoulder width apart and with the toes slightly rotated outwards. The platform was then adjusted to produce a 90-degree bend at the knee joints. Repetitions began with the knee flexed with no resistance and ended with the knee nearly completely extended. The 1-repetition maximum was recorded as the heaviest weight lifted only once. In the event that the participant could lift the entire weight stack more than once, they were instructed to perform repetitions until voluntary fatigue and maximal 1-repetition maximum volume was calculated as weight unit × repetitions.

Submaximal Graded Exercise Test

A Cornell graded submaximal treadmill test was administered by trained technicians and supervised by a clinical exercise physiologist. Participants completed the staged protocol until 85% of heart rate reserve or volitional fatigue. A clinical exercise physiologist monitored a 3-lead ECG for evidence of myocardial incontractility or irregular electrical activity during the test. Heart rate, blood pressure, and rate of perceived exertion were measured at each stage to monitor participant safety (data not reported). VO_{2max} was estimated using established equations [31].

Flexibility and Range of Motion

Measurements of maximal knee extension and flexion with a goniometer enabled calculation of knee range of motion (degree of maximal extension–degree of maximal flexion). Knee range of motion was measured with the participant lying supine and the ipsilateral hip and knee extended throughout the examination. The axis of the goniometer was centered on the lateral femoral condyle. The stationary arm was aligned along the femoral shaft toward the greater trochanter, while the moving arm was aligned with the fibula downward toward the lateral malleolus. Knee flexion was measured first by flexing the hip to 90°, and then instructing the participant to draw the heel as close to the buttocks as possible. From this position, the participant actively extended the knee until resistance was felt to measure knee extension.

For shoulder flexibility, participants lay in a prone position on the floor, forehead on the ground, and arms extended holding an 18-inch (45-cm) stick with both hands shoulder width apart. The participants raised the stick as high as possible off the floor while keeping the forehead on the ground and a technician measured and recorded the vertical distance achieved from the best of 3 trials.

A sit-and-reach test was performed to assess hamstring flexibility. Briefly, participants sat on the floor with knees extended and feet against the sit-and-reach box and at right angles to the floor. The participants reached forward as far as possible with knees locked and hands one on top of the other. The maximal reach (distance between the box's zero point and participants' reach point) from the best of 3 trials was recorded.

Surveys

Self-administered surveys—the Short Form-36 [32], International Physical Activity Questionnaire (IPAQ) [33], Barriers Self-Efficacy Scale (BARSE) [34], and Barriers to Being Active Quiz (BBAQ) [35]—were completed by participants in private.

The Short Form-36 is a multipurpose, short form, validated health survey of 36 questions. The Short Form-36 has 8 scaled scores; the scores are weighted sums of the questions in each section. Scores range from 0 to 100 with lower scores indicating more disability and higher scores indicating less disability. Sections include vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health.

The IPAQ covers 4 domains of physical activity: work-related, transportation, housework/gardening, and leisure time activity including questions about time spent sitting as an indicator of sedentary behavior. In each domain, the number of days per week and time per day spent in both moderate and vigorous activity are recorded. At work, during transportation and in leisure time, walking time is also included. Moderate intensity was defined as 4 MET (metabolic equivalent task) and vigorous intensity was defined as 8 MET. Outcome measures used were MET hours per week

The Barriers Specific Self-Efficacy Scale is a 13-item questionnaire with 11-point Likert scale response options designed to assess participants' perceived capabilities to exercise. For each item, participants indicate their confidence about executing their exercise behavior. Possible scores range from a minimum self-efficacy score of 0 to a maximum possible score of 100.

The Barriers to Being Physically Active Quiz is a 21-item measure assessing barriers to physical activity including lack of time, social influence, lack of energy, lack of willpower, fear of injury, lack of skill, and lack of resources. Each domain contains 3 items, with a total score range of 0 to 63. Respondents rate the degree of activity interference on a 4-point scale, ranging from 0 (very unlikely) to 3 (very likely).

Qualitative Methods

Qualitative research methods, including focus groups, can provide rich, descriptive data that can be missed when using quantitative methods. Furthermore, qualitative approaches can enhance collaboration with working people by offering them a forum for discussing the particular problems of their employment and health and for developing feasible intervention programs [36-38]. A semistructured protocol following standard focus group guidelines [39] was conducted by trained researchers [39,40]. Three private focus groups of 3 to 4 participants responded to a series of 9 questions, some with probing follow-ups, which explored their experiences in the training program and their health behaviors. A trained note taker took comprehensive notes on a laptop computer at each focus group, and proceedings were digitally audiorecorded. These notes were reviewed by the focus group moderator for clarity, thoroughness, and accuracy.

Analysis

For quantitative data, descriptive statistics summarizing clinical, performance, and numerical questionnaire data were analyzed using Excel (Microsoft Inc). Differences between pre- and postassessments were assessed using independent one-tailed t tests with significance set at $P<.05$.

Grounded theory allows for an inductive theory–building approach, one that does not require a prior theory [41]. Using a heuristic or common-sense approach based in grounded theory, 2 independent researchers (with a tiebreaker when necessary) analyzed the content of focus group discussions to identify common themes. The researchers discussed independent content analysis findings; however, due to the limited sample size, saturation of repetitive concepts (ie, point at which no new information, trends, or themes emerge from data) was not achieved [42].

Results

Clinical and Performance Results

Of 16 men who consented, one participant was excluded from participating because of evidence of myocardial dysfunction. A total of 15 men started the training program, but one withdrew due to an orthopedic injury incurred outside the research study. Therefore, 14 Caucasian males (mean 36.4, SD 2.6 years old) completed 20 training sessions over a total of 14 weeks; 2 participants were taking blood pressure medications, and 6 had a history of orthopedic injuries that did not prohibit their participation. Clinical outcomes are presented in Table 1. There were no significant changes to weight (P=.20), BMI (P=.15), percentage body fat (P=.16), or systolic blood pressure (P=.12). There was a significant decrease in diastolic blood pressure (P=.04), and the reduction in resting heart rate was trending toward significance (P=.08).

Table 1. Clinical outcomes.

Outcome	Pre, mean (SD)	Post, mean (SD)	*P* values
Height (cm)	179.8 (1.7)	N/A[a]	N/A
Weight (kg)	96.5 (4.9)	99.0 (4.5)	.20
BMI (kg/m^2)	30.1 (1.8)	31.0 (1.5)	.15
Body fat (%)	31.7 (2.6)	30.9 (2.3)	.16
Systolic blood pressure (mmHg)	129 (2)	125 (3)	.12
Diastolic blood pressure (mmHg)	93 (6)	78 (2)	.04
Resting heart rate (bpm)	80 (2)	76 (3)	.08

[a] N/A: not applicable.

From the health history questionnaire, average responses to physical activity patterns indicated that participants were mostly sitting or standing at work and that they perceived their levels of physical fitness to be below average. Half of the participants exercised 3-5 days/week for at least 6 months, but half reported no regular exercise. Participants reported the fat content in their diet was slightly above average, 10 out of 14 (71%) participants regularly consumed alcoholic beverages, and 11 out of 14 (79%) regularly consumed caffeine. Most (13/14, 93%) reported average to above average job stress.

Physical performance outcomes are reported in Table 2. All participants completed the sharpened Romberg balance test with eyes open. There were no significant changes in estimated VO_{2max} (P=.34), knee range of motion (left: P=.35; right: P=.31), or hamstring flexibility (P=.14). Shoulder flexibility (P<.001) and leg press 1-repetition maximum volume significantly increased (P=.04), and the increase in bench press 1-repetition maximum volume was trending toward significance (P=.07).

Table 2. Physical performance outcomes.

Outcome	Pre, mean (SD)	Post, mean (SD)	*P* values
Romberg balance closed (seconds)	58.9 (1.1)	57.0 (2.3)	.24
Estimated VO_{2max} (mL/kg/minute)	55.8 (3.3)	57.3 (4.0)	.34
Left leg knee range of motion (degrees)	142.1 (2.3)	141.1 (3.6)	.35
Right leg knee range of motion (degrees)	142.4 (2.9)	140.5 (3.5)	.31
Shoulder flexibility	14.6 (1.1)	18.8 (1.2)	<.001
Hamstring flexibility	12.5 (1.0)	13.3 (0.9)	.14
Leg press 1-repetition maximum volume (repetitions × weight unit)	5896 (1119)	7710 (1315)	.04
Bench press 1-repetition maximum volume (repetitions × weight unit)	2001 (480)	2781 (678)	.07

Survey Data

Changes in IPAQ responses indicated more time spent doing vigorous physical activity as part of work (METminutes/week—pre: mean 1971, SD 514; post: mean 5920, SD 2105; P=.03), more time spent walking as part of work (METminutes/week—pre: mean 3117, SD 722; post: mean 5074, SD 934; P=.03), and less time spent sitting on weekdays (minutes—pre: mean 287, SD 28; post: mean 214, SD 32; P=.04).

Overall, there were no differences in group averages for the Short Form-36 (P=.50), BBAQ (P=.44), or BARSE (P=.19). However, changes in Short Form-36 showed significantly improved responses to “In general, would you say your health is” (P=.048), and the responders felt their health had improved from “about the same” to “somewhat better now” when asked to compare their health to a year ago (P=.007). There was a significant improvement in average responses to “How much of the time during the past 4 weeks have you felt so down in the dumps that nothing could cheer you up?” (P=.04). However, changes in the BARSE indicated a significant decline in overcoming barriers to physical activity in the domains of lack of time (P=.03) and lack of energy (P=.045). In the BBAQ, there were significant declines in response to “I believe that I could exercise 3 times per week for the next 3 months if I had to exercise alone” (P=.04) and “I believe that I could exercise 3 times per week for the next 3 months if I was under personal stress of some kind” (P=.048).

Qualitative Results

Focus group themes are presented in Table 3. The firefighters reported positive feelings prior to starting the training program and liked the idea, citing enthusiasm of gaining fitness:

> *I wanted to regain some of what I’ve lost over the years.*

Many expressed reservations; a few attributed their reservations to disinterest, but most attributed it to nervousness, specifically not knowing what to expect and feeling out of shape.

By the end of the training program, the impressions were positive, and many expressed interest in continuing the program:

> *I really hope they can keep a program and designated times for that.*

It was even recommended that the program be extended throughout the entire firefighting department:

> *I would like to see the department mandate a time in the shift for PT [physical training]… It would push a lot of guys into physical training.*

Firefighters liked having the interns as trainers and appreciated the interns’ preparation but suggested assigning intern trainers specific to participants’ interests (cardiovascular versus strength). They liked the variety of exercises (eg, balance exercises and circuit training) and learning new exercises (eg, planks), but many suggested including more task-specific exercises and training:

> *Flipping the tire was more incorporative of what we actually do.*
>
> *Include a routine that would have a fireman drill.*

While the firefighters enjoyed training in the fitness facility for “getting out of the station” most felt, compared with training at the station, that it posed difficulties logistically. Other recommendations were to have more training rather than once or twice a week:

> *I feel like I would have gotten more out of it.*

Other than merely receiving exercise programming from the intern trainers, the firefighters reported receiving positive motivation but with different styles of support (eg, cheerleading versus drill sergeant). They felt being divided into groups inspired a bit of competition which helped with team motivation.

In terms of exercising outside of meeting times, some of the interns had prescribed “homework” to their group to encourage the firefighters to exercise on off days; the firefighters that were prescribed outside exercise reported completing it. Many of the younger firefighters reported incorporating extra exercises outside of training times of their own volition, but the older firefighters cited lack of time and motivation as barriers:

> *Life seemed too busy to be able to do it...*
>
> *...easier to work out in a group...*

Some thought they were more likely to incorporate exercise in the future using what they learned from the intern trainers.

Physical performance of their occupation was improved by increased endurance,

> *I don’t get as winded when I’m walking or doing things...*

and many firefighters noted climbing stairs with their gear was significantly easier. Several reported less mental fatigue citing general tasks felt easier:

> *Any time I put my gear on you can tell a difference.*

Other reported benefits were increased flexibility, better recovery and less soreness from firefighter runs or calls, and “more confidence in skills.”

The firefighters reported improvements around the station including more support and improved attitudes toward fitness. Some firefighters reported improvements in health behaviors among the group, including a noticeable influence on nutrition:

> *It’s definitely improved with eating better and feeling better.*
>
> *More fruit instead of sugary foods...*
>
> *...less soda, more water...*

There was more talk around the station about exercise, and many reported improved team building,

> *...play together, stay together...*
>
> *...seeing guys from other companies helped change the little bickering between them...*

This sentiment was reported by the captain and echoed by the group. Many firefighters noted more positive attitudes in their colleagues, which was also reported outside of work; many had better moods and attitudes:

> *Normally you leave here cranky, irritated and now I leave here in a good mood.*

Outside of work, firefighters reported several wellness benefits including feeling better overall, being more productive, and being more inclined to exercise and eat healthier when away from the station.

Overall, there was an increased affinity for exercise with plans to continue into the summer. All firefighters would recommend this program to other companies because it increased overall exercise time, incorporated accountability and team building, and led to physical and mental health benefits:

> *It was hard, but you get paid to have a personal trainer.*

Table 3. Focus groups themes.

Topics and themes	Findings
When reflecting to the start of the program:	
Positive feelings:	Looked forward to gaining fitness
Some reservations:	Uncertainty, nervousness, and some disinterest
Training program feedback:	
General feeedback:	Liked having interns as trainers and their positive motivation Enjoyed the variety of exercises, learning new exercises, and competition between groups Interested in continuing
Self-reported outcomes:	
Performance:	Increased endurance Less mental fatigue Increased flexibility Better recovery More confidence
Around the station:	Increased support from peers More positive attitudes Improved attitudes toward fitness Improved health behaviors Increased team building,
At home and in their personal lives:	Better mood Feeling better overall Feeling more productive More inclined to exercise and eat healthier when away from the station
Moving forward:	
Why they recommend participation:	Increased overall exercise time Accountability Team building Physical and mental health benefits
Specific recommendations:	Implement throughout the department Incorporate task-specific exercises and training Train specific to participants interests (cardio vs. strength) Incorporate more days of training

Discussion

While physiological (performance and clinical) outcomes have been widely reported [9-24], the comprehensive influence of occupational exercise training programs has not been fully explored, and participant feedback has not been reported within the literature. This semiexperimental, community-based participatory intervention pilot study found reported improvements in overall health, endurance, flexibility, and mood, as well as improvements to team environment and health behaviors around the station; however, there was a decline in overcoming barriers to physical activity. Positive reports as well as future recommendations indicate the success of this pilot study and promising avenues for implementing similar and more wide-reaching programs moving forward.

Combined interventions have been shown to be most effective in improving cardiovascular health in emergency personnel [43]. Therefore, in this pilot study, professional firefighters received personalized exercise recommendations, which incorporated strength, muscular endurance, cardiovascular, flexibility, and agility exercises, designed to improve functional outcomes. There was a significant reduction in diastolic blood pressure (*P*=.04), while resting heart rate reductions were trending toward significant (*P*=.08), which is in agreement with previous findings showing a 4-week circuit training program can improve vascular outcomes in firefighters [44]. Indeed, many fitness variables, including resting heart rate, contribute to firefighters performance in simulated firefighting tasks [45] suggesting the clinical outcomes in this study could translate to improved occupational performance and overall reductions in cardiovascular disease risk. This is supported by survey and focus group responses which indicated improvements in self-perceptions of overall health. Importantly, firefighters must excel in multiple areas of physical fitness including flexibility to climb in and out of the truck, power to perform forced entry maneuvers, muscular and cardiovascular endurance to carry equipment up flights of stairs, and strength to advance hose lines [27]. For performance outcomes, there was a significant increase in shoulder flexibility (*P*<.001) and leg press 1-repetition maximum (*P*=.04), and bench press 1-repetition maximum was trending toward significant (*P*=.07). Firefighting tasks are highly associated with muscle strength and endurance [45-50], and though firefighting tasks were not directly assessed, the qualitative responses from focus groups indicated improved endurance and flexibility.

Many clinical and performance measures were unchanged after the intervention, which could be attributed to the small sample size or insufficient exercise stimulus. For example, estimated VO_{2max} was unchanged, perhaps because the exercise stimulus from meeting once or twice a week was insufficient to elicit the necessary physiological aerobic adaptations to improve maximal oxygen consumption. Additionally, outcomes such as knee range of motion and balance were within normal ranges at baseline and would have been unchanged even with a rigorous exercise training program.

Independent of physiological outcomes, participants reported improvements in performance and overall health, including increased vigorous activity and more walking at work as well as reduced sitting time during weekdays. In terms of exercising outside of scheduled training times, the firefighters who were prescribed outside exercise reported completing it, and many of the younger firefighters reported incorporating extra exercise outside of training times of their own volition. These findings were supported by previous qualitative research that found younger firefighters were more health conscious [36]. Furthermore, the firefighters reported improvements around the station, including more support and improved attitudes toward fitness, which is supported by previous research that found participation in fitness training improves the perceptions of exercise in emergency personnel [51].

In addition to fitness, the firefighters reported improvements in other health behaviors, such as nutrition. Despite the lack of direct measures (eg, pedometers, nutrition intake surveys, etc), these findings are evidence of improvements to lifestyle behaviors suggesting the goal of inciting permanent behavior change was supported. However, survey data indicated a significant decline in overcoming barriers to physical activity in the domains of lack of time (*P*=.34) and lack of energy (*P*=.045) and in response to “I believe that I could exercise 3 times per week for the next 3 months if...” There were significant declines in response to “I had to exercise alone” (*P*=.042) and “I was under personal stress of some kind” (*P*=.048). Despite favorable impressions of exercise, some of these barriers (eg, lack of time and motivation) were echoed in the focus groups. Therefore, the goal of inciting permanent behavior change cannot conclusively be supported.

Participants reported improvements in mood and attitude as assessed by surveys and focus groups. Interestingly, in the focus groups, respondents cited improvements in their own moods and attitudes at work and home as well as improvements in those of their colleagues. Since firefighting has been shown to be associated with considerable psychological stress [52], the improvements in mood could indicate improvements in overall stress. While not a primary objective of this pilot study, these findings are certainly relevant to recommendations for future programs.

In focus groups, many participants reported improvements to the team environment: the captain felt that “seeing guys from other companies helped change the little bickering between them” and this sentiment was echoed by the group. One unforeseen mechanism driving this influence was the random allocation of firefighters to training groups: training with firefighters outside their unit promoted team building across the company. Additionally, the training sessions inspired a bit of competition among firefighters which helped with team motivation as well. Others [36] have noted that the culture of the fire station can influence exercise patterns and that firefighters work in close-knit teams (eg, sharing meals and training together) suggesting social support may be an important factor to behavior change. While previous research [43] has cited the potential of occupational health promotion programs to take advantage of the existing team structure within fire departments, to our knowledge, this is the first pilot study to directly assess this outcome. Working as a team is critical to successful firefighting and ensures the safety of the responders and those they serve. Therefore, the potential for an occupational exercise training program to improve team structure has significant implications for program implementation moving forward.

Impressions of this pilot program were positive and many expressed interest in continuing the program, even requesting more days per week of training. The design of the program, including having the interns as trainers and the variety of exercises, were received favorably. A primary outcome of this study was to inform recommendations for future programmatic implementation of occupational firefighter fitness programs. All firefighters would recommend this program to other companies because it increased overall exercise time, incorporated accountability and team building, and led to physical and mental health benefits. The participants recommended that the program be extended throughout the entire firefighting department, but many suggested including more task-specific exercises and training as well as limiting training to the fire stations rather than outside training facilities.

While the findings of this pilot study suggest support for the feasibility of this occupational exercise training program, the study is not without limitations. This project was implemented in a relatively urban setting within Appalachia, and because the individualized exercise programs were implemented by students as part of their coursework, this personal training was free to the firefighters. Also, because the fire captain specifically requested this occupational exercise program, it was a community-based participatory research study. Therefore, the findings of this study may not be generalizable to other settings such as rural areas with limited resources, minority populations, or fire companies that lack leadership commitment to the program. Additionally, a significant limitation of this pilot study was the small sample size, which can be associated with low reproducibility [53]. However, as previously described, the clinical and performance outcomes of this study are not novel and have been exhaustively reported in the literature [9-24].

Instead, these quantitative outcomes were included, in part, to demonstrate that the exercise intervention, though limited, with only 20 session over 14 weeks, was sufficient to elicit physiological changes (eg, improvements in strength and blood pressure). Additionally, the intervention is reflective of the realistic time commitment that can be expected from fire department occupational fitness programs: most departments have schedules in which firefighters are on duty 2 times per week, thus any training program implemented by the department during shift work would be limited in frequency of training sessions per week. While this may not allow for a more traditional training protocol (occurring 3 times per week), in this study, because sessions lasted 90 minutes, the training program met common recommendations of 150 minutes of exercise per week [54].

The novelty of this pilot program was the qualitative participant feedback including participants' enjoyment, lifestyle behavior changes, and team structure with the goal of informing recommendations for future programs. We found improvements in overall health, endurance, flexibility, and mood, as well as improvements to team environment and the health behaviors around the station suggesting that the implementation of this fitness program was well received by participants.

Moving forward, this project will be expanded throughout the city's fire department, offering free personal training from university exercise physiology students to all firefighters. While this study found favorable outcomes among participants, it is a feasibility study, and future research is warranted. In particular, qualitative feedback from fire department leadership that captures barriers to department-wide exercise training programs is needed before permanent programs can be implemented. Additionally, this study trained professional firefighters, but similar work could be evaluated in volunteer firefighters. The outcomes presented here are used to attempt to understand how best to intervene in firefighters' health promotion [28-30], but the role of exercise training in permanent behavior change and the influence of group participation on team structure and building should be more thoroughly explored. In this study, firefighters received personalized exercise guidance designed to improve functional outcomes by incorporating strength, muscular endurance, cardiovascular, flexibility, and agility exercises into the exercise programs; however, future research could evaluate a firefighting task-specific exercise training program with the goal of improving task-specific performance and overall effect on job performance.

The 14-week exercise training program improved clinical (diastolic blood pressure and resting heart rate) and performance (1-repetition maximum leg and bench press) outcomes, as well as self-reported physical activity (more vigorous activity and walking, less sitting time). Improvements in overall health, endurance, flexibility, and mood as well as improvements to team environment and the health behaviors around the station were reported; however, a decline in overcoming barriers to physical activity was also found. Overall, the impressions of this pilot program were positive because it increased time spent exercising, improved team building, and led to physical and mental health benefits. Recommendations moving forward are to extend the program throughout the fire department and to include more task-specific exercises and training.

Conflicts of Interest

None declared.

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Abbreviations

BARSE: Barriers Self-Efficacy Scale
BBAQ: Barriers to Being Active Quiz
ECG: electrocardiogram
IPAQ: International Physical Activity Questionnaire
MET: metabolic equivalent task

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